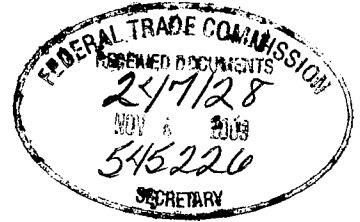


IN THE UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION



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

In the Matter of
DANIEL CHAPTER ONE,
a corporation, and

DOCKET NO. 9329

JAMES FEIJO,
Individually, and as an officer of
Daniel Chapter One.

PUBLIC DOCUMENT

RESPONDENTS' REPLY BRIEF

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

Dated: November 4, 2009

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INTRODUCTION

“What are they allowed to say?” At the close of oral argument the Administrative Law Judge asked the FTC Complaint Counsel this question. The question puts the fundamental issue in this case succinctly before the Commission. What can individuals in Respondents’ position say? The Respondents in this case are Daniel Chapter One, a ministry organized as a Corporation Sole under the laws of Washington State, and James Feijo, its overseer and only member.

James Feijo leads Daniel Chapter One as its overseer, a position established by the Corporation Sole statute of Washington State. A Corporation Sole is, according to The Guide to Representing Religious Organizations, published by the American Bar Association in 2009, “a common ‘religious’ corporate form that still exists in most, if not all, states...and is controlled by one person....” Daniel Chapter One maintains a home church, conducting bible studies, christenings, and other church activities in the home of the overseer and his family.

In addition to services in the home in which they live, owned by the ministry, the Feijos conduct services in other homes across the country and abroad. As part of the work of the ministry, the Feijos have taken Bibles to people behind the Iron Curtain who, during the Cold War, conducted church services secretly in their homes. These home church activities abroad included taking Bibles to Poland, East Germany and China (during the *Tiananmen Square* demonstrations). The ministry also maintains relationships with missionaries from their ministry in The Netherlands and Israel.

The Daniel Chapter One ministry believes, based on contents from the Christian Bible and from herbal science, that the human body has the innate capacity to heal itself and that herbs

exist that assist this natural process. In accordance with this belief, Daniel Chapter One formulates and provides herbs in various combinations, based on biblical guidance and herbal science, to individuals who believe, as the Feijos do, that herbs help strengthen the human body's immune system and other innate self healing capacities. Information about the Daniel Chapter One herbs appears on its web site, in its radio broadcasts and in various ministry publications such as newsletters and handbooks.

FTC Complaint Counsel complains about and seeks to prohibit certain statements made in these information sources. Complaint counsel says "They told consumers **"How to fight cancer is your choice!"** (emphasis by Complaint Counsel). Respondents stand by their right to tell people truthful information that can help them strengthen their natural capacities for well being. Complaint Counsel argues that any deviation from statements supported by placebo controlled double blind clinical studies or their equivalent constitutes misrepresentation under the FTC Act. Complaint Counsel argues that any statement about the role of herbs in assisting the body that is not supported by double blind studies constitutes an illegal claim that the herb can treat, cure, or prevent cancer, inhibit tumors, or ameliorate the adverse effects of radiation and chemotherapy,. Such a claim, Complaint Counsel says, makes the herb for which it is made a drug requiring double blind clinical trials that prove the truth of the statement

Respondents Daniel Chapter One and Mr. Feijo do not claim that the herbs they identify do anything other than assist the natural functions of the body. They provided five expert witnesses to attest to their approach to the natural healing capacities of the body. One expert was a world renowned herbal researcher who worked for nearly thirty years for the United States Department of Agriculture, for part of that time in a joint project with the National Cancer Institute as an herbal expert. He testified that herbal science data supported Respondents' statements about their herbal formulations.

Another expert, a naturopathic physician trained in herbal effects who reviewed the literature relied upon by Respondents to ensure that their statements about herbs were accurate, also testified that herbal literature relied upon by Respondents supported the statements they made about their formulations.

Respondents' third scientific expert, a member of the National Academy of Engineering, associated with the US National Academy of Sciences, and of the Swedish, Russian, and Japanese Academies of Science, with sixty years of scientific experience and a national reputation as a leader in understanding Complementary and Alternative Medicine modalities, testified to the growing scientific doubts about relying on placebo controlled double blind studies to separate truthful from untruthful information.

Respondents' fourth expert, with over thirty years of scientific study design, who uses one of Respondents' herbal formulations (not at issue in this case) testified, based on dozens of hours of detailed scientific conversation with Mr. Feijo, to the level of scientific competence Mr. Feijo brought to his development of herbal formulations. The fifth expert, with more than four decades of herbal formulation experience, described how he created one of the formulations at issue using sound herbal science based on the directions given to him.

Speaking of one ingredient in one of Respondents' formulations, the Administrative Law Judge pointed out to Complaint Counsel that "Your own expert said there was some promising research." It was in this context that the Administrative Law Judge asked Complaint Counsel "What can [people in Respondents' position] say?" That is the question this Commission needs to answer.

Complaint Counsel have stated repeatedly, as they did again in Complaint Counsel's Answering Brief ("CC Br."), that any claim about supporting and improving the structure and function of the body's natural systems for self defense or better wellness, that also mentioned cancer, requires double blind placebo controlled studies proving that it is effective against cancer. Complaint Counsel persisted in this mistaken argument even after their own expert witness testified that testing one single chemical entity to this level would cost 100 million dollars. Respondents' experts testified that one herbal ingredient in one of Respondents' formulations contained a minimum of 500 and possibly as many as 5000 single chemical entities.

Equally challenging to the government's case, Respondents engaged in the activities Complaint Counsel complains of for over twenty two years without a single consumer complaint. Only when the agency conducted an Internet surf seeking web sites that used both the word "cancer" and the words "dietary supplements" did Daniel Chapter One appear as a target. The agency found 130 originations that fit its criteria. It issued a press statement condemning all of them as law violators. The agency made no effort to distinguish those that, like Respondents, had sound herbal science substantiating their statements about supporting the natural systems of the body from those that were making unsubstantiated health claims. Indeed, it appears that no one with the competence to understand structure and function claims was ever consulted by the FTC.

Respondents offered over eighty witnesses with affidavits to testify to how important Respondent's herbal formulations were to their personal well being. Complaint Counsel and the Administrative Law Judge rejected this offer out of hand, claiming that what the user of the formulations believed was irrelevant. Complaint Counsel and the Administrative Law Judge claimed that they were in a position to tell from the face of the Respondents' statements about

their herbal formulation that Respondents misled people who used the formulations. Complaint Counsel argued, again Respondents believe erroneously, that the law requires no extrinsic evidence of deception to make their case.

Complaint Counsel's Answering Brief inaccurately states that the ALJ made 425 detailed independent Findings of Fact in his Initial Decision ("Decision"). In fact, the ALJ did not make independent Findings of Fact, but rather adopted Complaint Counsel's proposed Findings of Fact almost verbatim. This act alone warrants the utmost scrutiny by the Commission, as a matter of fundamental administrative law.

Among the positions that the Commission must take in order to affirm the Initial Decision are:

- It must find, for the first time, that the FTC Act, which confers jurisdiction on for profit entities and not-for-profit trade associations made up of for profit entities, includes jurisdiction over a not-for-profit religious ministry;
- It will have to conclude that in the legislation requiring substantiation of claims Congress intended that only double blind placebo controlled studies qualify as substantiation for statements such as those made by Respondents;
- It will have to conclude that demonstrating the absence of double blind studies is all that is required of the government to find a party liable for illegal statements;
- It will have to conclude that the Commission and only the Commission can decide exactly how an implied statement will be viewed by members of the public, and that extrinsic evidence of the effect of statements is no longer

relevant or required to find a violation of the Act.

- It must find that the Commission is absolved of the responsibility to provide extrinsic evidence that the statements at issue are false or misleading;
- It must find that the First Amendment protection of commercial speech does not apply to statements that the agency asserts imply something with which it does not agree, thus absolving the agency of the burden of proving that a statement is false or misleading;
- It will have to conclude that it need not apply the requirements of First Amendment protections that require the government to take only the least intrusive action to correct a wrong;
- It will have to conclude, paternalistically, that it, rather than the individuals engaged in the information exchanges about how to strengthen the natural protective functions of the body, is the authority to decide how people may treat their health and well being;
- It will have to conclude that it has the authority to override the individual conscience of Respondents and order them to tell people information designated by the Commission that Respondents do not believe to be true and that violates Respondents' religious beliefs.

Adding to the need for the Commission to take a fresh and considered look at the ALJ's ruling here is the continued insistence by Complaint Counsel, underlying each of their efforts to overreach the law set out above, that presumptions are good enough, that they need not provide evidence for the assertions they make, and that the burden of proof rests with the Respondents.

Complaint Counsel's Answering Brief continues to perpetuate serious Constitutional flaws in the process afforded Respondents in this case. Respondents believe that the law does not permit the Commission to take any, let alone all, of these positions and therefore asks that the Commission reject the Initial Decision and dismiss the Complaint against Respondents.

I. JURISDICTION

A. The ALJ determined that Respondent DCO is a religious ministry.

By finding, appropriately, that Respondent DCO is a religious ministry, and asserting that FTC has jurisdiction over it nonetheless, the ALJ takes FTC jurisdiction into unprecedented territory. Complaint Counsel's Answering Brief superficially recites the recipe for FTC jurisdiction over non-profit trade associations, but fails to answer the question that the Commission must consider: how far does FTC jurisdiction extend beyond a trade association and over religious ministries?

As a religious ministry, Respondent DCO meets the Internal Revenue Service (IRS) criteria for a non-profit organization subject to the exception of §508 of the IRS code. Complaint Counsel's Answering Brief dodges this point, and its implications.

Complaint Counsel's Answering Brief did not address or challenge the evidence of Respondent DCO's ministry. To reiterate, DCO began in 1983 as an unincorporated religious association. DCO principals traveled on missions to Poland, East Germany, and China. They established worshiping communities in Holland and Israel. They worked with individuals in nursing homes and with handicapped (and high performance) athletes since 1983.

It is equally unchallenged that Respondents addressed the health concerns of their followers as part of their missionary work. They worked with people as diverse as the elderly in

nursing homes, and with the physically and mentally challenged. As they worked with these individuals, guided by their Biblical studies and herbal science they began creating dietary guidelines drawn from the Bible. This work ultimately led to their developing the DCO products, as an expression of their ministry.

B. Religious ministries are protected by the law.

The FTC's "only charitable purposes" standard (stated at CC Br. p. 7) upon which its jurisdiction arguments is based, does not comport to US exempt organization law. A religious purpose, under the concept of Expressive Association, does not have to be "only charitable." Congress recognizes several grounds for exemption, listing "charitable" and "religious" as separate, but equal, grounds. By asserting an "only charitable purposes" standard FTC is attempting to impose a burden on religious organizations. To do this it must comply with the Religious Freedom Restoration Act of 1993 (P.L.103-141) – RFRA, which neither its argument nor its remedy does.

In adopting RFRA, Congress determined that "governments should not substantially burden religious exercise without compelling justification..." and that "laws 'neutral' toward religion may burden religious exercise..." Therefore Congress determined to protect the free exercise of religion as follows:

"Sect. 3. Free Exercise of Religion Protected. (a) In General. -- Government shall not substantially burden a person's exercise of religion, even if the burden results from a rule of general applicability, except as provided in subsection (b). (b) Exception. -- Government may substantially burden a person's exercise of religion only if it demonstrates that application of the burden to the person -- (1) is in the furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest. (c) Judicial Relief. -- A person whose religious exercise has been burdened in violation of this section may assert that violation as a claim or defense in a judicial proceeding and obtain appropriate relief against a government..."

The Supreme Court has both limited this law (doesn't apply to the States) and reaffirmed it: "Restoration Act of 1993 (RFRA), 107 Stat. 1488, as amended, 42 U.S.C. §2000bb et seq., ... adopts a statutory rule Under RFRA, the Federal Government may not, as a statutory matter, substantially burden a person's exercise of religion..." *Gonzales v. O Centro*, No. 04-1084 - February 21, 2006. The FTC's secular "only charitable" requirement on Daniel Chapter One burdens its religious expression unnecessarily. This burden is in opposition to the requirements of the act and improperly limits the ministry's exercise of its religious rights.

Likewise, Daniel Chapter One does not exist for the "profit" of its members, but rather as an expressive association effort, in the words of the Universal Declaration of Human Rights, Article 18, "to manifest ...religion or belief in teaching, practice, worship and observance." Without the expressive association right to teach about traditional herbal remedies, and to practice their beliefs with the use of such herbs, that fundamental religious right is burdened in violation of RFRA.

Contrary to Complaint Counsel's assertion (CC Br. p. 4): The Feijo's did not receive personal enrichment, but rather, properly benefited from a Designated Parsonage Allowance, excluded from Gross Income under Section 107 of the IRS Code. They provided services to the religious entity and were compensated by reimbursement of their expenses, but that form of compensation is excluded from Gross Income under federal law.

In the financial records relied upon by Complaint Counsel to establish Mr. Feijo's "for-profit" use of the money contained in the accounts examined, the amount of money used for purposes Complaint Counsel deemed inappropriate accounted for 3% of the total. This amount is well within the range of money permitted a religious organization to pay for the expenses of its

staff. Neither Mr. nor Mrs. Feijo takes a salary for the work they do for Daniel Chapter One.

Both are reimbursed for expenses.

C. The *Community Blood Bank* and *California Dental* cases establish boundaries to FTC jurisdiction beyond which Complaint Counsel and the ALJ would urge the Commission to reach with no accountability.

As the Commission knows, in *Community Blood Bank of the Kansas City Area, Inc. v. FTC*¹, the court rejected FTC jurisdiction over “any corporation engaged in business only for charitable purposes and which is forbidden by law to carry on business for profit” *Id.* at 1016. As the 8th Circuit said, Congress “did not intend to bring within the reach of the Commission any and all nonprofit corporations regardless of their purposes and activities.” *Id.* at 1018.

Next as the Commission knows, the U.S. Supreme Court further delineated the boundary of FTC jurisdiction over non-profit trade associations in *California Dental Association v. Federal Trade Commission*². The U.S. Supreme did so cautiously and discretely, with an analysis that was expressly limited to the work of non-profit trade associations. Furthermore, the Court required as a touchstone for FTC jurisdiction that the Commission provide evidence that the trade association provided **substantial** economic benefits to their for-profit members' businesses.

But the Supreme Court did not stop there. It laid down another element of the limits to FTC jurisdiction over non-profit organizations:

[A]n organization devoted solely to professional education may lie outside the FTC Act's jurisdictional reach, even though the quality of professional services ultimately affects the profits of those who deliver them.

¹ 405 F.2d 1011 (8th Cir. 1969).

² 526 U.S. 756 (1999).

The Commission must consider and address two comments within this quote from *California Dental Board*, because Complaint Counsel certainly did not. First, the Supreme Court expresses a presumption that the professional education work of a trade association probably lies outside FTC jurisdiction. How then does the FTC make the leap that religious ministries educating their followers about the uses of herbs are not situated similarly with the educational activities of trade associations, if not even more immune from FTC jurisdiction, considering the express Constitutional protections afforded religion?

Only by proving that the statements being challenged are false and misleading does the Commission have any chance of extending its jurisdiction over a non profit organization, particularly a religious ministry. In this case Complaint Counsel does not even attempt to prove Respondents' statements are false (Respondents' experts said the statements were true), or even try to prove that they implied a falsehood. Rather Complaint Counsel relied on the argument that Respondents failed to conduct placebo controlled double blind studies on the single chemical ingredients in the herbal formulations they prepared and therefore violated the law.

Second, the Supreme Court states that the work of the non-profit may inure to the benefit of those who deliver its services. Notwithstanding the evidence that neither DCO or James Feijo profited from Respondents' ministry, Complaint Counsel ignores this statement wholesale. Again, the ALJ finding that Respondents are a religious ministry requires more than the presumptive treatment afforded these issues by the evidence and Complaint Counsel's argument.

The ALJ acknowledged during the hearing that the U.S. Supreme Court has not yet established a clear boundary between non-profit organizations over which the FTC has jurisdiction and those over which it does not have jurisdiction. Nevertheless, Complaint

Counsel and the ALJ attempt to extend FTC jurisdiction over a religious ministry with disregard for the latent boundaries that the Supreme Court has established.

D. *Ohio Christian College* should prompt the Commission to decline jurisdiction.

Setting aside Complaint Counsel's incorrect sophistry about *California Dental Board*, Complaint Counsel's jurisdictional analysis is based almost exclusively on *In re Ohio Christian College*.³ Complaint Counsel's reliance on *Ohio Christian* is misinformed.

Notwithstanding the fact that *Ohio Christian* is almost forty (40) years old, and is not an expression of the judicial branch, it is interesting nonetheless. There, the principals of the putative non-profit organization had been enjoined in a state court proceeding, and had their property and files seized by a state attorney general. The Federal Trade Commission's decision noted that there were "a number of very suspicious circumstances" in regard to the operation of the Ohio Christian Church (OCC). *Id.* The Commission noted that the operation of the Church "was completely dominated by [the individual respondent]." *Id.* And the Commission noted that the testimony of the individual respondents' was "inherently incredible." *Id.*

Nevertheless, the Commission rejected FTC jurisdiction over the primary OCC religious institution against whom Complaint Counsel had brought charges. The Commission rejected jurisdiction based on *Community Blood Bank*. Indeed, *Ohio Christian* has been described – very recently and since *California Dental Board* - as holding that non-profit organizations are subject to FTC jurisdiction only when those organizations are found to be shams, and alter-egos of their

³ 80 F.T.C. 815 (1972).

principals.⁴

Here, there is no evidence that any of the Respondents have been subject to state court proceedings based on an alter-ego theory, unlike in *Ohio Christian*. The ALJ made no findings that the Feijos lacked credibility, unlike in *Ohio Christian*. The ALJ made no findings or conclusions that Respondent DCO is a sham or an alter-ego of the Feijos, unlike in *Ohio Christian*. To the contrary, the ALJ found Respondent DCO to be a religious ministry.

In fact, the only support Complaint Counsel cites for its argument that Respondent DCO is somehow inauthentic is a recent amendment to Washington State's legislation concerning corporations sole, which requires Respondent DCO to submit annually its address, state of incorporation and the names of its overseers and bishops to the Washington Secretary of State.⁵ This hardly constitutes "alter-ego" evidence.

Nevertheless, Complaint Counsel and the ALJ claim FTC jurisdiction over this religious ministry. They fail to explain how *California Dental Board* changes, much less addresses, the FTC's own rejection of jurisdiction in *Ohio Christian*. In fact, *California Dental Board* did nothing to extend FTC jurisdiction over religious ministries. But the Initial Decision glosses over that important point.

E. Complaint Counsel perpetuates unconstitutional adjudication by presumption and burden shifting.

It is noteworthy that Complaint Counsel is concerned with, and even stymied by, Respondents' citation to the IRS regulations concerning treatment of church-related income that may flow to religious workers. This is telling for three reasons.

⁴ *FTC v. Gill*, 183 F. Supp. 2d 1171, 1184 (U.S.D.C. Cent. CA, 2001).

⁵ See RCW 24.12, et. seq.

First, Complaint Counsel's concern reveals a lack of understanding about the fundamental elements of ministry-related income that bear on the FTC's lack of jurisdiction. This points out just how unprecedented, and improper, the FTC's assertion of jurisdiction would be here.

Second, Complaint Counsel's concern also reveals their presumption-based approach to the evidence. Since Complaint Counsel presumed that the fundamental elements of ministry-related income were immaterial, and therefore they need not consider the evidence or the law, they provided neither evidence nor law on the matter.

Third, Complaint Counsel expresses concern that Respondents should have explained why their evidence was relevant. This is another of Complaint Counsel's efforts to shift their own burden of proof onto Respondents. It was incumbent on Complaint Counsel to make their case, which they failed to do.

F. Complaint Counsel ignores that religious ministries may engage in commerce without destroying their character or subjecting themselves to FTC jurisdiction.

It is also noteworthy that Complaint Counsel altogether ignores the authority that holds that religious ministries like Respondent DCO may engage in commerce to further their charitable purpose.⁶

The posture of this case calls for the Commission to close the significant loopholes left open by Complaint Counsel's evidence, and by the Initial Decision. To close those loopholes in favor of FTC jurisdiction over the Respondents here will take the FTC in an unprecedented

⁶ See, e.g., O'Hara, *The Modern Corporate Sole*, 93 Dickinson Law Rev. 23 (1988); and *In re Catholic Bishop of Spokane*, 329 Bank. Rptr. 304 (E.D. WA 2005).

direction, and a direction that is contrary to an integrated reading of the holdings of *Community Blood Bank*, *Ohio Christian College* and *California Dental Board*.

II. FACTUAL CLARIFICATIONS

A. Complaint Counsel distorts the Record by selectively presenting supposed “facts.”

According to Complaint Counsel, “the **undisputed facts** here demonstrate that DCO is a business organized to sell its expensive products to the public that uses the profits it makes from such sales to fund the Feijo’s personal living and entertainment expenses.” CC Br. p. 8. (emphasis added). In fact every single one of these supposed “facts” is vigorously disputed by Respondents.

The issue, accurately stated, is whether DCO was organized and operated for such a business purpose, and whether the sales funded only the Feijo’s personal living and entertainment expenses. This remains not only a factual issue in controversy, but more important, an issue where the substantial evidence weighs against the government.

Completely missing from Complaint Counsel’s “history” of DCO (CC Br. pp. 4, 9) is the period from 1983 to the present in which DCO was first organized as an unincorporated religious association engaged in a world-wide religious ministry into which was folded its ministry of dietary supplements and then reorganized as a church utilizing the nonprofit corporate sole organizational structure under Washington State law. See Respondent’s Br. (“Resp. Br.”) pp. 30-31 and F. 11, 16 and 18.

Instead of acknowledging DCO’s religious ministry history as the Administrative Law Judge found it to be, Complaint Counsel attacks the bona fides of DCO as a corporate sole.

Complaint Counsel critiques DCO's Articles of Incorporation (CC Br. p. 10) as insufficient to establish DCO as a nonprofit corporation dedicated to charitable purposes even though the law of Washington state specifically and corporate sole law in general establish the nature of DCO as Respondents testified and completely the opposite of what Complaint Counsel claims..

Complaint Counsel fails to acknowledge that the Washington law and the Articles taken together establish DCO as a charitable trust, saying that the funds it receives may only be used for charitable purposes. Resp. Br. pp. 33-35, 37-38.

Instead of acknowledging the testimony of the Feijos that their personal lifestyle and activities are intimately related to DCO and comparable to that of the lifestyle and activities of a church pastor (See Resp. Br. 38-41), Complaint Counsel presumed that the living expenses of the Feijos were totally disconnected from the DCO ministry and beyond reasonableness. CC Br. pp 14, 15-16. For example, on page 14 of Complaint Counsel's Answering Brief, Complaint Counsel contrasts "the rental value of parsonages" with the presumed rental value of "Florida vacation homes," as if the DCO Florida residence is a "vacation" home rather than a modest home dedicated to the religious ministry of DCO. There is no evidence that the DCO Florida residence is a vacation home. See F. 55. Indeed Complaint Counsel present no evidence on the nature of the Florida building.

B. Respondents urge the Commission to give no weight to Complaint Counsel's factual distortions of the record.

Complaint Counsel's "factual" picture was infected by pejorative and disparaging adjectives that were unsupported by the record, and designed solely to present a distorted picture of the Feijos as religious hypocrites and charlatans.

"DCO is a multi-million dollar commercial operation run by James Feijo, who treats

DCO's assets as his own to **completely support himself and his family.**" CC Br. p. 4 (emphasis added). Complaint Counsel provides no citation to the record showing that government established that DCO assets are totally used for personal purposes.

To the contrary, the ALJ found that the Feijos have been actively engaged in the DCO ministry, including two hours per day on the radio (F. 109). The Feijos have given away DCO products (F. 21). The Respondent Feijo holds all DCO assets in trust (F. 40). Respondents have donated significant funds to "Creation Science" ministries (F. 73 and 74).

Complaint Counsel also abuses the record with this statement: "[T]here are certain circumstances under which legitimate church-related income [is] excluded from gross income, nothing suggests that the provisions cited to by Respondents were intended to exempt ... **expensive** restaurant meals from the tax laws." CC Br. p. 14 (emphasis added). There is nothing in the record to indicate that the restaurant meals purchased by the Feijos were expensive, that is, costing more than the cost of a restaurant meal that ordinary people might pay. Rather, the only evidence of the cost of restaurant meals was an aggregate figure of \$14,024 during a period from December 2005 through March 2009. F. 68. Broken down, that would mean that the Feijos spent approximately \$350.60 per month over a forty (40) month period for two people to eat out — the equivalent of \$11.68 per day for two people. That is hardly "expensive" under any circumstances, but especially in light of the undisputed fact that both Feijos are involved full-time in the DCO ministry, including significant travel. See, e.g., F. 38, 39, 48, 65, 85, 109, and 110.

Another of Complaint Counsel's misrepresentations come in regard to the challenged products: "The DCO products are **expensive.**" CC Br. p. 5 (emphasis added). See also p. 8,

“DCO is a business organized to sell its **expensive** products to the public that uses the profits ... to fund the Feijos personal living and entertainment expenses.” (emphasis added). Neither of these statements is supported by any citation to the Decision or to the record. Indeed, Complaint Counsel did not introduce any evidence that the price charged by DCO was high in relation to the quality of the product sold or the cost of comparable products in the market. Nor was there any such finding by the ALJ. Instead, the ALJ and Complaint Counsel just assumed that, because of the gross mark up, DCO’s cost/price margin was pure profit without taking into account any overhead and other expenses. Apparently neither the ALJ nor Complaint Counsel understands the difference between gross and net income. See Decision p. 70 and CC Br. p. 10.

Complaint Counsel commits its most egregious, offensive manipulation of the record with this statement: “Respondents **prey** upon desperate, sick consumers suffering from cancer.” CC Br. p. 6 (emphasis added). No citation is made to any fact found by ALJ to support this claim. To the contrary, ALJ found that Respondents have provided nutritional counseling and allowed people in need to stay in Respondents’ housing. F. 19. Respondents have donated their products, and provided them at discount. F. 20. Respondents have provided literature and other information concerning “spiritual and scientific approach” to better physical health. See, e.g., F. 85-87, 108-110. The government could not produce a single witness who had ever been harmed, or even dissatisfied with the Respondents or Respondents’ offerings. On the other hand Complaint Counsel and the ALJ refuse to receive or hear the affidavits or testimony from over eighty individuals willing to come to the hearing in Washington to tell how important the products under attack by the FTC were to their and their families’ well being.

Indeed, the government’s tactics in this case were to deny the need for evidence, rather than produce it. Complaint Counsel neither identified nor called a single consumer to testify that

they were sick and desperate -- suffering from cancer — and were preyed upon by Respondents, nor did they offer objective evidence that such a consumer exists. To the contrary, the government asserted that it was not required to produce any evidence whatsoever that any consumer of Respondents' products was misled or preyed upon by DCO. CC Br. pp. 32-35.

III. CONSTITUTIONAL ARGUMENTS: FIRST AMENDMENT PROTECTED SPEECH

A. Complaint Counsel's Answering Brief confirms the extreme degree to which the FTC is violating the Constitution.

Considering Complaint Counsel's errors in responding to the issues now before the Commission, it is appropriate to lead off the next steps of the analysis with the Constitutional issues. These Constitutional issues inform the ALJ's characterization of Respondents' First Amendment-protected speech.

1. Pearson v. Shalala controls the Constitutional issues in this case.

A close look at *Pearson v. Shalala*⁷ reveals the erroneous path on which Complaint Counsel and the ALJ are taking the Commission here.

First, it is important to understand the similarity of the issues between *Pearson* and this case. As the *Pearson* court states, that case concerned “health claims [about] dietary supplements” and “the broader regulatory framework applicable to dietary supplements.” *Id.* at 652. The situation here is no different. Next, the *Pearson* court acknowledged that there is “some definitional overlap between drugs and dietary supplements .” *Id.* Further still, and more specifically, the court considered how the agency used the standard of “significant scientific agreement” as a means of suppressing commercial speech.

⁷ 164 F. 3d 650 (D.C. Cir. 1999).

At the outset, only a biased eye would fail to see that the analytical framework of *Pearson* is the same as it is here, especially considering that the “significant scientific agreement” standard in *Pearson* is virtually identical to the standards employed by the ALJ in this case. The similarities do not stop there.

The *Pearson* court considered both Constitutional and Administrative Procedure Act [APA] challenges to the agency’s action. These are the same challenges that Respondents raise now.⁸

Appellants raise a host of challenges to the agency’s action. But the most important are that their First Amendment rights have been impaired [because the agency’s standard precluded approval of less-well supported claims accompanied by a disclaimer] and that under the Administrative Procedures Act, [the agency] was obligated . . . to articulate a standard a good deal more concrete than the undefined “significant scientific agreement.” *Id.* at ___

The specific analysis conducted by the *Pearson* court could very well be written for this case, almost word for word.

The first step concerns why the *Central Hudson* test does apply to this case, and why Complaint Counsel and the ALJ failed to meet the *Central Hudson* requirements.

a. Agency suppression of commercial speech violates Central Hudson.

The *Pearson* court declared the *Central Hudson* analysis to “the most powerful constitutional claim, [i.e.] that the government has violated the First Amendment by declining to employ a less draconian method – the use of disclaimers – to serve the government’s interest.” *Id.* at 654. The court considered the agency argument that is exactly what Complaint Counsel and the ALJ are selling here: health claims that fail to meet the impossibly-high and

⁸ The *Pearson* court passed on whether the agency’s suppression of speech under the guise of its impossibly-high “significant scientific agreement” standard constituted a prior restraint under the First Amendment. It did so because the court ruled against the agency on other grounds. The prior restraint challenge applies with force here, all the same.

simultaneously vague standard are inherently misleading.⁹ In response to that totalitarian approach, the *Pearson* court rightfully said this:

If such health claims could be thought inherently misleading, that would be the end of the inquiry. . . ‘But the States may not place an absolute prohibition on . . . potentially misleading information . . . if the information also may be presented in a way that is not deceptive.’ [citations omitted.]

As best we understand the government, its first argument runs along the following lines: that health claims lacking “significant scientific agreement” are inherently misleading because they have such awesome impact on consumers as to make it virtually impossible for them to exercise any judgment . . . It would be as if the consumers were asked to buy something while hypnotized . . . We think this contention is almost frivolous.” *Id.*

Before turning to the specific steps used by the *Pearson* court in applying *Central Hudson* to the same suppression of speech that the ALJ committed here, it is necessary to foreshadow some points about Respondents’ speech that are addressed anew below. The ALJ here critiqued Respondents’ claims not as express establishment claims, but on his unilateral overall net impression of Respondents’ non-establishment claims. Further, as the Commission has now digested repeatedly, the ALJ did so without a shred of extrinsic evidence about consumer perception or consumer harm.

Logic and common sense tell us that express establishment claims - when they are expressly false - are *inherently misleading*, as that concept is used by the *Pearson* court. But that was not the basis for the ALJ’s findings here. In comparison, non-establishment claims - when the overall net impression of which is evaluated without extrinsic evidence - are logically and by common sense *potentially misleading*, as that concept is used by the *Pearson* court. This was the approach and conclusion employed by the ALJ here.

⁹ *Id.* at 655.

There is one more piece to this puzzle to consider before returning to why the *Pearson* court's analysis of the *Central Hudson* test applies here. The Commission must consider this: on the one hand, Complaint Counsel's expert testified to the overall net impression of Respondents' claims.¹⁰ He further testified that he did not even know what a structure/function claim is. On the other hand, Respondents' experts, who were admitted as qualified experts, testified about Respondents' express statements, and testified that they were true based on substantiation, albeit not double-blind/placebo-based studies! In other words, the undisputed evidence was that (i) the Respondents' express statements were true; (ii) those express statements were substantiated, but not to the degree required by the agency's impossibly-high standard; and therefore (iii) the ALJ could declare the Respondents' speech to be misleading, and thus justify avoiding the *Central Hudson* analysis.

The *Pearson* court rejected this exact same approach based on the First Amendment and *Central Hudson*. There, the "significant questions under *Central Hudson* are . . . 'whether the [government's suppression of speech] *directly* advances the governmental interest . . . and whether the fit between [the ends and the means] is reasonable.'" *Id.* at 656, italics supplied by the *Pearson* court.

The court held that the agency's prophylactic suppression of speech (by virtue of an impossibly-high, vague standard) did not directly advance the governmental interest. Nor did that approach constitute a reasonable fit between the ends and the means. On the latter of these two points, the *Pearson* court noted the government's position: "The government insists that it is

¹⁰ Complaint Counsel persists in its Response Brief to create the misimpression that Respondents' admitted the overall net impression of their claims by virtue of an inadvertent ministerial error in their Answer. This misrepresents the record. Respondents tried to correct that error by a Motion to Amend, which was wrongfully denied by the ALJ. Respondents maintain that this was an error for which Respondents' appeal should be granted.

never obliged to [consider less draconian alternatives to suppression, i.e.] utilize the disclaimer approach, because the commercial speech doctrine does not embody a preference for disclosure over outright suppression. Our understanding of the doctrine is otherwise.” *Id.* at 657.

[W]hen the government chooses a policy of suppression over disclosure – at least where there is no showing that disclosure would not suffice to cure misleadingness – government disregards a ‘far less restrictive means.’ *Id.* at 658.

Although the government may have more leeway in choosing suppression over disclosure as a response to the problem of consumer confusion where the product affects health, it must still meet its burden of justifying a restriction on speech. . . ‘If the protections afforded commercial speech are to retain their force, we cannot allow rote invocation of the words *potentially misleading* to supplant the [government’s] burden to demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.’ *Edefield*, 507 U.S. at 771.¹¹

The Initial Decision in this case is especially onerous in light of the *Pearson* holding.

The ALJ’s consideration of the *Central Hudson* factors is superficial at best. His disregard of disclaimers as a means of restriction (and his cavalier treatment of Respondents’ religious-based disclosures, at that) is arbitrary and capricious by any measure, but especially when we consider these additional factors:

- Respondents are confirmed as a religious ministry.
- Respondents have been attacked by Complaint Counsel and within the Initial Decision for religious, political speech within their radio broadcasts.
- The government’s case lacked extrinsic evidence.
- The government has regulated by adjudication in furtherance of an unconstitutionally vague, and impossibly high, standard.
- The cumulative effect of the government’s prosecution, coupled with its remedy, is a prior restraint.

¹¹ *Pearson*, at 659, citing *Edenfeld v. Fane*, 507 U.S. 761 (1993).

b. Pearson confirms the requirement of extrinsic evidence.

A fair and thoughtful reading of *Pearson* will also dispel any doubt that extrinsic evidence is required of the government to meet its burden of proof. For instance, the court criticized the agency for relying on merely its own “pronouncement” that consumers would be harmed. *Id.* at 659. In the context of this criticism, the court noted that *Edenfield* invalidated the government’s suppression of speech “where the government failed to present ‘studies’ or ‘anecdotal evidence’ showing that the speech posed dangers of fraud, overreaching or compromised independence.” *Pearson*, at 559. In the same context, the *Pearson* court stated, “[W]e see no reason why the government’s evidentiary burden at the final step of *Central Hudson* should be any less than at the direct advancement step.” Further, *Pearson* questioned whether the government could even produce the necessary extrinsic evidence: “[W]e are skeptical that the government could demonstrate with empirical evidence that disclaimers . . . would bewilder consumers and fail to correct [alleged] deceptiveness . . .”. *Id.* at 659-660.

c. Pearson prohibits regulation by adjudication in response to vague standards.

The *Pearson* court did more than apply the *Central Hudson* test to invalidate improper suppression of speech in circumstances plainly and thoroughly similar to those here. The court also addressed the government’s need to properly define through regulation impermissibly vague standards. The court acknowledged the potential for this challenge to be framed as Constitutional claims under the First and Fifth Amendments, as well as under the APA, as Respondents do here. The court chose to address the challenge under the APA only:

Consideration of the constitutional claim seems unnecessary because we agree . . . that the APA requires the agency to . . . [give] definitional content to the phrase “significant scientific agreement.” We think this proposition is squarely rooted in

the prohibition under the APA that an agency not engage in arbitrary and capricious action. [citation omitted.] It simply will not do for a government agency to declare – without explanation – that a proposed course of private action is not approved. *Id.* at 660.

The *Pearson* court was not talking about adjudications, as Complaint Counsel would have the Commission believe. The court was talking about the need to issue regulations – sub-regulations, even - and make them clear and explicit.

[W]e are quite unimpressed with the government’s argument that the agency is justified in employing this standard without definition . . . The agency is entitled to proceed case by case or, more accurately, sub-regulation by sub-regulation, but it must be possible for the regulated class to perceive the principles which are guiding agency action. *Id.* at 660-661; emphasis added.

Finally on this point, Respondents clarify a misrepresentation by Complaint Counsel in their Response Brief. It is a small, but telling matter because it exemplifies that “win at all cost” approach of the government.

Complaint Counsel states that the *Pearson* court approved adjudications over more specific regulations and sub-regulations as a means of crafting the definition of its standards. That’s not close a proper reading of the *Pearson* court, however. Here’s the full quote:

The FDA’s authorization comes by an informal rulemaking under the APA. [citation omitted.] This choice of rulemaking rather than an adjudication – which would seem a more natural fit for this individualized determination – was mandated by Congress . . . *Pearson*, at 652.

In the first place, the *Pearson* court was commenting that the rulemaking approach for the FDA in that case was mandated by Congress, rather than exercised as a matter of agency discretion. In the second place, if the court was expressing any preference for individualized adjudications, it was doing so in regard to the application of a more well-defined standard. The court was not referring to the required rule-making process for crafting a clearer definition of the

standard itself. An adjudicatory application of the properly defined standard could occur only after the requirement of more specific sub-regulations had been met under the APA, as the *Pearson* court went on to explain. This important distinction was either lost on, or ignored by, Complaint Counsel.

B. The Overall Net Impression analysis and conclusion are unjustified and contrary to law.

From Respondents' point of view, the landscape of this case looks as follows.

On the one hand:

- Respondents have made express structure/function claims about the constituent elements of their products.
- Respondents have shown that considerable literature exists, upon which Respondents relied, to support their structure/function claims.
- Experts in the field of herbal and natural medicine concluded (i) that Respondents' primary express claims are structure/function claims about the mechanisms of action; and (ii) that those express claims are accurate.
- Respondents have provided a disclaimer that complies with DSHEA, and moreover that expressly indicates that their healing approach is part of their religious ministry.
- No one has been harmed, deceived, misled or fooled by Respondents or their products.
- Respondents have exercised their freedom of speech to cast doubt on the limited options offered by conventional cancer treatment, and to criticize a political system that suppresses their right to express those doubts.

On the other hand:

- The government disregards Respondents' structure/function claims. The government's expert doesn't know what a structure/function claim is. Hence, the ALJ neglected to consider how DSHEA applies to any of Respondents' express statements.
- Instead, the government contends that the overall net impression of Respondents'

message is that their products cure or treat cancer.

- The government contends that people using Respondents' products might be misled and thus harmed.
- The government contends that it is not required to prove that anyone was misled or harmed. The government contends that it is not required to prove that anyone might be misled or harmed. The government contends that it is entitled to make that presumption on its own.
- The government contends that Respondents disclaimers are insufficient. The government contends that it may declare those disclaimers insufficient without any evidence of consumer perception. The government contends that it is entitled to make that presumption on its own.
- The government contends that Respondents' truthful structure/function claims cannot be untangled from an allegedly misleading overall net impression. No disclaimer will suffice, and therefore Respondents' speech much be suppressed and subject to prior restraint for twenty (20) years.
- The government contends that Respondents' religious and political speech is commingled with their alleged commercial speech, and that their religious and political speech is so potentially harmful that Respondents cannot be trusted. The government uses this contention as further justification for twenty years of suppression and prior restraint of Respondents' speech.
- And now, the government expects Respondents to digest all of this as Constitutional and just in light of the recent *Lane Labs* decision, in which a respondent identically situated to Respondents followed the Commission's remedial order, relied on the Commission's performance attendant with that order, only to suffer an attack from the Commission to the tune of \$25 million in contempt sanctions because of that respondents' reliance on the Commission.¹²

Reasonable minds will forgive Respondents' skepticism and sense of irony about the government labeling them deceptive, like the pot calling the kettle black. Regardless, considering Complaint Counsel's discomfort with Respondents' rhetoric – accurate though it is – the following points add, clarify and confirm Respondents' position.

¹² One should not have to dig deep into the *Lane Labs* decision to see that the seed of adversity there was the same seed here: an impossible high, arbitrarily vague FTC standard that is incoherent with DSHEA. Like the *Pearson* court required in that case, the FTC needs proper rulemaking on these subjects.

1. **Respondents have not admitted the overall net impression of their claims.**

Complaint Counsel states that Respondents have admitted the overall net impression of their claims in their Answer to the Complaint (although Complaint Counsel concedes that the ALJ did not consider this alleged admission in his decision.) The record should be set straight. Respondents do not admit that the overall net impression as characterized by Complaint Counsel or the ALJ. Nor do they admit that the overall net impression of their claims is misleading.

Respondents moved to amend the ministerial error in their answer, and were rejected despite the lack of any prejudice to the government. Respondents maintain that this was reversible error.

Respondents sought to correct any confusion in the record by moving to amend their answer. See e.g. Respondents' Motion to Amend, dated February 10, 2009. The ALJ denied Respondents' Motion despite the lack of any prejudice to the government, and despite the fact that Respondents' proposed amendment conformed to the evidence in the record.¹³ Respondents maintain that this was reversible error in violation of *Foman v. Davis*.¹⁴ Regardless, there is no evidence in the record that Respondents have admitted the overall net impression manufactured in this proceeding by Complaint Counsel.

2. **The ALJ's misuse of Respondents' religious and political speech was arbitrary and capricious.**

Respondents pointed out in their opening Brief that the government has improperly

¹³ In regard to the express and overall net impression statements attributed to Respondents by Complaint Counsel, Trish Feijo testified during discovery, "Those are not my words. They're not statements we made. We do not make such definitive statements." See Respondents' Motion to Amend, citing Deposition Transcript of Tricia Feijo, p. 214:line 10 to p. 214: line 19-24.

¹⁴ 371 U.S. 178, 182, 83 S.Ct. 227, 9 L.Ed.2d 1160 (1962).

referred to, and used, Respondents' religious and political speech from radio broadcasts. Complaint Counsel improperly manipulated this speech as part of the overall net impression, arguing that Respondents' free speech justified sanctions against them.

In turn, the ALJ omitted from his analysis the abundant evidence of the Respondents' political, religious and educational efforts that established Respondents as a religious ministry. Yet, at the same time, the ALJ wielded Respondents' religious and political speech as a weapon against them when he turned to the issuing the Remedy. As stated in Respondents' opening Brief, the ALJ refused to address the evidence and legal analysis of Respondents' political and religious speech and activities when doing so served to portray Respondents as being engaged purely in commerce. Yet, when crafting a remedy that included an unconstitutional prior restraint, the ALJ used Respondents' political and religious speech and activity to their detriment.

Complaint Counsel does not address this specific point. The Commission should do so.

3. **Respondents' disclaimers are authentic and effective absent extrinsic evidence to the contrary.**

The *Pearson* court noted that the standards used by the agency here violate the First Amendment when those standards are used to suppress and chill free speech claims whose truthful, though allegedly less- well supported information, can be accompanied by disclaimers. It has been a long-standing principle that a remedy preferable to suppression is disclaimer in the form of disclosure of qualifying explanatory language. See e.g. *American Home Products v. FTC*.¹⁵ See also, *Bates v. State Bar of Arizona*¹⁶, quoting *In re R.M.J.*¹⁷, stating " that the

¹⁵ 695 F. 2d 681, 713 (3rd Cir. 1983), citing *Beneficial v. FTC*, 542 F.2d 611 (1976).

remedy [for potentially misleading advertising] in the first instance is not necessarily a prohibition but preferably a requirement of disclaimers or explanation."

The preference toward disclosure and disclaimer has become grounded in the *Central Hudson* test. See *Pearson*. The agency is required to consider disclosures and disclaimers as "far less restrictive means" to suppression – especially when there is no evidence to prove that the disclosures and disclaimers in question were insufficient. *Id.* at 658. The burden of proving the disclaimers insufficiency is on the government, and evidence is required to meet that burden. *Id.*

Here, the government offered no evidence to prove that Respondents' disclaimers were insufficient. As with every other element of their case, the government relied on presumption only.

4. **Complaint Counsel's self-serving justification for the omission of extrinsic evidence contradicts the Commission's own guidelines.**

Complaint Counsel does not address at all many of the Respondents' points about the Constitutional failings of "prosecution by presumption," "regulation by adjudication" and improper use of the preponderance standard. Those failings are addressed in more detail below.

It is just as telling that Complaint Counsel fails to explain away its own guidelines, especially in regard to the shifted burden of proof and the requirement for extrinsic evidence.

5. **Complaint Counsel does not address the ALJ's error in shifting the burden of proof.**

As Respondents pointed out, the Initial Decision effectively shifted the burden of proof to

¹⁶ 433 U.S. 350 (1977).

¹⁷ 455 U.S. 191 (1982).

the Respondents. To reiterate, there's no question that Complaint Counsel would have the burden of proving that Respondents' speech was outright false. But the Overall Net Impression approach changes the equation improperly. Employing the Overall Net Impression standard, and allowing it to be applied by presumption as opposed to extrinsic evidence, the government shifted the burden of proof to Respondents. In the absence of extrinsic evidence against them, Respondents were forced to prove a negative, i.e., to show that their claims were **not** misleading or deceptive.

The ALJ clearly expressed the shift in burden that the government fosters when he stated that Respondents have "the burden of establishing what substantiation they relied on for their product and [then] Complaint Counsel has the burden of proving that [Respondents'] purported substantiation is inadequate." *See* Decision, p. 100.

To meet this substantiation burden, Respondents were to demonstrate that they had "competent and reliable scientific evidence" for its claims. This brings us right back to the *Pearson* analysis discussed above, in which the D.C. Circuit held against the agency's standard. Furthermore, Respondents did not make establishment claim, i.e., they did not expressly represent that their claims were based on such scientific evidence. Furthermore, the government provided no proof that consumers were misled into believing that Respondents were making any scientific-establishment claim. Again, the *Pearson* analysis applies in every respect.

Complaint Counsel does little more than mimic in rote fashion old precedent, which does not answer the Constitutional questions that Respondents have raised here. The government's approach violates Due Process. But the errors of law do not stop there.

a. The ALJ misapplied the element of intention.

Complaint Counsel did not address the ALJ's error in finding that Respondents' subjective intent had no bearing on the overall net impression of their representations. The Commission should do so.

As previously stated, the evidence showed that Respondents did not intend for their products to be considered drugs at all. Such an intention would be contrary to their religious beliefs.

To the contrary, Respondents' claims were that their Biblically-based approach to health care – including the challenged products – could provide adjunct support for whatever path one freely chose to take for their cancer care regimen. Respondents took considerable steps to express their intent that their approach was not scientifically based, and not to replace the advice of a medical doctor.¹⁸

By ignoring the element of Respondents' intent, the ALJ committed another error of law. Subjective intent is element of proof when the statute requires it. In the case of DSHEA and 15 U.S.C. §55(c), intent is expressly an element of the government's burden of proof. See e.g. *NNFA v. FDA*¹⁹ and *NNFA v. Mathews, et. al.*²⁰ Complaint Counsel failed to prove intent, as the statute required. The ALJ improperly ignored the government's requirement in his Initial Decision.

6. The requirement of double-blind, placebo based studies is contrary to law.

It deserves emphasis that the government's expert did not know what a structure/function claim is, despite the fact that DSHEA's permission for such claims was central to the case.

¹⁸ Respondents' disclaimer included not only the required language, it also included substantial spiritually-based qualifications which were virtually ignored by the ALJ.

¹⁹ 504 F. 2d 761 (2nd Cir. 1975).

²⁰ 557 F. 2d 325 (2nd Cir. 1977).

Employment of a non-establishment, Overall Net Impression case by presumption allowed the government to ignore Respondents' express claims – express structure/function claims to which no real challenge has ever been made. It was only by justifying a complete disregard of Respondents' evidence about the substantiation for the express structure/function claims that the government could offer the expert's testimony.

As the Commission knows, Dr. Denis Miller was the only substantive witness offered to support the government's case. Based on his testimony, and nothing more, the ALJ presumed that only substantiation by double-blind, placebo-controlled clinical trials, qualify as reasonable substantiation for Respondents' alleged claims.

The problem with exclusive reliance on Dr. Miller's testimony is the same problem that infects this case from the outset. It is a problem that Complaint Counsel's rote Response brief dodges: The government's non-establishment, presumptive overall net impression case does not stand up to due process. Dr. Miller testified about the overall net impression fed to him by the government. He did not consider the Respondents' express structure/function claims, nor could he. He wasn't qualified to do so.

It is important to note, nevertheless, that Dr. Miller did testify about many of the constituent ingredients of the Respondents' products. He believed that many of them displayed mechanisms of action that were properly identified by the Respondents in their claims.

In any event, the FTC Act does not require double blind, placebo-controlled studies as the basis for reasonable substantiation. As described in Respondents' opening Brief, the FTC could not proclaim such a standard without APA rulemaking. See e.g. *Pearson*.

Other than conclusory statements that DSHEA does not apply to its presumptive overall net impression case, Complaint Counsel offers no coherent explanation for why DSHEA does

not apply to Respondents' express, non-establishment statements. The Commission must concede that the Food Drug and Cosmetic Act (FDCA) does not require double-blind, placebo-based studies for structure or function claims.

Complaint Counsel also fails to offer coherent rebuttal do the holding of that *FTC v.*

QT.²¹ The Commission must also concede this holding:

[A] statement that is plausible but has not been tested in the most reliable way cannot be condemned out of hand. The burden is on the Commission to prove that the statements are false. (This is one way in which the Federal Trade Commission Act differs from the Food and Drug Act.) Think about the seller of an adhesive bandage treated with a disinfectant such as iodine. The seller does not need to conduct tests before asserting that this product reduces the risk of infection from cuts. The bandage keeps foreign materials out of the cuts and kills some bacteria. It may be debatable how much the risk of infection falls, but the direction of the effect would be known, and the claim could not be condemned as false. Placebo-controlled, double-blind testing is not a legal requirement for consumer products. *QT*, at 861.

Mindful that Dr. Miller could not testify about the meaning of a structure/function claim, the government is left with no competent challenge to the expert testimony that Respondents produced. This testimony from Drs. Duke and LaMont supported Respondents' express, non-establishment claims, just as they also testified that the substantiation that exists for those claims is reasonable. Moreover, as Respondents' opening Brief points out and Complaint Counsel's Response Brief largely ignores, the testimony of Drs. Duke and LaMont is consistent with the FTC's own Guidelines.

To review, these Guidelines apply to Respondents' express statements, notwithstanding the government's attempt to misdirect the analysis away from those express statements by means of its presumptive overall net impression case. The Guidelines state:

- "The FTC's standard for evaluating substantiation [for dietary supplement claims] must be sufficiently flexible to ensure that consumers have access to information

²¹ 512 F. 3d 858 (7th Cir. 2008).

about emerging areas of science.” *FTC Guide: Dietary Supplements, An Advertising Guide for Industry*, p. 8.

- There is no requirement that a dietary supplement claim be supported by a specific number of studies. *FTC Guide: Dietary Supplements, An Advertising Guide for Industry*, p. 10.
- Research concerning the biological mechanism underlying the claimed action is acceptable as reasonable substantiation for claims about dietary supplements. *FTC Guide: Dietary Supplements, An Advertising Guide for Industry*, p. 10.

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

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

Dr. LaMont’s testimony was largely unchallenged. Yet, inexplicably, the ALJ chose to disregard it.

C. Complaint Counsel’s failure to address the procedural due process errors is telling.

Respondents urge the Commission to address the holes that Complaint Counsel’s Response left open by Complaint Counsel’s failure to address these points:

1. Regulation by Adjudication.

Complaint Counsel does not dispute that an agency may not articulate new principles through adjudication if doing so would disadvantage those who had relied on existing law. *Weight Watchers v. FTC.*²² “[T]he agency may not use adjudication to circumvent the APA’s rulemaking procedures by . . . amending . . . or bypassing a pending rulemaking proceeding.” *Id.* Accord, *Montgomery Ward v. FTC.*²³

Again, Complaint Counsel does not dispute the chronology that compels the government to establish by rulemaking the standards it seeks to enforce through adjudication now. That chronology bears repeating:

- On or about April 29, 1998, the FDA issued a proposed rule titled *Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body*.
- On or about August 27, 1998, the FTC issued its comments in response to this proposed rule. These comments included the following:
 - “The FTC and FDA have complementary jurisdiction to address the marketing of dietary supplements. . . Their shared jurisdiction means that the two agencies coordinate closely to ensure that their actions are consistent to the fullest extent feasible given the statutory authority of each.
 - “The newly proposed amendment to this rule defining permitted structure/function claims does not . . . explicitly restate that such claim be substantiated.”
 - *FTC staff recommend that any final rule reiterate explicitly the requirement that structure/function claims be adequately substantiated.*

²² 830 F. Supp. 539, 542 (W.D. WA 1993); 1993 U.S. Dist. LEXIS 12555.

²³ 691 F. 2d 1322 (9th Cir. 1982); 1982 U.S. App. LEXIS 24194.

(Italics supplied in original.)

- *[FTC] Staff also recommends that FDA include guidance in the final rule as to what constitutes adequate substantiation of a structure/function claim.* (Italics supplied in original.) This would help address uncertainty within the dietary supplement industry about how FDA applies the DSHEA substantiation requirement. It would also clarify how the FDA's approach to substantiation relates to FTC's substantiation standard.
- On January 15, 1999, the D.C. Circuit Court of Appeals issued its decision in *Pearson v. Shalala*, wherein the Court expressed concerns nearly identical to the FTC's concern expressed just months earlier about the lack of clear standards for adequate substantiation.²⁴
- The FDA's final rule was issued on or about January 6, 2000.²⁵ That rule includes nothing that addresses the FTC's concerns, nor the *Pearson* Court's directions.

The government's failure to establish by rulemaking the standards for adequate substantiation for dietary supplement health claims is arbitrary and capricious. See *Pearson*, at 660.

As Respondents stated in their opening Brief, the effect is especially egregious here where the ALJ has adjudicated the elements of the government's case by presumption and where he has allowed the burden of proof to shift to Respondents. This approach requires proper rulemaking, not regulation by adjudication.

2. **Adjudication by Presumption.**

Complaint Counsel also fails to address this issue, the foundation for which lies in

²⁴ As made clear by the *Pearson* court, the FDA's vague standard (significant scientific agreement) and the FTC's standard (reasonable scientific basis) are for all practical intents and purposes identical, and similarly vague.

²⁵ Federal Register: January 6, 2000; Vol. 65, No. 4.

*Stanley v. Illinois*²⁶ and *Mathews v. Eldridge*²⁷.

Respondents first remind the Commission about the *Stanley* case, where the Court addressed whether the State could forego due process requirements by **allowing presumptions to supplant evidence** in the interest of efficiency.

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 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.

Id. at 656-657.

Next, in *Mathews*, 424 U.S. at 335, the Court explained the three-part evaluation that courts must use to examine the minimum constitutional process due in a variety of procedural situations: (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.

Mathews requires the Commission to address the failings of adjudication-by-presumption in light of (i) the importance lies in understanding that importance of the First Amendment interest affected here; (2) the risk of an erroneous ban of truthful structure/function claims, and

²⁶ 405 U.S. 645 (1972).

²⁷ 424 U.S. 319 (1976).

(3) the minimal additional burden that would be placed on the government by requiring it to prove its case with actual extrinsic evidence under a “clear, cogent and convincing” standard, rather than presuming evidence under a “preponderance” standard.

3. The Government Improperly Applied the Preponderance Standard.

This leads to the third procedural due process issue ignored by Complaint Counsel, i.e. that the evidentiary standard of “clear, cogent and convincing” should apply to the substantive issues in this case based on *Addington v Texas*²⁸. *Addington* is a case that has never been limited to its facts, and the Commission must contend with it here.

Using the *Mathews* analysis, the Court addressed the standard of proof issue:

The function of a standard of proof, as that concept is embodied in the Due Process Clause and in the realm of fact-finding, is to "instruct the fact-finder concerning the degree of confidence our society thinks he should have in the correctness of factual conclusions for a particular type of adjudication." *In re Winship*, 397 U.S. 358, 370 (1970) (Harlan, J., concurring). The standard serves to allocate the risk of error between the litigants and to indicate the relative importance attached to the ultimate decision.

In regard to the “clear, cogent and convincing” standard, the Court said this at

424-425:

One typical use of the standard is in civil cases involving allegations of fraud or some other quasi-criminal wrongdoing by the defendant. **The interests at stake in those cases are deemed to be more substantial than mere loss of money and some jurisdictions accordingly reduce the risk to the defendant of having his reputation tarnished erroneously by increasing the plaintiff's burden of proof.** Similarly, this Court has used the "clear, unequivocal and convincing" standard of proof to protect particularly important individual interests in various civil cases. . . . [quoting *Tippett v. Maryland*²⁹] a “standard of proof is more than an empty semantic exercise.” In cases involving individual rights, whether criminal or civil, “[the] standard of proof [at a minimum] reflects the value society places on individual liberty.”

²⁸ 441 U.S. 418 (1979).

²⁹ 436 F. 2d 1153, 1166 (CA 4, 1971).

(Emphasis added.)

As Respondents stated in their opening Brief, and Complaint Counsel chose to ignore, the ALJ rejected the “clear, cogent and convincing” standard based on cases that involved only proof about FTC jurisdiction. Those cases do not concern Due Process owed to the fundamental constitutional issues involved here. Indeed, this case does not involve “mere loss of money.”

[I]n certain limited circumstances, the heightened burden of clear and convincing evidence is required "when the government seeks to take unusual coercive action - action more dramatic than entering an award of money damages or other conventional relief - against an individual." [citing *Price Waterhouse v. Hopkins*³⁰; other citations omitted.]³¹

Respondents remind the Commission that they are faced with the following:

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

Complaint Counsel's silence on these topics should constitute admissions.

³⁰ 490 U.S. 228, 253 (1989)

³¹ *Coleman v. Anne Arundel Cty. Police Dept.*, 797 A. 2d 770, 791 (Md. 2002).

D. Summary of Constitutional Arguments: If the Commission adopts the ALJ's Initial Decision it will affirm the position that a party making an expressly false claim has more Constitutional protection than one making a truthful but allegedly misleading claim

Complaint Counsel has embraced the ALJ's Initial Decision against DCO as one which in no way violates the First Amendment. CC Br., pp. 49-58. See ALJ Op., pp. 112-117.

However, Complaint Counsel disregards wholesale most of DCO's First Amendment arguments, while making erroneous claims about the one First Amendment issue which it does address — the Commercial Speech doctrine.

Even then, Complaint Counsel erroneously refuses to apply the First Amendment Commercial Speech test to this case. The result is that while a party accused of making a false claim has strong constitutional rights—burden of proof on the government, least intrusive remedy, congruence with government interest and remedy, evidence of harm, etc.—a party accused of making a claim that has the possibility of misleading consumers, even if true, has no constitutional protections.

This outcome results from the following ways that Complaint Counsel and the Administrative Law judge have ignored or distorted the constitutional issues in this case.

1. Complaint Counsel has failed even to respond to any of DCO's foundational First Amendment Claims.

Complaint Counsel's entire discussion of First Amendment Arguments is predicated on a demonstrably false assertion — that "on appeal" DCO has "apparently concede[d] that the speech in question is commercial speech." CC Br., p. 49. The claim of an apparent concession is demonstrably bogus. Certainly DCO has contended that the ALJ "misapplied the *Central Hudson* test" laid down by the Supreme Court to govern First Amendment commercial speech

claims, but DCO has never limited its First Amendment claims to that single contention, and even noted expressly in its opening brief that it made no such concession. *See* Resp. Br., p. 14, n.1. Rather, throughout its Appeal Brief, DCO has contended that the FTC’s action in this case has transgressed the First Amendment in several distinct ways, reiterated below, not limited to the commercial speech doctrine.

a. DCO’s participation in the national public policy debate.

In its Introduction to the Argument section of its Appeal Brief, DCO urged the Commission to assess the complaint against DCO in the context of an ongoing national public policy debate “between health orthodoxy and advocates for different approaches.” Resp. Br., pp. 5-7. (Here, DCO invoked the FTC’s discredited decision in the 1967 *Rodale Press*, 407 F. 2d 1252, case — in which a commissioner had warned against the FTC imposing an unconstitutional health care “orthodoxy” upon the American people.)

b. DCO’s operation as a religious ministry.

DCO called attention to the fact that the ALJ had ignored the fact that DCO’s herbal statements were an integral part of a “religious ministry.” Resp. Br., pp. 5-7, 62-63. (Here, DCO extended its First Amendment concern from the imposition of an “orthodoxy” of opinion to the FTC’s current effort to artificially separate DCO’s efforts to promote its formulations from its overall religious ministry.)

c. Government licensing of words.

DCO reminded the Commission of its aborted 1974 effort to ban the use of words, such as “natural,” “organic,” and “health foods,” cautioning the Commission not to affirm the ALJ’s Initial Decision which is based upon a highly debatable word-smithing effort to say “herbal supplements” equal “pharmaceutical drugs.” Resp. Br., pp. 7-9.

In the instant adversarial procedure, one would think that Complaint Counsel would defend the ALJ opinion by responding on the merits to these serious threats to DCO's First Amendment rights. In choosing not to respond, Complaint Counsel has presumed upon the deference of this Commission. This stratagem should not be rewarded. Even though Complaint Counsel may work for the Commission which is hearing this appeal, where no argument is advanced by Complaint Counsel, there can be no deference.

Specifically Respondents make clear that there are raising a number of constitutional issues in addition to their protection of these statements as commercial speech if it is indeed commercial speech a fact contested by Respondents.

2. **Complaint Counsel misunderstands the continuing constitutional vitality and significance of *United States v. Johnson* which can be a valuable guide to the Commission.**

DCO has contended that, in addressing the First Amendment issues in this case, the Commission must employ the long-standing "constitutional logic" that distinguishes matters of "opinion" from matters of "fact." It pointed out that two eminent justices of the Supreme Court understood and spelled out that distinction nearly a century ago in *United States v. Johnson*, 221 U.S. 488 (1911). DCO Br., pp. 9-11. Complaint Counsel, however, would dismiss the constitutional wisdom of Justice Holmes and Chief Justice Hughes as mere "dicta," no longer relevant because the language in the statute addressed in *Johnson* has been amended. CC Br., pp. 52-53. This misreads the meaning of constitutional protections and the structure of constitutional legal analysis. While the statutory landscape has changed, the constitutional paradigm of the *Johnson* decision —

distinguishing “fact” and “opinion” — remains the same. *See, e.g., Gertz v. Robert Welch, Inc.*, 418 U.S. 323, 339-40 (1974).

By employing the “**reasonable basis** theory” rather than the **actual falsity** theory, Complaint Counsel and the ALJ have unconstitutionally entered into the realm of opinion rather than fact. By this shift Complaint Counsel and the ALJ lay out the structural way in which they deprive a party making a statement that is allegedly possibly misleading of constitutional rights that a party making an allegedly actually false statement retains. Indeed, by substituting “the overall net impression of DCO’s advertisements to determine” DCO’s cancer cure claims, Complaint Counsel has **imputed to DCO claims that it never made**.

Thus, the ALJ and Complaint Counsel transmuted DCO’s testimonial statements of the efficacy of its herbal supplements into “objective” health claims unsupported by any scientific opinion that would be acceptable to the FTC. *See* CC Br., pp. 28-31. (To the Complaint and the ALJ scientific opinion is synonymous with placebo controlled double blind studies) In so finding and arguing, the ALJ and Complaint Counsel crossed the line, not only misconstruing the FTC’s authority under sections 5(a)(1) and 12 of the FTC Act (*see* Resp. Br., pp. 44-45) but also, in the process, failing to “provide sufficient breathing room for protected speech.” *See* Resp. Br., pp. 64-65.

As the Supreme Court explained in *Illinois ex rel Madigan v. Telemarketing Associates, Inc.*, 538 U.S. 600 (2003), when the enforcement of a government policy against deceptive or false representations sweeps away indiscriminately both protected and unprotected speech, the government bears the “full” burden of proof that the communicator has made a “false representation of a material fact knowing the

representation was false.” *Id.*, 538 U.S. at 619-20. By substituting its standard of “reasonableness” for actual falsehood or deception, the ALJ and Complaint Counsel have imposed upon DCO an unconstitutional “prior restraint,” having imposed on DCO “an uphill burden to prove their conduct lawful.” *Id.* They acknowledge they could not take such a position against a party alleged to have made an actually false statement.

In *United States v. Johnson*, Holmes and Hughes contested over this fact v opinion ground. Hughes in the minority argued that the Constitution did not prohibit a law against advertisements that were demonstrably false. Holmes in he majority argued that when it came to the effectiveness of an alleged remedy whether it worked or not was a matter of opinion and therefore protected even if demonstrably false. Respondents’ argue here that to make a case that a statement is misleading the government must provide some evidence of that fact. Complaint counsel and the ALJ say no evidence of harm, falsity or confusion is necessary. The government’s presumption and common sense is all that is necessary. This is a much weaker burden on the government then the Oone it accepts when prosecuting a case in which it alleges the falsity of a statement.

3. **The ALJ and Complaint Counsel have misapplied the First Amendment Commercial Speech Doctrine.**

Complaint Counsel argues (CC Br., p. 49) and the ALJ found (Decision p. 113), that DCO’s statements promoting its products could be construed as nothing more than “commercial speech,” and therefore not protected by the First Amendment.

As pointed out above and in its appeal brief, DCO relies heavily on *Pearson v. Shalala*. In *Pearson*, the Court of Appeals for the District of Columbia Circuit applied the 3-part test of *Central Hudson* to an FDA action against a dietary supplement. The

agency argued that the supplement was “misbranded” because its cancer cure claims were unsupported by “significant scientific agreement.” *Id.*, 164 F.3d at 653-64. In parallel fashion, this FTC action against DCO’s dietary supplements is based on the ground that DCO’s cancer cure claims were “deceptive” because they were unsupported by “competent and reliable scientific evidence” *See* Decision, pp. 99-107. (While respondents’ experts said competent herbal scientific evidence supported respondents’ statements the government argued that the definition of “competent scientific evidence” was placebo controlled double blind studies.)

Respondents point out above in their previous briefs that both the FDA in *Pearson* and the FTC here have claimed that the First Amendment commercial speech doctrine does **not** apply. It does not apply, the agencies argue, because neither the brand in *Pearson* nor the herbal formulation statements here met the respective agency’s “scientific” standard and, thus, the brand in *Pearson* and DCO’s representations were “misleading.” The agencies then argue that Constitution protection for commercial speech set out in *Hudson* do not apply to “misleading” speech.

The *Pearson* Court rejected the FDA’s contention, and applied the *Central Hudson* 3-part test. In this case, however, The ALJ ignored the *Pearson* opinion, and disallowed application of the Central Hudson test.

In its Answering Brief, Complaint Counsel has made a valiant, but vain, attempt to distinguish the *Pearson* ruling from this case. In *Pearson*, Complaint Counsel has argued, the FDA had established its “scientific” standard “*a priori*” by **rulemaking** rather than by *ad hoc* **adjudication**, thereby precluding any “individualized determination” of the efficacy or safety of any particular dietary supplement. CC Br., p.

52. By contrast, Complaint Counsel has contended, the FTC “scientific” standard would allow for “individualized determinations” whether the particular claims made by DCO were substantiated by that standard. *Id.* As pointed out above this is both a misreading of the Pearson courts statement and an inversion of principles of administrative law that require clear statements of clear rules so that individual can know how to comply.

Common to both *Pearson* and this case, however, the FTC “scientific” standard by which DCO’s product representations has been measured is just as fixed as that of the FDA. Moreover, while the FDA standard was fixed by the **formal Administrative Procedure Act rulemaking process**, the FTC standard emanated from the much less formalized process of “industry guidelines” which themselves foreclose any consideration of “[a]necdotal evidence about the individual experience of consumers” on that ground that such evidence is “not sufficient to substantiate claims about the effects of a supplement.” *See Dietary Supplements: An Advertising Guide for Industry*, p.10 (Federal Trade Commission, Bureau of Consumer Protection: April 2001).

According to the ALJ’s Initial Decision, it is FTC policy to reject any “consumer health” claims for dietary supplements that do not meet the “high level of substantiation, such as scientific tests,” because such health claims “are difficult or impossible for consumers to evaluate for themselves.” Decision, p. 102. It matters not whether the statement is true if it does not meet the FTC standard of doubled blind placebo controlled studies it is rejected—no evidence of harm, no proof that consumers are misled, no fitting remedy to legitimate government interest. No double blind studies no statements. This is not an approach that complaint counsel or ALJ could sustain against an allegation that a statement it chose to suppress was false.

As the *Pearson* Court ruled such a policy is based upon a “paternalistic assumption” that is foreign to the First Amendment, and must be rejected. *Pearson*, 164 F.3d at 655. *See also* Resp. Br., pp. 16-17. As James Madison stated in 1792, it is “the nature of republican government that the **ensorial power** is in the people over the Government, and **not in the Government over the people.**” *See New York Times v. Sullivan* (emphasis added).

Complaint Counsel’s effort to put *Pearson* aside fails for an additional reason. In his zeal to discount DCO’s claim that, under the commercial speech doctrine, the government has the burden of proving that DCO’s advertisements were **actually misleading** (Resp. Br., pp. 18-26), Complaint Counsel asserted that DCO “offer[ed] no cases where [the FTC’s] well-established principle” that to be “deceptive an advertisement only needs to be *likely to mislead* consumers ... was found to violate the First Amendment.” *See* CC Br., p. 50 (italics original).

To the contrary, in *Pearson*, the court of appeals found that, even though the dietary supplement claims were “potentially misleading,” nonetheless the FDA action against those supplements did not comply with the *Central Hudson* test protecting commercial speech. *See Pearson*, 164 F.3d at 655-661. Once again the use of the “*likely to mislead*” standard (the government in this case provided not evidence that the statements it challenge might mislead let alone were “likely to mislead”) makes a mockery of any distinction between false and misleading statements. Since, by complaint counsel’s argument and ALJ’s Initial Opinion, is so easy to suppress a “misleading” statement why go the extra work of charging a party with false statements.

4. **The proposed Order coercing DCO to communicate the FTC's Order to consumers violates DCO's Free Exercise of Religion.**

In one short paragraph pooh-poohing DCO's religious exercise claim, Complaint Counsel cites *Church of Scientology v. Richardson*, 437 F.2d 214 (9th Cir. 1971) to support its assertion that DCO has no genuine religious freedom claim in this case. CC Br., p. 58. But that case is inapposite, as it did not involve the enforcement of any statute prohibiting "false or misleading" claims. Rather, as the court specifically pointed out, the issue addressed was whether the FDA enforcement of a statute that required the label on a particular healing device to bear adequate directions for its use, as required by law. *Id.*, 437 F.2d at 218. The court concluded that it "could determine the E-meter's intended use without evaluating the truth or falsity of any related 'religious' claim." *Id.*

In fact, the Court took pains to distinguish an earlier D.C. Court of Appeals decision (also, in a Scientology case) where the FDA had attempted enforcement of a statute forbidding "false or misleading" labeling of the same device. *Id.* In that earlier case, the court rejected the FDA's argument, analogous to that of Complaint counsel here, that "religion is simply irrelevant." *Founding Church of Scientology v. United States*, 409 F. 2d 1146, 1154 (D.C. Cir. 1969). Rather, invoking *United States v. Ballard*, 322 U.S. 78 (1944), the D.C. Court ruled that the "holding of the case seems to be that **regulation of religious action which involves the testing in court the truth or falsity of religious beliefs is barred by the First Amendment.**" *Id.*, 409 F.2d at 1156. (Emphasis added.)

Once again we see the distinction that fact and opinion that Holmes and Hughes struggled with in *US v. Johnson*. The Scientology case cited by Complaint Counsel

concerns directions for use—matters of fact directly analogues to those Holmes recognized as appropriately required in Johnson. The Second Scientology case ignored by Complaint Counsel goes directly to opinion—in this case religious opinion—which no law can suppress.

Applying the FTC’s “reasonable basis theory” and its “competent and reliable scientific evidence” standard, the ALJ determined that “testimonials do not constitute adequate substantiation for health-related efficacy claims in advertising.” Decision, p. 105. However testimonials are useful in addressing the question of whether or not the statements made are misleading and/or harmful issues upon which the government argues it need not present evidence and which respondents argue that that without out evidence on this point the complaint must be dismissed. This is again an example of a distinction creating more constitutional rights for a party charged with making false statements than on making statements that are alleged to be misleading.

In addition the ALJ dismissed without discussion the testimonial foundation upon which DCO’s ministry is based. *See, e.g.,* Decision., F. 182-87, 196-208. That evidentiary foundation, in turn, is based upon DCO’s religious faith in God’s revelation that he has “given us herbs in His creation and nutrients that can heal cancer, even cure cancer.” F. 216. This is a direct clash between knowing and believing through experience and knowing and believing through double blind placebo controlled studies. The outcome of this clash cannot be determined by the double blind study side asserting that it is right by common sense and it need not subject its belief to the test of evidence.

The demonstrated fact that God’s revelation in the Holy Bible as confirmed by the witness and testimony of his family on earth serves as a fountainhead for the entire DCO

ministry (see F. 16) was dismissively swept aside because the FTC's "scientific" standard allowed for no other test of truth or falsity than one which is inherently secular. In short, the FTC standard brands as false any claim of a healing property in any dietary supplement that is based upon the revelation of God, and the experience of individual people as confirmed by individual testimonies.

According to Complaint Counsel, however, the free exercise of religion guarantee is preserved in this case because DCO and the Feijos are "free to believe whatever they want and to practice their faith as they see fit." CC Br. p. 58. However, under Complaint Counsel's subordination of religious practice to the beneficent control of the state, DCO's free exercise could not involve testifying to the power of God, and the use of foods, supplements and herbs based on the demonstrated truth of his revelation.

Indeed, if the proposed Orders in this case are adopted by the Commission, DCO and the Feijo's would be forced to repudiate publicly "their faith" in God's revealed truth and be forced to embrace and proclaim as their own the FTC's faith in so-called "science." *See* Resp. Br., pp. 64-65. The importance of this situation rest on the fact that the outcome sought by the government is sought without recourse to any evidence that the Feijos' statements are wrong, untrue, misleading, dangerous, or inappropriate. The government takes the simple position that we are right because we say we are right and common (scientific) sense supports us. It is Respondents' position that clearly the Constitution protects religious opinion in this case and it indeed protects all opinion as explained by Holmes in *Johnson*.

IV. REMEDY

A. The Remedy must be rejected.

Complaint Counsel devotes little attention to Respondents' points about the remedy other than repeating canned, non-responsive boilerplate rhetoric. Respondents urge the Commission to give ample consideration to these points, beginning with the recent *Lane Labs* decision.

1. ***Lane Labs* foreshadows the path on which this case is headed.**

The similarities between this case and the Commission's failed enforcement action against Lane Labs cannot be overstated. Both cases concern the structure/function claims made by dietary supplement providers. Both cases concern the amount of substantiation necessary to support those structure function claims. Both cases illuminate the vague and arbitrary standards that the government has used to this point to justify its illegal presumptions and overbroad remedies.

As before, Judge Cavanaugh's *Lane Labs* opinion carries considerable weight here. The Commission will recall that Judge Cavanaugh considered the substantiation relied upon by the manufacturer – substantiation that was considerably less than double-blind clinical trials. He credited the manufacturer with the following comment by stating, “This is not a case of a company making claims out of thin air.” As Respondents pointed out before, the testimony of Drs. Duke and LaMont proved that Respondents' claims were also not made from thin air. This alone distinguishes Respondents' case from the outcomes in *QT* and *Direct Marketing*, in which the courts noted that the substantiation offered by respondents there amounted to little or nothing.

Recall also that Judge Cavanaugh stated that, “[the manufacturer] provided credible medical testimony that the products in question are good products and could

have the results advertised . . .” This is exactly the proof and testimony provided by Drs. Duke and LaMont on behalf of Respondents here.

This statement from Judge Cavanaugh also bears repeating, just as it also bears a response from the Commission, which Complaint Counsel utterly failed to accomplish in its Response:

[T]he Court notes that there has been no physical harm to the public. The FTC seeks to [enforce the remedy] to cure consumer injury . . . Despite the FTC’s claims, the FTC provides no evidence that consumers have complained that they were physically harmed by the use of [the] supplements. This compounds the fundamental fairness issues in this case.

2. RFRA has been violated.

Complaint Counsel’s half-page of analysis does not explain why the Religious Freedom Restoration Act of 1993 (RFRA) does not apply here. The U.S. Supreme Court has made it clear that RFRA applies to the actions of Federal agencies and programs. Under RFRA, the government may not burden a person’s exercise of religion, "even if the burden results from a rule of general applicability." §2000bb–1(a). The only exception recognized by the statute requires the Government to satisfy the compelling interest test—to "demonstrat[e] that application of the burden to the person—(1) is in furtherance of a compelling government interest; and (2) is the least restrictive means of furthering that compelling governmental interest." §2000bb–1(b). A person whose religious practices are burdened in violation of RFRA "may assert that violation as a claim or defense in a judicial proceeding and obtain appropriate relief." §2000bb–1(c). "*Gonzales v O Centro*. In this regard, RFRA mirrors the *Central Hudson* test.

The RFRA and *Central Hudson* standards integrate to prohibit the very strategy

and outcome fostered by the government here. Consider anew these statements:

If the First Amendment means anything, it means that regulating speech must be a last - not first - resort. . . We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information. . . Even if the Government did argue that it had an interest in preventing misleading advertisements, this interest could be satisfied by the far less restrictive alternative of requiring each compounded drug to be labeled with a warning that the drug had not undergone FDA testing and that its risks were unknown.³²

When the context of that speech is religious in nature, issued by a judicially-confirmed religious ministry, as is the case here, government suppression is prohibited.

[N]either this court nor any branch of this government will consider the merits or fallacies of a religion. Nor will the court compare the beliefs, dogmas, and practices of a newly organized religion with those of an older, more established religion. Nor will the court praise or condemn a religion, however excellent or fanatical or preposterous it may seem. Were the court to do so, it would impinge upon the guarantee of the First Amendment.³³

a. The Commission's use of Respondents' religious broadcast is a gross violation of RFRA and the Constitution.

The ALJ completely ignores DCO's claim that its promotional activities concerning the healing products is an integral part of an educational, charitable and religious mission, and thus, protected by the First Amendment religion, speech and press guarantees. As noted in Part I above, the ALJ diminishes the unrebutted testimony of the Feijos that DCO is engaged in a nonprofit educational, charitable and religious mission, belittling its corporate sole status and its substantial religious ministry. Instead, the ALJ

³² *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002).

³³ *Universal Life Church, Inc. vs. United States*, 372 F. Supp. 770, 776 (E.D. Cal 1974).

presents DCO as an exclusively commercial enterprise, downplaying at every chance the nonprofit charitable and religious aspects of the ministry.

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

As they now stand, the ALJ’s Findings of Fact offer weak support for this constitutional claim. Although there is some evidence that the promotional materials for the products are linked to an overall educational and religious mission, the ALJ’s findings are written in such a way as to emphasize the commercial, not the educational. *See, e.g.*, Bioguide: Spiritual, physical and Biblical approach to body wholeness. F. No. 85-89, Decision, pp. 14-15; Disclaimers. Testimony about God and His Creation on website etc. F. No. 296-306. Decision, pp. 48-50. It would be necessary to take these findings and give them an educational/Biblical emphasis and to search the record to determine if the ALJ erroneously failed to include facts establishing the DCO’s educational and religious nature, in his zeal to establish DCO as a purely commercial enterprise.

3. **Complaint Counsel’s covert reliance on consent orders involving non-religious organizations to justify the ALJ’s remedy is dishonest.**

In its Response, Complaint Counsel puts before the Commission a litany of string cites to administrative cases, characterized as support for the ALJ’s remedy, and more

specifically, as support for the government-required letter to Respondents' followers. Complaint Counsel's characterization of these cites as binding judicial authority is inaccurate and dishonest.

Complaint Counsel has not produced a case from a court of appellate jurisdiction in which that court upheld the requirement that a "consumer letter" be sent by a religious ministry to its followers, in which the ministry is ordered to make statements that are in direct contradiction to its ministry. If a notice is warranted at all, Respondents suggest that it should contain nothing more than a link to all the electronic files in this case, so that Respondents' followers can decide for themselves, as the Constitution and the Supreme Court's Constitutional analysis would require.

4. **The Remedy compels Respondents to adopt government religious speech.**

The ALJ understood the potential for the required letter to violate Respondents' Constitutional rights. He acknowledged that "the proposed letter attached to the Complaint could be seen as requiring Respondents to adopt as their own statements and opinions that are contrary to the beliefs to which Respondents testified at trial." Decision, p. 121. Nevertheless, the modification he proposed is inadequate. Respondents incorporate the semantic and contextual analysis of their opening Brief on this point, and urge the Commission to consider the implications of that analysis in depth, especially considering that Complaint Counsel leaves that analysis unchallenged.

It bears repeating that the ALJ conceded that the FTC did not proceed against the Respondents under a "falsity theory." *Compare* Decision, p. 99, n.4 *with* Decision, 121. There is no basis for Respondents to send the required letter other than to force

Respondents into a confession that they made “false and unsubstantiated” claims. T

Again, this is not just unprecedented. It is contrary to Respondents’ deeply held religious beliefs and their right to free exercise of religious ministry. As cited in Respondents’ opening Brief, *See West Virginia State Board of Education v. Barnette*, 319 U.S. 624 (1943). As also stated, the government’s remedy on this point is contrary to Mr. Feijo’s right “to refrain from speaking at all.” *See Wooley v. Maynard*, 430 U.S. 705 (1977).

b. Complaint Counsel failed to address the charitable solicitation issue.

Respondents have pointed out that the government’s effort to isolate Respondents’ alleged commercial speech from their overall religious and political mission is comparable to the efforts by government agencies to isolate an organization’s charitable solicitations where those solicitations are integral to that organization’s political mission. This is an important point, which Complaint Counsel dodged. It warrants a response by the Commission on review now.

The Supreme Court has resoundingly rejected the government’s approach in circumstances like this one. As Respondents previously point out:

Soliciting financial support is undoubtedly subject to reasonable regulation but the latter must be undertaken with due regard for the reality that solicitation is characteristically intertwined with informative and perhaps persuasive speech seeking support for particular causes or for particular views on economic, political or social issues, and for the reality that without solicitation the flow of such information and advocacy would likely cease.³⁴

That same standard has been embraced by the Supreme Court in its latest

³⁴ *Village of Schaumburg v. Citizens for a Better Environment*, 444 U.S. 620, 632 (1980).

charitable solicitation case in order to “provide sufficient breathing room for protected speech.” *Illinois ex rel Madigan v. Telemarketing Associates, Inc.*, 538 U.S. 600, 620-21 (2003). For the reasons stated in their January Motion to Dismiss, the *New York Times v. Sullivan* “actual malice” standard applies here.

That heavy presumption of unconstitutionality applies equally to the FTC and any other administrative agency empowered by Congress to enjoin the future publication of allegedly “deceptive” statements. Indeed, if State and Defense Department’s appeal to “national security” was found constitutionally insufficient — as the Court did in the Pentagon Papers case — the FTC’s appeal to the need for “competent and reliable scientific evidence” in this case is clearly insufficient. As Justice Brennan observed in the Pentagon Papers case, the First Amendment prohibits a court injunction based upon “surmise or conjecture that untoward consequences may result.” *Id.*, 403 U.S. at 725-26. The First Amendment doctrine of prior restraint would also prohibit an FTC order enjoining Respondents when that order is based upon the FTC’s “overall net impression” that Respondents’ promotional statements are misleading without any concrete evidence that anyone was misled by such statements or physically harmed.

While the FTC may have no qualms about enforcing its orthodoxy of double-blind, placebo-based tests upon Respondents, the First Amendment religion guarantees forbids the government from imposing upon the American people any such form of orthodoxy — in the name of “science” or in any government-approved belief system. *West Virginia State Board of Education v. Barnette*, 319 U.S. 624 (1943). After all, it is one thing for the FTC to enjoin a person from making false scientific claims for their products, but it is quite another thing to enjoin a person from making truthful claims that

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the FTC finds to be “deceptive” because those claims do not conform to the FTC’s established scientific world view.

V. CONCLUSION

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

CERTIFICATE OF SERVICE

I certify that on November 4, 2009, pursuant to Federal Trade Commission Rules of Practice 4.2(c) and 4.4(b), I caused the foregoing Respondents' Reply Brief to be served and filed, as follows:

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

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

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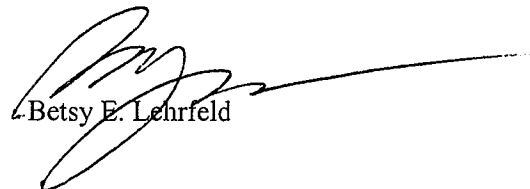
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I further certify that the electronic copy sent to the Secretary of the Commission is a true and correct copy of the paper original, and that a paper copy with an original signature is being filed with the Secretary of the Commission on the same day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


Betsy E. Lehrfeld