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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

DOCKET NO. 9329

IN THE MATTER OF
DANIEL CHAPTER ONE, a corporation

and

JAMES FEIJO, individually and as an officer of Daniel Chapter One

ANSWERING BRIEF OF COUNSEL SUPPORTING THE COMPLAINT

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INTRODUCTION

Judge Chappell got it right. He made 425 detailed findings of fact and then applied well-established precedent to those findings. Based on those findings and conclusions, Judge Chappell issued a cease and desist Order consistent with Federal Trade Commission ("FTC") practice and precedent.

Regarding jurisdiction, Judge Chappell correctly found that Respondent Daniel Chapter One ("DCO") operates a multi-million dollar commercial enterprise, and that Respondent James Feijo ("Feijo") treats DCO's funds as his own. The ALJ correctly found that the FTC has jurisdiction over both Respondents.

Regarding the advertisements, Judge Chappell correctly found that a facial analysis of Daniel Chapter One's advertisements for Bio*Shark, 7 Herb Formula, GDU, and BioMixx (the "Challenged Products") demonstrates that Respondents made claims that their products could treat, cure, or prevent cancer, inhibit tumors, or ameliorate the adverse effects of radiation and chemotherapy. They told consumers **"How to fight cancer is your choice!"** and that the Challenged Products were "Daniel Chapter One's Cancer solution" which would "stop tumor growth" and "battle cancer." The record in this case reveals that Respondents lacked any reasonable substantiation for those claims, making those claims deceptive.

In their appeal, Respondents make no effort to demonstrate that the ALJ's Findings of Fact were not supported by the evidence. Indeed, in this advertising case, the Respondents discuss everything but the advertisements at issue. Respondents' decision to ignore their advertisements is not surprising, because the advertisements at issue make the claims alleged in the Complaint.

Similarly, Respondents make no serious effort to distinguish the legal authority relied

upon by Judge Chappell. Rather, Respondents spout rhetoric invoking Due Process and the First Amendment but ignore the long string of well-established precedents on which Judge Chappell relied and based his decision.

Respondents build their argument on a flawed foundation. Respondents premise their rhetoric on the notion that absent extrinsic evidence they can only be found liable for the exact words used in their advertisements. Respondents assert that because the claims alleged in the Complaint go beyond the exact words of their advertisements and Complaint Counsel offered no extrinsic evidence, the ALJ erred in finding that the claims alleged in the Complaint were made. Respondents ignore and fail to distinguish the well-recognized body of law (upon which the ALJ relied) finding that a court and the Commission can conduct a facial analysis of the advertisements to determine what claims were made. Indeed, rather than addressing the detailed findings of fact made by the ALJ concerning the claims made by the advertisements, Respondents simply ignore them and then complain that the ALJ adjudicated by presumption. Respondents' decision to ignore the claims conveyed by their advertisements does not make those advertisements disappear.

Respondents build upon this error in discussing substantiation. Respondents at trial proffered "experts" who were not even medical doctors, who could not and did not opine on whether DCO possessed substantiation for the claims alleged in the Complaint. Rather, DCO's experts limited their opinions to selected excerpts from some of the advertisements. The ALJ correctly noted this error, but the Respondents continue to argue in this fashion on appeal. Respondents ignore that a facial analysis of the advertisements reveals that the Respondents tout the Challenged Products as effective cancer and tumor treatments and then chastize the ALJ for relying on a world-recognized oncologist to find the claims made unsubstantiated. Respondents

ignore that the advertisements tout the Challenged Products as effective cancer and tumor treatments and argue that because no cancer treatment claims were made they need not offer the level of substantiation necessary to support such claims.

Respondents' First Amendment argument, the penthouse in this house of cards, rests on the same shaky foundation. The ALJ correctly found that because the advertisements were deceptive they were entitled to no First Amendment protection. Based on the same flawed arguments, Respondents assert that the advertisements have not been adequately shown to be false and, therefore, First Amendment protection applies.

The ALJ's Initial Decision contains detailed findings of fact well supported by the evidence and applies straight-forward and well-established law to those facts. Nothing in the Respondents' rhetoric changes that. The Initial Decision should be affirmed.[1]

STATEMENT OF FACTS

A. History of the Proceedings

On September 16, 2008, the FTC issued the Complaint in this matter. The Court held a hearing on jurisdiction on April 21, 2009. On April 22, 2009, the ALJ issued a ruling from the bench that Complaint Counsel had demonstrated, by a preponderance of the evidence, that jurisdiction exists in the case. The trial commenced on April 23, 2009 and the testimonial portion concluded on April 27, 2009. Closing arguments were heard on July 9, 2009. A total of eleven witnesses testified at the hearing on jurisdiction and at trial. In an initial decision filed on

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[1] On appeal, the Commission may make its own legal determinations and *de novo* factual findings from the hearing record. *See* 5 U.S.C. 557(b) ("On appeal from or review of the initial decision, the agency has all the powers which it would have in making the initial decision except as it may limit the issues on notice or by rule."); *see also* Federal Register, Vol. 74, No. 8 (16 CFR Parts 3 and 4 Rules of Practice; Final Rule) (January 13, 2009).

August 5, 2009 (the "Decision"), the ALJ found that the FTC has jurisdiction over Respondents, held that Respondents are liable under Sections 5(a) and 12 of the FTC Act, and issued a cease and desist Order.

B. Summary of the Relevant Facts

1. DCO Operated as a For-Profit Enterprise to Funnel Money to the Feijos.

DCO opened as a health food store in 1986. F. 12.[2] From 1990 to 1997, DCO was a for-profit Rhode Island corporation that was organized "[t]o engage in the sale, retail, wholesale and distribution of health products, including but not limited to health foods and supplements, namely those with special nutritive qualities and values." F. 22-27. In 2002, DCO was organized as a corporation sole under Washington state laws. F 28. James Feijo serves as DCO's overseer and trustee for all DCO assets. F. 5-6. Patricia Feijo is Respondent James Feijo's wife and DCO's Secretary. F. 7.

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. DCO pays all of the Feijos' living expenses. F. 58. James Feijo does not have his own individual bank account. F. 76. Sometime in the mid-1990s, James Feijo stopped paying personal income taxes. F. 78, Transcript of Hearing on Jurisdiction at p. 78. Respondents do not maintain any records of how much DCO money is spent on the Feijos' living expenses. F. 59. However, it is undisputed that Mr. and Mrs. Feijo use DCO's funds so that they can (i) live in and make use of two houses, one in Florida on country club land with a pool in the back; and (ii) drive two Cadillacs. Moreover, Complaint Counsel obtained banking records showing that James Feijo has frequently used an

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[2] "F. _" refers to the ALJ's Findings of Fact set forth in the Decision at pp. 6-66.

American Express Business Gold Card, in the names of Daniel Chapter One and Patricia Feijo, to which Mr. Feijo is also a signatory, to eat at restaurants, play golf on a regular basis, purchase golf club memberships, and purchase cigars and other retail items. F. 64-66. Approximately $9,936 was charged for golf expenses on DCO's American Express Business Gold Card from December 2005 through March 2009, F. 67; approximately $14,024 was charged for restaurant expenses, F. 68; approximately $28,582 was charged for automobile expenses, F. 69; and approximately $1,077 was charged to buy cigars. F. 70. The Feijos incurred expenses eating at restaurants such as PF Changs and the Cheesecake Factory despite the fact that the Feijos claim that the name for DCO comes from the Book of Daniel in the Old Testament of the Bible in which Daniel and his men were held in captivity and were expected to eat the king's very rich diet of meats and wine, but instead ate and drank only pulse and water. F. 17, Complaint Counsel's Exhibit ("CX") 48.

The Feijos' lifestyle is funded by the 150-200 products DCO sells to consumers, including the Challenged Products. F. 8. Over one thousand consumers have purchased DCO's products. F. 81. DCO has generated approximately $2 million in annual sales for 2006, 2007, and 2008. F. 9, 80. Respondents' sales of the Challenged Products constitute 20 or 30 percent of these annual sales. F. 80. The DCO products are expensive. An FTC investigator, Michael Marino, purchased one bottle of each of the Challenged Products which together cost $175.75. F. 147-57. Nothing on the DCO Website indicated to the FTC's investigator that a consumer would have to be part of any religious community in order to purchase the Challenged Products, or that they could be obtained in exchange for a "donation," purchased at a reduced price, or received for free. F. 149-50.

2. Respondents Advertised That The Challenged Products Could Prevent, Treat, or Cure Cancer and/or Tumors Without Any Scientific Substantiation for Such Claims.

Respondents disseminate information about the Challenged Products to the public through a variety of media, including the Internet, written publications, and a radio show. F. 158. Any consumer can be directed to the DCO Website by entering the term "cancer" in a Google search. F. 162. Respondents prey upon desperate, sick consumers suffering from cancer.

Respondents represent in their advertisements and promotional materials that the Challenged Products are effective in preventing, treating, or curing cancer or tumors. Respondents encourage consumers who "suffer from any type of cancer" "**to buy the products**" they describe as **"Daniel Chapter One's Cancer solutions,"** assuring consumers that **"How to fight cancer is your choice!"** F. 180 (bold in original). They tout the Challenged Products as products that "stop tumor growth," "fight[] tumor formation," "battle[] cancer," and "eliminate[] pre-cancerous growth." F. 180, 182, 184, 221-23, 226, 229, 234, 238-41, 253, 266, 283. Their "Cancer News webpage" refers to specific cures and products – "Dad's throat cancer cured – 7 Herb and more," "Nancy – Cured Breast Cancer in 3 months – 7 Herb and GDU," and "Robert – Prostate cured from DC1 products." F. 187.

Indeed, Respondents initially admitted in their answer that they made the following health and disease claims about the Challenged Products:

a. Bio*Shark inhibits tumor growth;

b. Bio*Shark is effective in the treatment of cancer;

c. 7 Herb Formula is effective in the treatment or cure of cancer;

d. 7 Herb Formula inhibits tumor formation;

e. GDU eliminates tumors;

f. GDU is effective in the treatment of cancer;

g. BioMixx is effective in the treatment of cancer; and

h. Bio Mixx heals the destructive effects of radiation and chemotherapy.

Respondents' Answer at ¶ 14.

Respondents did not conduct or direct others to conduct any scientific testing of the effects of the Challenged Products, and offered no evidence of any such testing having been performed by others. F. 308. Instead of relying upon scientific testing to substantiate their advertising claims, Respondents claimed that they relied on personal observations, customer testimonials, and a variety of books, magazines, and articles about how certain substances in the Challenged Products could be utilized. F. 316-18. Their proffered experts were not medical doctors and had no specialized training or experience regarding cancer or cancer treatment. F. 335-337. Even Respondents' purported experts admitted, however, that because the Challenged Products have not been tested, their effectiveness in the prevention, treatment, or cure of cancer is not known. F. 364.

ARGUMENT

I. THE ALJ CORRECTLY CONCLUDED THAT THE FTC HAS JURISDICTION OVER RESPONDENTS.

In determining whether an allegedly nonprofit corporation is within the jurisdiction of Section 4 of the FTC Act, the FTC essentially looks to (i) whether the corporation is "organized for and actually engaged in business for only charitable purposes" and (ii) whether the corporation derives any profit for itself or its members. Respondents argue that "[i]n its organization and operation, DCO is a not for profit religious organization and as such is not

subject to the jurisdiction of the Federal Trade Commission." Respondents' Appeal Brief at 31 ("Resp't Br."). However, 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 Feijos' personal living and entertainment expenses. This "profit" to the Feijos puts Respondents squarely within the FTC's jurisdiction.

A. The FTC Has Jurisdiction Over Corporations Engaged in Business for Their Own or Their Members' Profit.

Section 5(a)(1)-(2) of the FTC Act grants the FTC the authority to "prevent unfair or deceptive acts or practices in or affecting commerce" by "persons, partnerships, or corporations." 15 U.S.C. § 45(a)(1)-(2) *cited in* Decision at 69. Section 4 of the FTC Act defines "corporation" in part as "any company, trust, so-called Massachusetts trust, or association, incorporated or unincorporated, ...without shares of capital or capital stock or certificates of interest, except partnerships, which is organized to carry on business for its own profit or that of its members." 15 U.S.C. § 44 *cited in* Decision at 69. Courts and the Commission have consistently held that any entity organized as a nonprofit is within the jurisdiction of the FTC if the entity in fact engages in business for its own profit or that of its members. Decision at 69 *citing Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 766-67 (1999); *Cmty. Blood Bank v. FTC*, 405 F.2d 1011, 1017 (8th Cir. 1969). In *Community Blood Bank*, the seminal case concerning jurisdiction under the FTC Act, the Court of Appeals explained that "under § 4 the Commission lacks jurisdiction over nonprofit corporations without shares of capital, which are organized for and actually engaged in business for only charitable purposes, and do not derive any 'profit' for themselves or their members within the meaning of the word 'profit' as attributed to corporations having shares of capital." 405 F.2d at 1022 *quoted in* Decision at 69.

Commenting on *Community Blood Bank*, the Commission stated: "The court thus established a two-pronged test looking both to the source of the [entity's] income, *i.e.*, to whether the corporation is 'organized for and actually engaged in business for only charitable purposes,' and to the destination of the income, *i.e.*, to whether either the corporation or its members derive profit." Decision at 69 *quoting In re Coll. Football Ass'n*, 117 F.T.C. 971, 994 (1990). Under *College Football Association*, either prong of the test provides a basis for establishing jurisdiction. *See* 117 F.T.C. at 993 ("[w]hile we agree that the distribution of funds to private persons or for-profit companies as opposed to their use for 'recognized public purposes' is one basis for finding an entity to be organized to carry on business for . . . profit,' we conclude that the source of the income provides another basis for such a finding . . .").

As correctly found by the ALJ based on a preponderance of the evidence, (i) DCO is not a business organized or engaged in only charitable purposes and (ii) DCO engages in business for its own profit or that of its members.

B. DCO Operates as a Commercial Enterprise and is Not a Business Organized or Engaged in Business For Only Charitable Purposes.

1. Respondents Operate a Commercial Enterprise, Not a Charitable Organization.

While Respondents continue to assert that DCO is a not-for-profit religious organization, Resp't Br. at 31, the evidence demonstrates that DCO operates as a commercial enterprise. DCO was incorporated as a *for-profit* corporation from 1990 to 1997 and sold the Challenged Products during the 1990s. F.12-13, 22-23, 27. Indeed, DCO's Articles of Incorporation during this period stated that DCO was organized as a for-profit corporation: "To engage in the sale, retail, wholesale and distribution of health products, including but not limited to health foods and supplements, namely those with special nutritive qualities and values." Decision at 70 *citing* F.

23. In 2002, DCO changed its corporate form to a corporation sole and continued to sell the Challenged Products. Decision at 70 *citing* F. 8-9, 28. However, this change in form did not alter DCO's commercial nature.

Indeed, as noted by the ALJ, Respondents have generated approximately $2 million in annual sales for the years 2006, 2007, and 2008 for DCO's nearly 200 products. Decision at 70 *citing* F. 9. Respondents' sales of the Challenged Products constitute twenty or thirty percent of these annual sales. *Id. citing* F. 80. While Respondents claim that they "maintain a charitable program that allows anyone to obtain products for free," they failed to provide any documents to indicate whether and how much of DCO's products they have given away. Resp't Br. at 30; Decision at 73 *citing* F. 54. Instead, the ALJ found that Respondents charge consumers three to ten times what it costs DCO to purchase the Challenged Products from manufacturers. Decision at 70 *citing* F. 83, 127-29, 140-42, 144-46. DCO has a toll-free phone number and a call center and operates websites through which consumers may purchase DCO products. *Id. citing* F. 84, 99, 103-04. DCO also sells its products through stores in several states and through various distributors, including chiropractic centers. *Id. citing* F. 116-19. The DCO Website invites consumers to shop at DCO's "On-Line Store" and the "About Us" section on the website describes the company as a "health food store" or "health food supplement store." *Id. citing* F. 32, 105. Michael Marino, an FTC undercover investigator, purchased the Challenged Products from the DCO Website for $175.75. F. 147, 157. Nothing on the DCO Website indicated that the Challenged Products could be obtained in exchange for a donation, purchased at a reduced price, or received for free. F. 149. After purchasing the products, Marino received an email thanking him for his purchase and offering a ten percent discount on a subsequent purchase. F. 152. In their Websites and brochures, Respondents compare their products to those of their

competitors. (DCO Website stating: "Daniel Chapter One is the first and only company to add Siberian ginseng to the formula"). Decision at 70 *citing* F. 137-38.

Finally, Respondents' unsupported assertion that DCO operates at a breakeven point or less does not allow them to evade jurisdiction. Resp't Br. at 35. First, as the ALJ found, DCO's revenues apparently exceeded its expenses, since DCO was able to completely support two individuals and their homes (see *infra* pp.15-16) and to maintain surpluses of hundreds of thousands of dollars for extended periods of time in various accounts.[3] Decision at 70-71 *citing* F. 42-45. Second, a showing that DCO was successful in running its business is not required for jurisdiction to exist. *See Cal. Dental*, 526 U.S. at 768 n.6 ("It should go without saying that the FTC Act does not require for Commission jurisdiction that members of an entity turn a profit on their membership, but only that the entity be organized to carry on business for members' profit"); *In re Ohio Christian (of Calvary Grace Christian Churches of Faith, Inc.)* 80 F.T.C. 815, 849-50 (1972) (stating that the fact that respondents "were apparently not very successful in their enterprise was of 'little consequence'").

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[3] Respondents destroyed documents and failed to comply fully with discovery requests regarding their finances, even after being ordered to do so. Accordingly, Complaint Counsel asked for an adverse inference that the information sought from Respondents in discovery would have defeated Respondents' nonprofit argument. The ALJ concluded, that "[a]lthough an adverse inference in this case may have been appropriate, it is not necessary here, because the facts are sufficient to demonstrate that DCO operated as a business for its own profit or that of its members." Decision at 71 n.2. The ALJ found that (i) James Feijo did not change DCO's policy of not maintaining records after learning that the FTC had brought a proceeding against him and DCO; (ii) DCO did not change its document retention policies after receiving the Court's first and second orders to produce certain documents to Complaint Counsel; (iii) James Feijo had the authority to change DCO's document retention policies after being ordered to produce responsive documents to Complaint Counsel; and (iv) DCO continued to discard documents, even after the ALJ ordered Respondents to produce certain documents to Complaint Counsel. F. 50-53.

2. DCO is Not a Business Organized for Only Charitable Purposes.

In arguing that the FTC lacks jurisdiction, Respondents rely heavily on DCO's organization as a corporation sole under the laws of the State of Washington.[4] Decision at 71. However, courts and the Commission look to the substance, rather than the form, of incorporation in determining jurisdiction under the FTC Act. *See* Decision at 71, *citing Cmty. Blood Bank*, 405 F.2d at 1019 ("mere form of incorporation does not put [an entity] outside the jurisdiction of the Commission"). As the ALJ properly found, "[r]egardless of DCO's form of incorporation, the evidence shows that DCO bears none of the substantive indicia of a corporation that is truly organized only for charitable purposes." Decision at 71.

DCO's Articles of Incorporation do not declare that DCO was organized exclusively for charitable or other clearly nonprofit purposes, but instead include provisions permitting "other worthwhile projects for the common good of Daniel Chapter One at large." Decision at 73 *citing* F. 29-30. DCO's Articles of Incorporation, unlike those in *Community Blood Bank*, also do not provide for distribution of its assets upon dissolution solely to other nonprofit entities or prohibit distribution of its earnings to the benefit of any individual or for-profit corporation. Decision at

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[4] According to an IRS Revenue Ruling, "[a] 'corporation sole' is a corporate form authorized under certain state laws to enable *bona fide* religious leaders to hold property and conduct business for the benefit of the religious entity." Rev. Rul. 2004-27, I.R.B. 2004-12 (March 22, 2004), *available at* http://www.irs.gov/irb/2004-12_IRB/ar11.html. A proper corporation sole may own property and enter into contracts, but only for the purposes of that religious entity and not for the incorporator's personal benefit. *Id.* A corporation sole does not receive special status under the federal tax laws unless it qualifies as a § 501(c)(3) entity with the IRS. *See id.* The IRS has warned that corporations sole are often not used for their intended purpose and have instead become vehicles for tax evasion. *See e.g.,* IRS Rev. Rul. 2004-27. Earlier this year, Washington State passed a bill that banned the formation of corporations sole after August 1, 2009, and requires existing corporations sole registered with the state to file annual reports. The Washington Secretary of State explained that "[t]he entity has been reserved for churches and religious societies but has seen a significant amount of abuse over the years by individuals using the corporation sole designation for tax evasion purposes." http://www/secstate.wa.gov/corps/CorporationSoleLegislativeChanges.aspx.

73 *citing* F. 30.[5]

In addition, DCO is not registered with the Internal Revenue Service as a tax-exempt organization under Section 501(c)(3) or any other section of the IRS Code. Decision at 71 *citing* F. 31.[6] Respondents contend that it is immaterial for jurisdictional purposes that DCO does not have a Section 501(c)(3) tax exemption because they claim that churches do not need to obtain such an exemption, pursuant to Section 508(c)(1)(A) of the IRS Code. *See* Decision at 72. However, as explained by the ALJ, "[c]ontrary to Respondents' argument, Section 508(c)(1)(A) exempts churches from certain notice requirements applicable to other entities seeking to obtain a Section 501(c)(3) tax exemption, and has no bearing on the issue of FTC jurisdiction." Decision at 72. The ALJ further explained that because DCO distributes funds for the use of both James and Patricia Feijo, private individuals and DCO's corporate officers (discussed below), DCO would not qualify as a tax-exempt nonprofit corporation under either the Internal Revenue Code or laws of the State of Washington. Decision at 73 *citing* 26 U.S.C. § 501(c)(3) and Rev. Code Wash. § 24.03.005.

In their brief, Respondents, for the first time in this action, point to several additional sections of IRS Code for the proposition that certain church-related income is exempt from federal income taxes. Resp't Br. at 38-40. Respondents also raise for the first time an IRS Code

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[5] Article 8 of DCO's Articles of Incorporation evidences that DCO somehow believes it is sovereign from the United States of America. *See* CX 31 (DCO's Articles of Incorporation). This belief manifests itself in DCO's and Feijo's failure to pay taxes and apparent belief that they may disregard the laws of this country with impunity.

[6] In evaluating the FTC's jurisdiction, "[t]he Commission has long recognized that while the terms employed in other statutes and interpretation adopted by other agencies are not controlling, the treatment of exemptions for nonprofit corporations by other branches of the Federal Government is helpful." *See* Decision at 72 *quoting In re College Football Ass'n*, 117 F.T.C. at 994 (citations omitted).

section and a Treasury Regulation relating to the Minister's Parsonage Allowance[7] arguing that, pursuant to this allowance, "DCO funds used for James Feijo's home and other incidentals are not income to him," and "as a matter of law, those funds do not inure to his benefit and thus under no circumstances could be considered profit." *Id.* at 40. Respondents also state that, "[v]ery clearly, the ALJ did not consider these provisions to any extent whatsoever." *Id.*

First, the ALJ is not required to raise and consider *sua sponte* any provisions in the tax code that apply to churches and ministers for the purposes of determining Respondents' jurisdiction. Second, Respondents have not in any way established that these IRS Code sections or Treasury Regulations apply to them, let alone that they would change the ALJ's ultimate ruling that the FTC has jurisdiction in this case. Third, while undoubtedly there are certain circumstances under which legitimate church-related income and the rental value of parsonages are excluded from gross income, nothing suggests that the provisions cited to by Respondents were intended to exempt Florida vacation homes, Cadillacs, golf club memberships, tennis lessons, cigars, and expensive restaurant meals from the tax laws. The ALJ expressly found that "[t]his contribution of funds to the Feijos defeats Respondents' claim that DCO is operated exclusively for charitable purposes." Decision at 73.

C. DCO Engages in Business for its Own Profit or That of its Members.

As explained by the ALJ, "whether Respondent DCO is a ministry is not dispositive in determining the FTC's jurisdiction over Respondent's activities. Instead, the pivotal inquiry is whether Respondent DCO engaged in business for its own profit or that of its members." *See*

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[7] Section 107 of the Internal Revenue Code and Treasury Regulation § 1.107-1 relate to the exclusion from gross income of the rental value of parsonages (the home furnished to a minister as part of his compensation).

Decision at 74 *citing California Dental*, 526 U.S. at 766-67; *Community Blood Bank*, 405 F.2d at 1021. The ALJ further explained that "the Commission has made clear that, for finding jurisdiction, what matters is not what respondents' subjective motivations are, but whether respondents' actions inure to their own financial benefit." Decision at 74. Respondents' activities here clearly inured to their own financial benefit.

"[T]he distribution of funds to private persons or for-profit companies as opposed to their use for 'recognized public purposes' is one basis for finding an entity to be 'organized to carry on business for . . . profit." Decision at 74 *citing In re College Football Ass'n*, 117 F.T.C. 971, 993; *In re American Medical Ass'n*, 1979 FTC Lexis 182, at *240 (stating that Section 4 of the FTC Act does not require a transfer or delivery of monetary profits to the members of a non-stock corporation, but only pecuniary benefits to its members from the corporation's activities); *In re Ohio Christian Coll.*, 80 F.T.C. at 848 ("Profit does not necessarily mean a direct return by way of dividends, interest, capital account or salaries. A savings of expense which would otherwise necessarily be incurred is also a profit to the person benefitted.") (citation omitted).

Based on the evidence regarding the funds distributed to the Feijos, it is difficult to understand how Respondents continue to maintain that none of DCO's property inures to the private benefit of the Feijos, let alone that the Feijos "have taken an effective vow of poverty." Resp't Br. at 31. Indeed, the ALJ found:

- James Feijo does not have his own individual bank account, but rather uses DCO's bank account as his own; Decision at 75 *citing* F. 76, Decision at 76.
- DCO pays all of the Feijos' expenses, including pool and gardening services for the Feijo house in Florida; Patricia Feijo's tennis club membership; James Feijo's membership at the Green Valley Country Club in Rhode Island; and during the period from December 2005 to March 2009, American Express Card charges for golf expenses of $9,936, restaurant expenses of $14,024, automobile expenses of $28,582, and cigar expenses of $1,077; Decision at 75 *citing* F. 58, 61-70.

- DCO or its affiliate owns two houses (one in Rhode Island and one in Florida, on country club land with a pool in the back), in which the Feijos stay without paying rent; *Id. citing* F. 55.

- DCO owns two cars (a 2003 Cadillac and a 2004 Cadillac) which the Feijos use; *Id. citing* F. 56-57.

- Both James and Patricia Feijo freely use DCO credit cards for personal expenses; *Id. citing* F. 66.

- The Feijos do not file tax returns with regard to the money they receive from DCO and James Feijo stopped paying individual income taxes prior to DCO's incorporation as a corporation sole[8]; F. 60, 78.

After reviewing this evidence, the ALJ concluded, "[t]his distribution of funds, which amounts to a saving of expense which might otherwise be incurred by the Feijos, is a profit to the Feijos and provides a basis for finding that DCO is organized to carry on business for profit." Decision at 75.

In their Brief, Respondents argue that the ALJ determined that the expenses paid to the Feijos enabled them to "live lavishly, " Resp't Br. at 38, when the ALJ actually stated that "it is not necessary for the Feijos to live lavishly for jurisdiction to be proper under Section 4." Decision at 75. The ALJ explained:

> The Supreme Court, in *California Dental*, specifically rejected the notion that the profit received must be substantial: 'There is accordingly no apparent reason to let the statute's application turn on meeting some threshold percentage of activity for this purpose [of profit], or even satisfying a softer formulation calling for a substantial part of the nonprofit entity's total activities to be aimed at its members' pecuniary benefit. To be sure, proximate relation to lucre must appear . . .' ***It is sufficient for the purpose of finding jurisdiction that the economic benefits conferred are***

[8] James Feijo testified that he decided to stop paying income taxes before DCO was formally incorporated as a corporation sole. To the best of his recollection, he paid income taxes in the mid-1990s. Transcript of Hearing on Jurisdiction at 78.

more than 'de minimis' or 'merely presumed.'

Decision at 75 *quoting Cal. Dental*, 526 U.S. at 766, 767, and 767 n.6. (emphasis added). Respondents falsely assert that the *California Dental* Court adopted a standard that "the Commission has jurisdiction over 'anticompetitive practices by nonprofit associations whose activities provid[e] **substantial** economic benefits to their for-profit members' businesses.'" Resp't Br. at 31. The ALJ, however, applied the correct standard and concluded, "[i]n this case, the complete financial support of James and Patricia Feijo, including, among other things, two homes, two cars, tennis lessons, rounds of golf, cigars, restaurant meals, and club memberships, constitutes neither simply presumed nor *de minimis* economic benefits." Decision at 75.

The Commission found jurisdiction on similar facts to those here in *Ohio Christian College*. There, the Commission observed that:

> The cavalier treatment of the corporate assets and finances leads us to conclude that respondents considered them their own. The individual respondent . . . has complete control over the purse strings, he sets all salaries (including his own), determines all allocation and expenditures, signs all checks and exercises plenary power over the affairs of the school. The record shows the corporation was organized and controlled so that the individual respondents could take what they wanted prior to any further disposition or commingling of funds.

80 F.T.C at 848-49. Here, the ALJ concluded:

> [i]n this case, as well, James Feijo treated the income and expenditures of DCO cavalierly. He claimed to keep no financial records, and to have no idea of how much money DCO had or how much money was spent on various aspects of its operations or for the support of the Feijos' living expenses. Moreover, since James Feijo had no individual bank account, he used DCO's assets at will, thereby treating those assets as his own. As in *Ohio Christian College*, such circumstances support jurisdiction over DCO as an entity that is organized to carry on business for profit.

Decision at 76.

After finding that DCO is organized to carry on business for profit, the ALJ also correctly concluded that DCO engages in business for the profit of James Feijo. Decision at 76. After noting that, as a corporation sole, DCO has one member, James Feijo, the ALJ explained that the economic benefits the Feijos receive "constitute profit to James Feijo. Thus, DCO engages in business for the profit of its sole member, James Feijo." *Id.*

D. The FTC Has Jurisdiction Over James Feijo.

"If individuals direct and control the acts and practices of a corporation amenable to the FTC's jurisdiction, then they too may be made subject to the FTC's jurisdiction." Decision at 77 *citing In re Ohio Christian Coll.*, 80 F.T.C. at 845; *FTC v. Amy Travel Serv., Inc*, 875 F.2d 564, 573 (7th Cir. 1989) (holding that individual who either participated directly in or had the authority to control deceptive acts or practices may be held liable under the FTC Act for the violations of his corporation).

As the ALJ found, "Respondent James Feijo both participated directly in and had the authority to control the acts or practices challenged in this case." Decision at 77. The evidence cited to by the ALJ on this point included:

- Respondents admit that James Feijo is responsible for the activities of Respondent DCO as its overseer; Decision at 77 *citing* F. 5.
- The activities for which James Feijo is responsible include the development, creation, production, and distribution of the Challenged Products; the creation, management, and maintenance of DCO's toll-free telephone number through which consumers may order the Challenged Products; the setting of prices for Challenged Products; and the creation, drafting, and approval of the directions for usage and the recommended dosages of the Challenged Products; *Id. citing* F. 37-39, 100.
- James Feijo and his wife are responsible for the information contained in DCO's advertising and promotional materials; *Id. citing* F. 165-66, 173, 178.

- James Feijo and his wife co-host a DCO radio program, on which they have counseled individuals who have called into the program about taking DCO's products; *Id. citing* F. 108-10, 178.

- James Feijo is the trustee for all of DCO's assets; *Id. citing* F. 6, 40.

Based on such evidence, the ALJ correctly concluded:

> Respondent James Feijo had the authority to direct and control, in fact did direct and control, and participated directly in the challenged acts or practices of DCO, a corporation that is subject to the FTC's jurisdiction. Accordingly, Respondent James Feijo is a person over whom the Commission has jurisdiction, and he may be held individually liable under the FTC Act for the deceptive acts and practices found below.

Decision at 77.

E. Respondents Engage in Interstate Commerce.

As noted by the ALJ, Respondents admit in their Answer that they distribute the Challenged Products in commerce. *Id. citing* Respondents' Answer ¶ 4. DCO operates a call center and websites through which consumers may purchase the Challenged Products and DCO has sold its products nationally through a number of stores, distributors, and chiropractic centers, including those in Florida, Georgia, Missouri, and Pennsylvania. Decision at 77-78 *citing* F. 99, 103-04, 116-17, 119. As the ALJ found, these sales are in or affecting commerce. *Id.* at 78 *citing United States v. Robertson*, 514 U.S. 669, 672 (1995).

The ALJ also found that Respondents' advertisements of its products through DCO Websites which reach a national audience invoke the FTC's jurisdiction. *Id. citing FTC v. Simeon Mgmt. Corp.*, 391 F. Supp. 697, 703 (N.D. Cal. 1975). The ALJ correctly concluded that "[t]he evidence clearly demonstrates that Respondents advertise and sell products, including the Challenged Products, throughout the United States, and that their sales are in or affecting commerce." *Id.*

II. THE ALJ CORRECTLY CONCLUDED THAT RESPONDENTS' ADVERTISING IS DECEPTIVE OR MISLEADING.

A. Introduction

Section 5(a)(1) of the FTC Act declares unlawful "unfair or deceptive acts or practices in or affecting commerce." 15 U.S.C. § 45(a)(1). Section 12 of the FTC Act makes it unlawful "for any person, partnership, or corporation to disseminate, or cause to be disseminated, any false advertisement . . . [b]y any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase in or having an effect upon commerce of food, drugs, devices, services, or cosmetics." Decision at 79 *quoting* 15 U.S.C. § 52.

In addressing the Court's ruling that Respondents violated Sections 5 and 12, the linchpin of Respondents' argument is that "the Initial Decision turns entirely on the ALJ's improper presumptions, accepted in lieu of extrinsic evidence." Resp't Br. at 45. Respondents assert that any analysis of the advertisements that finds that claims were made beyond the exact words used in the advertisements requires extrinsic evidence. *Id.* at 48-50. In making this argument, Respondents ignore, and make no effort to distinguish, the ample and well-settled body of law relied upon by the ALJ in framing his analysis of the advertisements. Similarly, Respondents ignore, and make no effort to challenge, the detailed factual findings (*over 100*) made by the ALJ describing how Respondents disseminate advertisements claiming that the Challenged Products, individually or collectively, prevent, treat, or cure cancer, inhibit tumors, or ameliorate the adverse effects of radiation and chemotherapy, without having a reasonable basis to substantiate their claims. Decision at 5, F. 179-295. Moreover, Respondents failed to offer any competing facial or textual analysis of the advertisements. In light of the ALJ's detailed findings, Respondents' claim that the ALJ's decision turns on "presumptions" is

nonsense. In short, Respondents have chosen to ignore both the law and the evidence. Nothing in Respondents' rhetoric provides any justification for setting aside the ALJ's factual findings or disregarding the well-established legal principles the ALJ applied.

B. Respondents Disseminated Advertisements to Induce Purchases of Food or Drugs.

Prior to determining that the DCO advertisements regarding the Challenged Products are deceptive and misleading under Section 5 and false (because they are unsubstantiated) under Section 12, the ALJ correctly determined as a preliminary matter that the DCO materials at issue constitute: (1) the dissemination of advertisements; (2) for the purpose of inducing, or which are likely to induce, purchases in or affecting commerce; (3) of "food" or "drugs." Decision at 79.

1. The ALJ Correctly Found That Materials Disseminated About the Challenged Products Constitute Advertisements.

The ALJ found that "the evidence amply demonstrates that the DCO materials at issue in this case constitute the dissemination of 'advertisements' for purposes of Section 12." *Id.* As the ALJ noted, "Respondent Feijo admits that DCO advertises on the DCO Website." *Id.*, F 161. Respondents disseminate information about the Challenged Products to the public, over the Internet, through the web sites www.danielchapterone.com, www.7herbformula.com, www.gdu2000.com, www.dc1pages.com, and www.dc1store.com. Decision at 79, F 158, 161. Consumers can additionally locate the DCO Website by entering the term "cancer" in a Google search. Decision at 79, F 162. Respondents also disseminate information about the Challenged Products to the public through printed materials, also available on the DCO Website, including the "BioGuide," "Cancer Newsletter," "The Most Simple Guide to the Most Difficult Diseases," and the "BioMolecular Nutrition Product Catalog." Decision at 79, F. 163-64, 169-

70, 172. Lastly, information about the Challenged Products is disseminated to the public via "Daniel Chapter One Health Watch," the Monday through Friday two-hour radio program. Decision at 79, F 175-77.

The DCO Websites, the BioGuide, and the Cancer Newsletter all promote the Challenged Products through product descriptions and testimonials. F. 179-80, 183-88, 190, 195, 197-201, 203-10. The BioMolecular Nutrition Product Catalog describes and promotes the characteristics of the Challenged Products. F. 91, 233, 256, 279. Lastly, the radio program uses "health advice" to promote the Challenged Products. F. 213-17.

2. DCO's Advertisements Are For the Purpose of Inducing, and Did Induce, Purchases of the Challenged Products In or Affecting Commerce.

The ALJ properly concluded that, "it is clear that Respondents' advertisements are 'intended to' induce sales. Moreover, there is no question that DCO in fact made sales, and that its sales are 'in or affecting commerce.'" Decision at 80 *citing* F. 9, 80-81, 218. The ALJ rejected Respondents' contention that their products are offered for suggested donations and not for purchase as "contrary to the evidence." *See supra*, at 10. The ALJ found that (i) the DCO Website contains icons inviting consumers to "Buy Now," *see e.g.* F. 106, 221; (ii) DCO has spent money on advertising its products, F. 159-60; (iii) DCO's BioGuide (its Cancer Newsletter) and its "Most Simple Guide to the Most Complicated Diseases" prominently feature DCO's toll-free call center number, F. 90, 94, 163, 167, 174; and (iv) consumers are given the toll-free call center number on the DCO radio program. F. 102, 111.

As part of their advertising efforts, Respondents engage in comparative advertising to sell their products. For example, on their web sites www.danielchapterone.com and www.dc1pages.com, Respondents respond to complaints that 7 Herb Formula "costs too much"

by asserting "Essiac formulas normally retail for $45 to $69 per bottle. If you compare that to the cost of a hospital stay and drug treatment, this is cheap! Daniel Chapter One's 7 Herb Formula is equally priced with most other brands but with ours you get a great deal more. Remember you are not only getting 32 ounces per bottle, when some of the other brands are only 16 ounces; you are also getting 2 more expensive herbs (Cat's Claw and Siberian Ginseng). We use 3 times the herbs and prepare each individually using a double water filtering process. If that is the case you must at least double the price they are asking to get equal price comparison." F. 137.

3. The Challenged Products Are Food and/or Drugs.

Respondents argue that the ALJ erred as a matter of law in finding that their products are "drugs," contending that "Respondents took considerable steps to express their intent that their approach was not based on drug tests, and was not to replace the advice of a medical doctor or other health professional." Resp't Br. at 44. However, Respondents' purported intent notwithstanding, this is simply not the law, and the ALJ properly so found.

For the purposes of Section 12, "food" is defined as, among other things, "articles used for food or drink for man," and "drug" is defined as, among other things, "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man." 15 U.S.C. § 55(b), (c) *cited in* Decision at 80. As the ALJ explained, "[c]ourts and the Commission have routinely treated dietary supplements as falling within the scope of Section 12." Decision 80-81, *citing FTC v. Nat'l Urological Group, Inc.*, No. 1:04-CV-3294, 2008 U.S. Dist. LEXIS 44145 (N.D. Ga. June 4, 2008); *FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285, 297 (D. Mass. 2008); *FTC v. Garvey*, 383 F.3d 891 (9th Cir. 2004); *Shafe v. FTC*, 256 F.2d 661, 663 (6th Cir. 1958). Based on the foregoing authorities, the ALJ concluded that the DCO products

constitute 'food' and/or 'drug[s]' within the scope of Section 12." Decision at 81, *citing In re Gen. Nutrition, Inc.*, No. 9175, 113 F.T.C. 146, 1986 FTC LEXIS 74, at *4 (Feb. 24, 1986).

C. The ALJ Properly Found That Respondents' Advertising is Deceptive or Misleading.

An "advertisement is deceptive under the Act if it is likely to mislead consumers, acting reasonably under the circumstances, in a material respect." *Kraft, Inc. v. FTC*, 970 F.2d 311, 314 (7th Cir. 1992) (*citing* Sections 5 and 12) *cited in* Decision at 80-81. As noted by the ALJ, the Commission engages in a three-part inquiry to determine whether advertising is deceptive: (1) whether the advertisements convey the claims alleged; (2) whether the claims are false or misleading; and (3) whether the claims are material to prospective consumers. Decision at 81, *citing Kraft v. FTC*, 970 F.2d at 314; *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1095 (9th Cir. 1994); *FTC v. Direct Mktg. Concepts*, 569 F. Supp. 2d at 297. Based upon this analysis and as set forth below, the ALJ concluded that "Respondents' advertising is deceptive." Decision at 81.

Contrary to Respondents' argument, Complaint Counsel is not required to prove that Respondents' acts or practices are not only deceptive, but also "unfair" as defined under Section 5(n) of the FTC Act. As explained by the ALJ, "Respondents cite no authority for their contention that the evidence must show that deceptive trade practices are also unfair because of substantial consumer injury. Moreover, the law is contrary to Respondents' position. It is well established that proof of deception does not require proof of actual consumer injury. This is because misrepresentations harm consumer choice, and in this regard, injure both consumers and competition. Accordingly, the harm resulting from a deceptive practice renders such practice 'unfair' as well." Decision at 108 (citations omitted).

1. The DCO Advertisements Make the Claims Alleged in the Complaint.

(a) Summary of the Claims

In answering the Complaint, Respondents admitted that they made the following claims, each of which was alleged in the Complaint:

- Bio*Shark inhibits tumor growth;
- Bio*Shark is effective in the treatment of cancer;
- 7 Herb Formula is effective in the treatment or cure of cancer;
- 7 Herb Formula inhibits tumor formation;
- GDU eliminates tumors;
- GDU is effective in the treatment of cancer;
- BioMixx is effective in the treatment of cancer; and
- Bio Mixx heals the destructive effects of radiation and chemotherapy.

Respondents' Answer at ¶ 14. However, rather than relying only upon Respondents' own admissions, the ALJ carefully examined the overall net impression of DCO's advertisements to determine that Respondents made the claims alleged by Complaint Counsel.

(b) Summary of DCO's Advertisements

On their Websites, radio program, and in various publications, Respondents tout the Challenged Products as products that "stop tumor growth," "fight[] tumor formation," "battle[] cancer," and "eliminate[] pre-cancerous growth." F. 180, 182, 184, 221-23, 226, 229, 234, 238-41, 253, 266, 283. As the ALJ found, Respondents disseminated advertisements that the Challenged Products could be used for all types of cancer and fight and stop tumors.

Respondents recommend taking the Challenged Products "**If you suffer from any type**

of cancer," F. 180 (emphasis added) and, in their *The Most Simple Guide to the Most Difficult Diseases: The Doctors' How-To Quick Reference Guide*, recommend the Challenged Products on the "cancer" page for "***All types of Cancer***," F. 192 (emphasis in original). The Challenged Products appear in Respondents' Cancer Newsletter, *How to Fight Cancer is Your Choice!!!*, which is "strictly all about the products for cancer." F. 194-95. The Cancer Newsletter contains descriptions of various DCO products that "a person can choose to use to help them fight cancer," including BioShark, GDU, BioMixx, and 7 Herb Formula. F. 195.

Respondents describe the Challenged Products on the DCO web page, "Cancer News," as "**Daniel Chapter One's Cancer solutions**," F. 180 (emphasis in original), and specifically advise consumers on both this web page and in the Cancer Newsletter to take the Challenged Products to "fight" cancer. F. 180, 195.

The DCO web page "Cancer News" promotes the Challenged Products as follows:

> If you suffer from any type of cancer, Daniel Chapter One suggests taking this products [sic]:
> 7*Herb Formula ™ 2 ounces in juice or water (minimum intake) 2 times daily
> Bio*Shark ™. . .
> BioMixx ™. . .
> GDU Caps ™. . .
>
> **The above information is taken from The Most Simple Guide to the most difficult diseases, the doctors' how-to quick reference guide.**
>
> For more information call Jim and Trish during the Radio Show.

Immediately following this text is a prominent picture of bottles of BioMixx, 7 Herb Formula, Bio*Shark, and GDU, and adjacent to that, is a statement in bold: "**Daniel Chapter One's Cancer solutions**." Under the picture, the text states:

> **To Buy the products click here**
>
> **How to fight cancer is your choice!**

F. 180 (emphasis in original).

Respondents use testimonials to convince consumers that the Challenged Products will help them "fight" and "battle" cancer and end up in remission. For example, one consumer testimonial claiming – under the heading "**7 Herb Formula battles cancer**" (emphasis in original) that Tracey had "three inoperable tumors," and that, when she "decided not to do chemotherapy or radiation, my "father sent me Bio*Mixx and 7 Herb Formula. Each day as I took it and got it into my system more and more, the better I felt. Then I added Garlic Pur, Siberian Ginseng and BioShark. I am now in complete remission." F. 184.

On their radio program, DCO Healthwatch, Respondents touted the Challenged Products. For example, on one show Patricia Feijo urged consumers:

> "[W]hile the FTC does not want us saying that anything natural can be used to treat cancer and that nothing certainly can cure cancer, we know that the truth is different than what they want us to say. The truth is God has given us herbs in His creation and nutrients that can heal cancer, even cure cancer." F. 216.

Respondents also specifically claim that the Challenged Products will "battle tumors," "stop tumor growth," "fight tumor formation," and "digest . . . unwanted tumors." F. 204, 223, 237, 239, 244, 263. On the DCO Web site, Respondents advise consumers that: "With Jim Feijo's addition to the [7 Herb] formula, we now have the most effective and potent formula available in the battle against tumors." F. 246. In their product catalog and on their Web site, Respondents claim that the 7 Herb Formula will "fight pathogenic bacteria and tumor formation." F. 237, 239. Similarly, in their product catalog, Respondents claim that GDU "[c]ontains natural proteolytic enzymes (from pineapple source bromelain) to help digest protein - even that of unwanted tumors and cysts. This formula also helps to relieve pain and heal inflammation." F. 263. They likewise claimed that their Bio*Shark Shark Cartilage "Stops

tumor growth in its tracks." F. 223. Respondents also used a testimonial in their product catalog to claim that BioMixx, 7 Herb Formula, and Bio*Shark worked on "three inoperable tumors" so well that one "just above the brain stem . . . has completely disappeared," one on the liver "is shrinking," and one behind the heart "has shrunk over 50%." F. 204.

(c) The ALJ Properly Looked to the Overall Net Impression of Respondents' Advertisements.

In their appeal brief, Respondents continue to assert that DCO's advertising does not use the words, "diagnose, mitigate, cure or prevent" and that their "express statements" about the Challenged Products "describe how the products and/or their constituent ingredients support the 'structure or function' of the human body." As noted by the ALJ, "Respondents' arguments disregard both the law and common sense, which recognize that claims may be either express or implied." Decision at 82, *citing In re Kraft, Inc.*, No. 9208, 114 F.T.C. 40, 120, 1991 FTC LEXIS 38, at *10 (Jan. 30, 1991), *aff'd*, 970 F.2d 311 (7th Cir. 1992); *In re Thompson Med. Co.*, 104 F.T.C. 648, 788, 1984 FTC LEXIS 6, at *311 (1984).

As the ALJ explained, the "primary evidence of the claims an advertisement conveys to reasonable consumers is the advertisement itself." Decision at 82 *citing In re Telebrands Corp.*, No. 9313, 140 F.T.C. 278, 290, 2005 FTC LEXIS 178 (Sept. 19, 2005), *aff'd*, 457 F.3d 354 (4th Cir. 2006); *In re Novartis Corp.*, No. 9279, 127 F.T.C. 580, 680, 1999 FTC LEXIS 90, at *37-38 (May 13, 1999); *In re Kraft*, 1991 FTC LEXIS 38, at *12. Moreover, "the Commission looks to the overall net impression created by the advertisement as a whole, by examining the interaction of all of the different elements in the advertisement, rather than focusing on the individual elements in isolation." Decision at 82 *citing Am. Home Prods. Corp. v. FTC*, 695 F.2d 681, 687 (3d Cir. 1982); *In re Kraft*, 1991 FTC LEXIS 38, at *14; *In re Thompson Med. Co.*, 104 F.T.C.

at 323 n.17, 1984 FTC LEXIS 6, at *324 n.17. As the Second Circuit noted in *FTC v. Sterling Drug, Inc.*,

> [T]he cardinal factor is the probable effect which the advertiser's handiwork will have upon the eye and mind of the reader. It is therefore necessary in these cases to consider the advertisement in its entirety and not to engage in disputatious dissection. The entire mosaic should be viewed rather than each tile separately. 'The buying public does not ordinarily carefully study or weigh each word in an advertisement. . . .'

317 F.2d 669, 674 (2d Cir. 1963) (*quoting Aronberg v. FTC*, 132 F.2d 165, 167 (7th Cir. 1942)) *cited in* Decision at 82.

The ALJ correctly explained that "assessing the overall net impression of an advertisement includes examining the interaction of such elements as language and visual images." Decision at 82, *citing In re Telebrands*, 140 F.T.C. at 290; *In re Kraft*, 1991 FTC LEXIS 38, at *13. "Testimonials are also a key element in the overall net impression of an advertisement." *Id. citing FTC v. Bronson Partners, LLC*, 564 F. Supp. 2d 119, 125 (D. Conn. 2008) ("[W]hen an advertisement contains a testimonial reflecting the experience of an individual with a product, there is an implicit representation that such experience reflects the typical or ordinary results anyone may anticipate from use of the product.") (*quoting Porter & Dietsch, Inc.*, 90 F.T.C. 770, 1977 FTC LEXIS 11, at *147 (1977)). "Testimonials not only make representations about the advertised product, but also reinforce representations implied through other elements of the advertisement." *Id. citing FTC v. QT, Inc.*, 448 F. Supp. 2d, 908, 920-21, 929-32 (N.D. Ill. 2006).

Moreover, "an advertisement may convey numerous representations, and the same advertising elements may be amenable to more than one reasonable interpretation." Decision at 82-83 *citing In re Kraft*, 1991 FTC LEXIS 38, at *11 n.8; *In re Thompson Med.*, 104 F.T.C. at

789 n.7, 1984 FTC LEXIS 6, at *312 n.7. The ALJ also noted that the representations alleged in the Complaint need not be the only reasonable interpretations of the challenged advertising. Decision at 83, *citing In re Kraft*, 1991 FTC LEXIS 38, at *11 n.8; *In re Thompson Med.*, 104 F.T.C. at 789, n.7, 1984 FTC LEXIS 6, at *312 n.7; *In re Bristol-Myers Co.*, 102 F.T.C. 21, 320 (1983). In addition, "[s]tatements susceptible of both a misleading and a truthful interpretation will be construed against the advertiser." Decision at 83, *citing FTC v. Bronson Partners*, 564 F. Supp. 2d at 127 n.6 (*quoting Country Tweeds, Inc. v. FTC*, 326 F.2d 144, 148 (2d Cir. 1964)).

(d) The ALJ Properly Assessed the Overall Net Impression of Respondents' Advertisements Based on the Evidence.

Far from basing his conclusions on "improper presumptions" as Respondents assert, the ALJ made *over 100 factual findings* concerning DCO's advertisements for the Challenged Products and then carefully analyzed the overall net impression of those advertisements. Decision at 24-48, 83-97, F. 179-295. This analysis entailed looking at DCO's advertisements for the Challenged Products collectively and individually as they appear on (i) the "Cancer News" webpage on the DCO Website; (ii) the "Cancer Treatment" advertisement on the DCO Website www.dc1pages.com; (iii) DCO's publication, "The Most Simple Guide to the Most Difficult Diseases,"; (iv) DCO's publication, the "Cancer Newsletter,"; (v) DCO's publication, the "BioGuide"; and (vi) DCO's BioMolecular Nutrition Product Catalog. *Id.*

The ALJ's analyzed these advertisements by examining: (i) the text of the advertisement, including any product descriptions, statements or quotes; (ii) the presence of any written or audio testimonials and their content; (iii) the size of the type; (iv) the location of the words or statements in relation to one another in the advertisement; (v) the presence of bold type or highlighted text; (v) any visual images, including photographs; and (vii) links to other webpages.

In connection with this analysis, the ALJ concluded:

> ***[B]ased on the overall net impression of the DCO advertisements for the Challenged Products, taken as a whole, the advertisements make the claims alleged in the Complaint.*** If not expressly made, these claims are clearly implied through the interaction of the advertising's words, visual images, and testimonials. In some cases, the representations are so strongly implied as to be virtually synonymous with express claims.

Decision at 83 (emphasis added).

(e) Respondents' Purported Disclaimers Do Not Immunize their Advertisements from Liability.

In their brief, Respondents make a vague reference to disclaimer language in their advertisements, asserting that their disclaimer "included not only the required language" but also "included substantial spiritually-based qualifications which were virtually ignored by the ALJ." Resp't Br. at 44, n.15. To the extent that Respondents are asserting that the disclaimers in some way allow them to avoid liability, this argument has already been soundly rejected by the ALJ.

Respondents' asserted that their website advertising contains the following disclaimer: "These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent disease." Decision at 96 (citations omitted). The ALJ quoted this disclaimer and noted that relatively similar disclaimers, but briefer and without the FDA reference, appear on the bottom of certain webpages from www.dc1pages.com, at the bottom of webpages on danielchapterone.com, at the end of the BioGuide, and on the last page of the Cancer Newsletter. *Id. citing* F. 296-300.

The ALJ explained that:

> 'Disclaimers or qualifications in any particular ad are not adequate to avoid liability unless they are sufficiently prominent and unambiguous to change the apparent meaning of the claims and to leave an accurate impression. Anything less is only likely to cause

> confusion by creating contradictory double meanings.' *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1497 (1st Cir. 1989) (citations omitted). Applying these standards to evaluate the [DCO] disclaimer, as well as similar disclaimers in the DCO advertising materials, it is readily apparent that the disclaimers are ineffective to alter the overall net impression of the advertisements or to leave an accurate impression.

Decision at 96.

In connection with examining Respondents' disclaimers, the ALJ found that (i) Respondents' "purported disclaimers are not prominent in any advertisement"; and (ii) "the language disclaiming any intent to 'treat' any disease only serves to confuse in this case by interjecting a message that is contradictory to the overall net impression that the Challenged Products do treat cancer." Decision at 96. The ALJ then concluded, "[b]ecause the purported disclaimers are not prominent or unambiguous, and create confusion with messages that contradict the advertisements' overall messages, the disclaimers are ineffective. . . . Accordingly, the disclaimers in Respondents' advertisements in this case are not adequate to avoid liability." *Id.* at 97 (citations omitted). Respondents have provided no basis here to question that finding.

(f) Interpreting the Respondents' Advertisements Does Not Require Extrinsic Evidence.

Respondents argue that any interpretation of the advertisements beyond their exact words requires extrinsic evidence. Resp't Br. at 49. This is simply not the law. Indeed, as the ALJ found, both the Commission and the courts "have squarely rejected the notion that extrinsic evidence is always necessary in order to prove an implied claim." Decision at 97.

As the Commission explained in *Thompson Medical*:

> [T]he Commission employs two different techniques in evaluating whether an advertisement contains implied claims. One is to look at evidence from the advertisement itself. We often conclude that an advertisement contains an implied claim by evaluating the

> conten[t] of the advertisement and the circumstances surrounding it. This technique is primarily useful in evaluating advertisements whose language or depictions are clear enough, though not express, for us to conclude with confidence after examining the interaction of all the different elements in them that they contain a particular implied claim. If our initial review of evidence from the advertisement itself does not allow us to conclude with confidence that it is reasonable to read an advertisement as containing a particular implied message, we will not find the ad to make the implied claim unless extrinsic evidence allows us to conclude that such a reading of the ad is reasonable.

104 F.T.C. at 789.

The ALJ also discussed the decision in *Kraft v. Federal Trade Commission*, where the court affirmed the Commission's holding that Kraft's advertising, which stated that Kraft uses "five ounces of milk" per slice of cheese, implied that its cheese had the same calcium content as that portion of milk. 970 F.2d at 313 *cited in* Decision at 98. In finding an implied claim, the Commission relied on the advertising itself and did not rely on any extrinsic evidence of consumer perceptions of the advertising. On appeal, Kraft argued that the Commission should be required, as a matter of law, to support its findings with extrinsic evidence in all cases involving implied claims. The court, finding Kraft's argument "unavailing as a matter of law," observed:

> Courts, including the Supreme Court, have uniformly rejected imposing such a requirement on the FTC, and we decline to do so as well. We hold that the Commission may rely on its own reasoned analysis to determine what claims, including implied ones, are conveyed in a challenged advertisement, so long as those claims are reasonably clear from the face of the advertisement . . . The implied claims Kraft made are reasonably clear from the face of the advertisements . . . Hence, the Commission was not required to utilize consumer surveys in reaching its decision.

970 F.2d at 319-20 *cited in* Decision at 98. (citations omitted).

The ALJ found that, in this case, Respondents' advertising claims are even more clearly

implied than those in *Kraft*. The ALJ concluded:

> The interaction of product descriptions, advertisement headings, visual images, testimonial titles, and testimonial texts, among other elements, is more than sufficient to conclude with confidence that the advertisements at issue make the claims alleged in the Complaint. The implied claims in Respondents' advertising are beyond 'reasonably clear.' They are clear and conspicuous from the advertising itself. Accordingly, no extrinsic evidence is necessary to interpret the claims.

Decision at 98 *citing FTC v. Nat'l Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *42 n.12 (entering summary judgment in false advertising case where facial analysis of dietary supplement advertisements showed clearly implied claims of effectiveness for treatment of erectile dysfunction, holding that extrinsic evidence of consumer perceptions was unnecessary as a matter of law.); *FTC v. QT, Inc.*, 448 F. Supp. 2d at 958 ("The courts and the FTC have consistently recognized that implied claims fall along a continuum from those which are so conspicuous as to be virtually synonymous with express claims to those which are barely discernible. It is only at the latter end of the continuum that extrinsic evidence is necessary.") (*quoting FTC v. Febre*, No. 94 C 3625, 1996 U.S. Dist. LEXIS 9487, at *14 (N.D. Ill. July 3, 1996)).[9]

The ALJ concluded that extrinsic evidence was not necessary here, where Respondents again and again refer to the Challenged Products as products that can "fight" and "battle" cancer and "stop tumor growth." The ALJ rejected Respondents' contention that extrinsic evidence was necessary here because Respondents claimed that their advertising was targeted at individuals

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[9] For additional cases holding that extrinsic evidence is not necessary, *see In re Telebrands*, 140 F.T.C. at 290 ("The Commission may rely on the ad itself and need not resort to extrinsic evidence if the text or depictions are clear enough that the Commission can 'conclude with confidence' that the claim is conveyed to reasonable consumers."); *Bronson*, 564 F. Supp. 2d at 126 ("Even if an advertisement makes a claim by implication, extrinsic evidence is not always necessary.")

devoted to natural health in general and the constituents of Respondents' religious ministry in particular. Resp't Br. at 51. As the ALJ explained:

> While it is true that, if an advertisement is targeted at a particular group, the Commission analyzes the advertisements from the perspective of reasonable consumers within that group, *In re Telebrands*, 140 F.T.C. at 291, in this case there is insufficient evidence to conclude that Respondents' advertising was directed only at the target group Respondents allege. Rather, the evidence shows that anyone can access the advertisements. . . . Accordingly, it is not necessary to interpret Respondents' claims from the perspective of Respondents' purported target group and extrinsic evidence is not necessary for that purpose.

Decision at 98-99.

For evidence on this point, the ALJ noted that: (i) the DCO publication "The Most Simple Guide," is available on the DCO Website and anyone can download it. F. 163; (ii) the BioGuide and the Cancer Newsletter are available on-line through the DCO Website. F. 169, 172; (iii) consumers can locate the DCO Website by entering the term "cancer" in a Google search. F. 162; and (iv) nothing on the DCO Website indicated to the FTC investigator who made the undercover purchase in this case that a consumer would have to be part of any religious community in order to purchase the Challenged Products. F. 150.

2. Respondents' Claims Are Deceptive or Misleading.

The ALJ correctly noted that there are two legal theories to prove that an advertisement is deceptive or misleading, the "falsity" theory and the "reasonable basis" theory. Decision at 99 *citing FTC v. Pantron I*, 33 F.3d at 1096; *In re Thompson Medical Co.*, 104 F.T.C. at 818-19. As the ALJ explained, this case only makes allegations under the reasonable basis theory, and, accordingly, the ALJ's analysis only considered that theory.

"The reasonable basis theory holds that claims about a product's attributes, performance,

or efficacy ('objective' product claims) carry with them the express or implied representation that the advertiser had a reasonable basis substantiating the claims at the time the claims were made." Decision at 99 *citing In re Thompson Med. Co.*, 104 F.T.C. at 813; *FTC v. Direct Mktg. Concepts*, 569 F. Supp. 2d at 298; *In re Kroger*, No. C-9102, 1978 FTC LEXIS 332, at *15 (1978). The ALJ found that Respondents' advertising claims, including claims that the Challenged Products are "Cancer Treatments" and "Cancer Solutions," are objective products claims because the claims are stated in positive terms and are not qualified to be statements of opinion. *Id.* (citation omitted). The ALJ further found that Respondents' testimonials constitute objective claims that the products inhibit tumors or are otherwise effective in the treatment of cancer. *Id.* (citation omitted). The ALJ then concluded that, "Respondents implied that they had a reasonable basis to substantiate these claims." *Id.* (citation omitted).

The ALJ further explained that:

> In determining whether an advertiser has satisfied the reasonable basis requirement, it must be determined (1) what level of substantiation the advertiser is required to have for its advertising claims, and then (2) whether the advertiser possessed and relied on that level of substantiation[10]. . . . ***If an advertiser does not have a reasonable basis substantiating its claims, the representations are deceptive or misleading.***

Decision at 100 *citing FTC v. Pantron I*, 33 F.3d at 1096; *FTC v. Sabal*, 32 F. Supp. 2d 1004, 1007 (N.D. Ill. 1998); *FTC v. QT, Inc.*, 448 F. Supp. 2d at 959-60. (emphasis added). As discussed further below and as found by the ALJ, "the appropriate level of substantiation for

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[10] While Respondents' argument that the ALJ "erroneously shifted the burden of proof" in connection with substantiation is somewhat difficult to discern, it is clear that the ALJ applied well-settled law in finding that "Respondents have the burden of establishing what substantiation they relied on for their product claims and Complaint Counsel has the burden of proving that Respondents' purported substantiation is inadequate." Decision at 100 *citing FTC v. QT, Inc.*, 448 F. Supp. 2d at 959.

health-related efficacy claims, such as those made by Respondents here, is 'competent and reliable scientific evidence.' Because Respondents did not possess or rely upon such evidence, Respondents' advertising claims are misleading." Decision at 100.

(a) Competent and Reliable Scientific Evidence is Required for Health-Related Efficacy Claims.

As the ALJ explained, the level of substantiation required depends on whether the advertising claims at issue are (1) establishment claims or (2) non-establishment claims. Decision at 100 *citing Thompson Med. Co. v. FTC*, 791 F.2d 189, 194 (D.C. Cir. 1986). Establishment claims are those that contain representations regarding the amount of support the advertiser has for its product claims. *Id.* (other citations omitted). By contrast, "a non-establishment claim is simply a claim about a product's attributes, performance, or efficacy, without indicating any particular level of support for such claim." Decision at 100 *citing In re Thompson Med. Co.*, 104 F.T.C. at 815. As noted by the ALJ, DCO's advertisements do not represent that claims have been proven by scientific testing, except in a very few cases. Decision at 101 *citing* F. 225, 231, 247. Moreover, Complaint Counsel did not allege or argue that Respondents' advertisements constitute establishment claims. Accordingly, the claims at issue are deemed non-establishment claims. Decision at 101.

As discussed above, the ALJ's thorough analysis of Respondents' advertising materials demonstrates that the overall net impression of this advertising is that the Challenged Products, individually or collectively, prevent, treat, or cure cancer, inhibit tumors, or ameliorate the adverse effects of chemotherapy or radiation. (*See supra*, at 25-31) As the ALJ properly found, these are health-related efficacy claims. Decision at 101-02. "It is well established that health-related efficacy claims, including those made about dietary supplements specifically, must be

substantiated by 'competent and reliable scientific evidence.'" Decision at 101 *citing FTC v. Natural Solution, Inc.*, No. CV 06-6112-JFW, 2007 U.S. Dist. LEXIS 60783, at *11-12 (C.D. Cal. Aug. 7, 2007); *FTC v. Nat'l Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *43-44; *FTC v. Direct Mktg. Concepts*, 569 F. Supp. 2d at 300, 303.[11]

(b) Respondents Did Not Possess or Rely Upon Competent and Reliable Scientific Evidence to Support Their Claims.

The ALJ properly found that:

> Respondents did not possess or rely upon competent and reliable scientific evidence to substantiate their claims that any of the Challenged Products is effective, either alone or in combination with other DCO products, in the prevention, treatment, or cure of cancer, in inhibiting tumor formation, or in ameliorating the adverse effects of radiation and chemotherapy, and in fact, no such evidence exists.

Decision at 104.

Although Respondents promote their products by touting the "science" of BioMolecular Nutrition and James Feijo's scientific breakthroughs, Respondents produced absolutely no documents substantiating any scientific research done by James Feijo or DCO regarding the Challenged Products. CX 21. The only substantiation provided by Respondents were articles and journals written by others that were not admitted for the truth of the matters asserted therein.

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[11] As the ALJ explained, the foregoing authorities concluded that competent and reliable scientific evidence was the appropriate level of substantiation for health-related efficacy claims without first considering each of the *Pfizer* factors. These factors, which were articulated in *Thompson Medical*, are (1) the product involved; (2) the type of claim; (3) the benefits of a truthful claim; (4) the ease of developing substantiation for the claim; (5) the consequences of a false claim; and (6) the amount of substantiation experts in the field would agree is reasonable. Decision at 101 *citing In re Thompson Med.*, 104 F.T.C. at 821, *In re Pfizer, Inc.*, 81 F.T.C. 23 (1972). Nonetheless, the ALJ considered each of the *Pfizer* factors and concluded that "to the extent specific applications of the *Pfizer* factors is necessary for health-related efficacy claims, such application yields the same result: Respondents must have possessed and relied upon competent and reliable scientific evidence to substantiate the health-related efficacy claims that they made." Decision at 101-04.

April 27, 2009 Trial Transcript, Volume 3, p. 610.

Complaint counsel introduced the report and testimony of Denis Miller, M.D. Dr. Miller is a board-certified pediatric hematologist/oncologist. The ALJ found that (i) he has the appropriate degree of training, experience, and familiarity with the relevant area of research to render expert opinions in the area of cancer, cancer research, and research methodology; and (ii) he was the only witness in the case qualified as an expert in cancer research and cancer treatment. Decision at 103, F. 326. Dr Miller's opinions, which the ALJ found were thorough and well-reasoned, were that competent and reliable scientific evidence is required to demonstrate that a cancer treatment is effective; that competent and reliable scientific evidence means controlled clinical studies; that animal and in vitro studies are insufficient; and that testimonials have no scientific validity. Decision at 103 *citing* F. 343-53. Dr. Miller reviewed all of the Respondents' proffered substantiation and found none of it to constitute competent and reliable scientific evidence. *See* F. 362-386, CX 52.

As the ALJ noted, "the materials relied upon by Respondents as substantiation consisted of author opinions and reviews of literature on the use of herbal medicines for a number of different diseases, including cancer." Decision at 105 *citing* F. 365. However, "[m]ere compilations of citations, which do not contain independent analysis or support for claims made in advertising, do not constitute substantiation." *Id.* at 105. Moreover, most of the studies referenced by Respondents are not peer-reviewed papers. Significantly, Respondents' substantiation materials did not include any controlled clinical trials. *Id. citing* F. 365. Indeed, Respondents admitted that they did not conduct or direct others to conduct any scientific testing of the effects of the Challenged Products, and they are not aware of any such testing having been conducted by others. F. 308.

While Respondents' purported substantiation included non-clinical in vitro or animal studies, these serve only to demonstrate potential activity and safety. *Id. citing* F. 345, 366. Such potential activity, the Court properly concluded, is insufficient substantiation for claimed anti-cancer effect. *Id. citing FTC v. Natural Solution*, 2007 U.S. Dist. LEXIS 60783, at *14-15. Rather, "competent and reliable scientific evidence to substantiate Respondents' claims requires controlled, clinical studies." *Id. citing* F. 343-48. As the court noted in another FTC case,

> The vast majority of the materials purportedly relied on by defendants for support of their product efficacy claims, to the extent they purport to be studies, contain serious methodological and technical flaws, and therefore cannot be characterized as serious scientific research. Many of these materials involve animal and in vitro (test tube) studies, without medical proof that effects would be the same in humans.

FTC v. Slim Am., Inc.,77 F.Supp. 2d 1263, 1274 (S.D. Fla. 1999).

Some studies upon which Respondents relied evaluated isolated compounds that are present in certain of the Challenged Products. As in *National Urological Group* and *Natural Solution*, and as stated by Dr. Miller, testing only certain components of a Challenged Product does not substitute for an actual evaluation of each of the Challenged Products itself. Decision at 104. The ALJ specifically found, based on Dr. Miller's expert report, that the Challenged Products each needed to be tested, not the individual product components of any product. The ALJ explained that "one cannot extrapolate from results of a published non-clinical study of curcumin," for example, "that GDU can eliminate tumors." Decision at 104. "GDU itself, or each active ingredient in GDU, must be subjected to the same experimental conditions as those to which the curcumin was subjected." Decision at 104, F. 367. As the ALJ found, "[i]n the instant case, the Challenged Products were not tested to determine if they had the claimed effects." Decision at 104 *citing* F. 308-14.

The ALJ further explained that "[c]laims that a dietary supplement treats a medical condition must be substantiated by clinical or scientific testing on the product itself; testing only component ingredients of the product is insufficient, unless the testing is on an exact duplicate of the product's combination of active ingredients." Decision at 104 *citing FTC v. Nat'l Urological Group*, 2008 US. Dist. LEXIS 44145, at *79; *FTC v. Natural Solution*, 2007 U.S. Dist. LEXIS 60783 at 14-15 n.6.

The ALJ also addressed Respondents' argument that the literature upon which they relied constitutes "reasonable" support for their "express statements" which they contend are "structure/function" claims. After reiterating the overall net impression of the DCO advertising, the ALJ explained that "[t]he fact that there may have been some basis to support the 'express' words of product descriptions, taken out of context, is immaterial because Respondents had no competent and reliable scientific evidence to substantiate the overall net impression conveyed by their advertisements." Decision at 106 *citing FTC v. Bronson Partners*, 564 F. Supp. 2d at 133-34.

While Respondents offered testimonials in support of their claims, these testimonials "do not constitute valid scientific evidence because, among other reasons, it cannot be confirmed that the speakers had cancer, or that the speakers' reported responses were not due to other treatment modalities." *Id.* at 105 *citing Koch v. FTC*, 206 F.2d 311, 315-16 (6th Cir. 1953) (giving case histories no weight in verifying treatment claims, where the clinical data were based upon insufficient diagnosis or indicated use of conventional treatment along with the product). As the ALJ noted, case law consistently holds that testimonials do not constitute adequate substantiation for health-related efficacy claims in advertising. Decision at 105-06 *citing FTC v. QT, Inc.*, 512 F.3d 858, 862 (7th Cir. 2008); *Simeon Mgmt. Corp. v. FTC*, 579 F.2d 1137, 1143-44 (9th Cir.

1978); *In re Warner-Lambert Co.*, No. 8891, 86 F.T.C. 1398, 1496, 1975 FTC LEXIS 12, at *213 (Dec. 9, 1975), *aff'd*, 562 F.2d 749 (D.C. Cir. 1977).

After thoroughly addressing Respondents' lack of substantiation for their claims, the ALJ discussed Respondents' use of experts in the case, observing that: (i) Respondents did not seek, nor did any of their proffered experts offer, an opinion as to whether there was competent and reliable scientific evidence to support the claims that were alleged in the Complaint; (ii) Respondents' proffered experts were not asked to review, and none of them did review, any of the DCO advertising at issue; (iii) none of Respondents' proffered experts (with the possible exception of one) opined as to what level of substantiation is necessary or appropriate for claims a dietary supplement prevents, treats, or cures cancer; and (iv) none of Respondents' proffered experts had any expertise in treating cancer, or in testing the efficacy of proposed cancer treatments, or were even medical doctors. Decision at 106 *citing* F. 338-40, 387-89, 395-400, 404-10, 418-25. The ALJ concluded that:

> [N]one of Respondents' proffered experts offered any opinions on any material, contested issue in the case, and the opinions that Respondents' proffered experts did offer are entitled to little, if any, weight.

Id.

(c) Respondents' Other Defenses and Arguments Regarding Substantiation Lack Merit.

Respondents have raised a number of additional arguments in connection with the level of substantiation required in connection with Complaint Counsel's allegations. As set forth below, none of these arguments have merit or alter the ALJ's conclusion that Respondents have violated Sections 5 and 12 of the FTC Act in connection with their advertisements of the Challenged Products.

(i) Respondents' Argument Regarding Double-Blind Placebo Studies Is Irrelevant.

Respondents assert that placebo-controlled, double-blind studies are not required for adequate substantiation under the FTC Act. Respondents argue that the court in *FTC v. QT, Inc.*, 512 F.3d 858, stated: "Nothing in the Federal Trade Commission Act . . . requires placebo-controlled, double-blind studies. . . . Placebo-controlled, double-blind testing is not a legal requirement for consumer products." 512 F.3d at 861. The ALJ addressed this argument by noting that:

> Respondents ignore the fact that the appellate court affirmed the district court's holdings that substantiation for health-related efficacy claims must be based on competent and reliable scientific evidence, and that the studies upon which defendants relied were inadequate under that standard. Moreover, the appellate court held that its conclusion regarding double-blind, placebo-controlled studies was of no help to the defendants because, as the district court had found after exhaustive analysis of the defendants' studies, 'defendants ha[d] no proof' to support their advertising claims.

Decision at 109 *citing FTC v. QT, Inc.*, 512 F.3d at 862. Complaint counsel interpret the Seventh Circuit's statement to mean only that such studies are not required in every instance. Otherwise, that statement would be inconsistent with a long line of Commission cases holding that adequate and well-controlled double-blind clinical testing is the standard where such evidence is required in the relevant scientific or medical community to substantiate that the claim is true. *See, e.g., In re Thompson Medical Co.*, 104 F.T.C. at 826; *Removatron Int'l Corp.*, 884 F.2d at 299-301.

Indeed, as discussed above, the evidence in this case demonstrates that competent and reliable scientific evidence, consisting of controlled clinical studies of the Challenged Products, *is* required to substantiate that the challenged claims are true. F. 343-48. Dr. Miller, who was the only expert the ALJ found qualified to testify about cancer research and cancer treatment,

testified that competent and reliable scientific evidence in this field "means controlled clinical studies" and the ALJ found that his opinions were "thorough and well-reasoned." Decision at 103.[12] Clearly, under the record in this case, the FTC Act does require that the challenged claims be substantiated by controlled clinical studies of the Challenged Products.

Respondents had no such controlled clinical studies. F. 365. Indeed, as the ALJ explained:

> In the instant case as well, the language in *Federal Trade Commission v. QT, Inc.* regarding placebo-controlled, double-blind studies does not help Respondents because . . . Respondents did not possess or rely upon any adequate substantiation for their claims that the Challenged Products prevent, treat, or cure cancer.

Id. at 109.

(ii) *Lane Labs* Does Not Alter the Substantiation Standard.

Respondents cite *FTC v. Lane Labs-USA, Inc.*, No. 00-CV-3174 (MDC) (unpublished decision dated Aug. 10, 2009), for the proposition that adequate substantiation can consist of "credible medical testimony that the products in question are good products and could have the results advertised." Resp't Br. at 56. Complaint Counsel believes that the *Lane Labs*' decision was wrongly decided, and it is currently on appeal. *Lane Labs* does not provide any meaningful precedent to this case. The appropriate legal standard for claims that *any* product, including dietary supplements, can prevent, treat, or cure cancer or tumors is, as the ALJ found, competent and reliable scientific evidence to demonstrate that a cancer treatment is effective, which means

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[12] The ALJ also found that even Respondents' proferred experts did not dispute Dr. Miller's opinion "that competent and reliable scientific evidence is the appropriate standard for substantiating cancer claims" and one of the proferred experts (LaMont) would include human clinical trials in her definition of competent and reliable scientific evidence. Decision at 104; *see also* Decision at 106 ("Respondents did not seek, nor did any of their proffered experts offer, an opinion as to whether there was competent and reliable scientific evidence to support the claims that were alleged in the Complaint").

controlled clinical studies. *See* Decision at 103-04.

In any event, the facts in *Lane Labs* are clearly distinguishable and do not help Respondents here. First, *Lane Labs* involved a motion for contempt based on a violation of an FTC order and, as Judge Cavanaugh noted, the power to punish for contempt is discretionary and "[t]o establish contempt the movant bears the burden of proving by clear and convincing evidence that the respondent violated a court order." *Lane Labs*, at 11. The court looked at the narrow question of whether there was substantial compliance with the order and whether the defendants took reasonable steps to comply with the order and simply found that the FTC had not demonstrated by clear and convincing evidence that there was not substantial compliance. Judge Cavanaugh found that the defendants took numerous steps to ensure compliance with the orders, including meeting with researchers, vetting claims, keeping a substantiation file, submitting voluminous compliance reports to the FTC between 2001 and 2006, and hiring a compliance officer. *Id.* at 13-15.

Second, Judge Cavanaugh qualified Lane Labs' two experts, Dr. Michael Frank Holick and Dr. Machalle M. Seibel (both of whom were medical doctors). *Lane Labs* at 8-10. In contrast, here, the ALJ properly determined that Respondents' proffered experts (none of whom were medical doctors) were *not* qualified. F. 335. None of Respondents' proffered experts reviewed the advertising claims at issue; none was asked to render an opinion as to whether Respondents' purported substantiation materials constituted competent and reliable scientific evidence substantiating a claim that any of the Challenged Products prevent, treat, or cure cancer; none has specialized training or experience regarding cancer or cancer treatment; and none has conducted clinical studies regarding cancer treatments. F. 336-42; *see also infra* p. 42. Simply put, unlike in *Lane Labs*, the ALJ found that the Respondents offered *no* credible medical

testimony with regard to the Challenged Products.

Judge Cavanaugh also found that "[n]either of the FTC's experts stated that the supplements marketed by Lane Labs are not effective or constitute a health risk to the public," (*Lane Labs* at 13), in sharp contrast to the facts here, where the ALJ found that "[t]he evidence shows that foregoing a proven cancer treatment in favor of an ineffective treatment would be injurious to a patient's health. In addition, side effects and/or inappropriate dosing of a dietary supplement can cause harmful interactions that interfere with cancer treatment." Decision at 103 *citing* F. 357-61.

(iii) Respondents Do Not Make Structure-Function Claims Under DSHEA.

Respondents argue that a different substantiation standard should apply to their claims because the claims can be considered "structure-function" claims under the Dietary Supplement Health and Education Act (DSHEA). Respondents appear to maintain that DSHEA either controls how the FTC Act should be interpreted (Resp't Br. at 44) or supplants the FTC's authority over dietary supplements (Resp't Br. at 45). Respondents offer no legal authority for these baseless assertions.

The FDA's regulatory distinctions between structure-function claims and health claims under DSHEA do not apply to Section 5 of the FTC Act. As noted in the FTC staff's guide, *Dietary Supplements: An Advertising Guide for Industry* (hereinafter "*Dietary Supplements Guide*"), "advertising for *any* product – including dietary supplements – must be truthful, not misleading, and substantiated." FTC, *Dietary Supplements: An Advertising Guide for Industry* at 1 (2001). The FTC staff warned "*all parties who participate directly or indirectly in the marketing of dietary supplements have an obligation to make sure that claims are presented*

truthfully and to check the adequacy of the support behind those claims." *Id.* at 2 (italics in original).

DSHEA in no way altered the FTC's approach to truth in advertising, and, in fact, is fully consistent with the FTC's approach. *See* 21 U.S.C. § 343(r)(6). FTC staff explained in the *Dietary Supplements Guide* that "a statement about a product's effect on a normal 'structure or function' of the body may also convey to consumers an implied claim that the product is beneficial for the treatment of a disease. If elements of the ad imply that the product also provides a disease benefit, the advertiser must be able to substantiate the implied disease claim even if the ad contains no express reference to disease." *Dietary Supplements Guide* at 4. Respondents cannot explain how their "Disease Guide," "Cancer Newsletter," and other cancer-related advertisements do not make disease claims.

Respondents' claims at issue here are not structure-function claims. Rather, as discussed above, Respondents represent that the Challenged Products mitigate, treat, cure, or prevent cancer or tumors, and, as a result, Respondents' DSHEA argument fails. Respondents' argument that their advertisements contain merely "structure-function" claims, and not health claims, simply ignores the advertisements themselves. One need only refer to Respondents' publication "The Most Simple Guide to the Most Difficult Diseases," which recommends DCO products for particular diseases. F. 163. As detailed above, Respondents' advertisements and promotional material are replete with serious disease claims about the efficacy of the DCO Products in preventing, treating, or curing cancer. Respondents cannot hide behind DSHEA to make cancer claims with impunity.

3. Respondents' Advertising Claims Are Material.

"A claim is considered material if it 'involves information that is important to consumers and, hence, likely to affect their choice of, or conduct regarding a product.'" Decision at 107 *citing Kraft v. FTC*, 970 F.2d at 322. Health-related efficacy claims are consistently held to involve information that is important to consumers. Decision at 107 *citing FTC v. Direct Mktg. Concepts*, 569 F. Supp. 2d at 299-300; *FTC v. QT, Inc.*, 448 F. Supp. 2d at 966. Furthermore, as the ALJ noted, the Commission is entitled to presume materiality for claims involving health concerns. Decision at 107 *citing Kraft v. FTC*, 970 F.2d at 323. This presumption may be rebutted with extrinsic evidence indicating that the claims are not material. *Id. citing FTC v. Nat'l Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *81.

The ALJ found that Respondents' claims regarding the Challenged Products "unquestionably relate to health concerns," and that since claims that relate to health concerns are material, "Respondents' claims are clearly material." Decision at 107. The ALJ also observed that, "Respondents did not make any argument, or attempt to introduce any evidence, that their claims are not material to consumers." *Id.* Accordingly, the ALJ concluded that "Respondents' claims are deemed material." *Id.* Respondents have not challenged that finding on appeal.[13]

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[13] Respondents also argue that proof of actual consumer harm is necessary to find a violation. However, once again, Respondents misapprehend well-established FTC law. Although deceptive claims are actionable only if they are material to consumers' decisions to buy or use the product, an element of proof that Complaint Counsel have met, the FTC need not prove actual injury to consumers. *See Deception Policy Statement, appended to In re Cliffdale Assoc., Inc.*, 103 F.T.C. 110 (1984), *cited with approval in Kraft* 970 F.2d at 314.

III. RESPONDENTS' FIRST AMENDMENT ARGUMENTS ARE ERRONEOUS.

A. Deceptive Commercial Speech Is Entitled to No First Amendment Protection.

Judge Chappell correctly found that Respondents' advertisements constituted deceptive commercial speech and deserved no First Amendment protection. Decision at 113. On appeal, Respondents apparently concede that the speech in question is commercial speech. Respondents now argue that Complaint Counsel and the ALJ have misapplied the *Central Hudson* test. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980). In *Central Hudson*, the Supreme Court articulated a four-part test for reviewing whether a regulation governing commercial speech violates the First Amendment:

> At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.

Id. at 566. The ALJ properly concluded that the inquiry ended at the first step of the *Central Hudson* analysis because the speech in question was deceptive. Decision at 115.

The government may prohibit false or misleading commercial speech entirely. *See In re R. M. J.*, 455 U.S. 191, 203 (1982) ("Misleading advertising may be prohibited entirely"); *Peel v. Attorney Registration & Disciplinary Comm'n*, 496 U.S. 91, 100 (1990); *see also FTC v. Pantron I*, 33 F.3d at 1096; *FTC v. Sabal*, 32 F. Supp. 2d at 1007. Thus, *deceptive* commercial speech, such as the speech the ALJ found here, is not protected by the First Amendment. *See Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 638 (1985) ("The States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive,

or misleading"); *FTC v. Nat'l Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *29-30 (*citing Bristol-Myers Co. v. FTC*, 738 F.2d 554, 562 (2d Cir. 1984) ("[D]eceptive advertising enjoys no constitutional protection"). Morever, commercial speech which is "actually," as opposed to just "potentially" misleading, receives no First Amendment protection, and health related efficacy claims that are not substantiated are misleading commercial speech. *FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d at 306 (the court noted that health-related efficacy claims require competent and reliable evidence as substantiation, or otherwise they are misleading).

Respondents apparently challenge the ALJ's ruling because the ALJ found the advertisements deceptive and without First Amendment protection without requiring Complaint Counsel to prove that the advertisements were false or that consumers actually were misled. Resp't Br. at 20-26. Respondents simply cloak their arguments about facial analysis and substantiation in First Amendment garb. Respondents cite no case where requiring reasonable substantiation for the claims made based on a facial analysis was found to infringe on the First Amendment. Similarly, the FTC has long held that to be deceptive an advertisement only needs to be *likely to mislead* consumers. *See, e.g., Kraft v. FTC*, 970 F.2d at 314. Again, Respondents offer no cases where this well-established principle was found to violate the First Amendment.

Instead, Respondents rely on cases that the ALJ properly distinguished, as involving challenges to regulations banning certain categories of commercial speech that had not been found to be misleading. *See* Decision at 116. *See also Fla. Bar v. Went For It, Inc.*, 515 U.S. 618, 620-24 (1995) (finding that the Florida Bar Rules prohibiting personal injury lawyers from sending targeted direct-mail solicitations to victims and their relatives for thirty days following an accident or disaster did not violate the First Amendment); *Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation Bd. of Accountancy*, 512 U.S. 136, 139, 142 (1994) (finding that Board's decision

censoring petitioner was incompatible with the First Amendment but recognizing that "false, deceptive, or misleading commercial speech may be banned"); *Edenfeld v. Fane*, 507 U.S. 761, 765-66 (1993) (finding that Florida's rule prohibiting certified public accountants from engaging in "direct, in-person, uninvited solicitation" is inconsistent with the free speech guarantees of the First Amendment when the speech involved is truthful and nondeceptive); *Peel*, 496 U.S. at 100, 110-11 (finding that an attorney's letterhead was not actually or inherently misleading, concluding that a lawyer has a constitutional right, under the standards applicable to commercial speech, to advertise his or her certification, but stating that "[m]isleading advertising may be prohibited entirely"); *In re R.M.J.*, 455 U.S. at 206-07 ("there is no finding that appellant's speech was misleading" but noting that "the States retain the authority to regulate advertising that is inherently misleading or that has proved to be misleading in practice").

Finally, although Respondents have asserted that their sale of the Challenged Products and any attendant advertising claims are a part of their religious ministry, this purported link does not change the commercial nature of the speech at issue. In *Bolger v. Youngs Drug Products Corporation*, the Supreme Court concluded that advertisements were commercial speech, "notwithstanding the fact that they contain discussions of important public issues." 463 U.S. 60, 67-68 (1983). Indeed, to find otherwise would allow advertisers to "immunize false or misleading product information from government regulation simply by including references to public issues." *Id.* at 68. It is well-settled that "[m]isleading advertising may be prohibited entirely." *Zauderer*, 471 U.S. at 638; *In re R.M.J.*, 455 U.S. at 203.

B. Respondents' Reliance on *Pearson v. Shalala* Is Misplaced

Respondents assert that the D.C. Circuit's opinion in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) should control the First Amendment analysis. Resp't Br. at 25. Respondents'

reliance is misplaced.

In *Pearson*, dietary supplement manufacturers challenged the FDA's prohibition on all health claims for dietary supplements, except when the agency determined *a priori* that there was "significant scientific" agreement that evidence supported a particular claim. The D.C. Circuit condemned this prohibition, criticizing the FDA's "choice of a rulemaking rather than an adjudication – which would seem a more natural fit for this individualized determination." *Pearson*, 164 F.3d at 652. On appeal of a challenge to the rules, the FDA first tried to justify the blanket prohibition on all supplement claims lacking significant scientific agreement as to their health benefits on the basis that all such claims were inherently misleading. Although reaffirming that "[i]nherently misleading advertising may be prohibited entirely," the court found that the contention that all such health claims regardless of any disclaimers or disclosures were inherently misleading to be almost frivolous. *Id.* at 655.

Here, the FTC has taken the path that the court chided the FDA for not taking – adjudication. Complaint Counsel presented evidence and the ALJ made careful findings regarding the particular claims made and the substantiation (or not) for those claims. The D.C. Circuit's First Amendment concerns regarding overly broad regulation have no bearing on this adjudication.

C. *United States v. Johnson* Has No Application to This Case.

Respondents contend that dicta from *United States v. Johnson*, a 1911 Supreme Court case decided nearly 100 years ago and four years before Congress passed the FTC Act, should guide the Commission. Respondents are wrong; the *Johnson* decision has no application to this case. First, *Johnson* was a criminal case addressing a narrow question of statutory interpretation relating to the meaning of the term "misbranded" under the Food and Drugs Act of June 30, 1906.

The instant case is a civil action under the FTC Act. Second, the Court in *Johnson* specifically noted that it would "say nothing as to the limits of constitutional power." *United States v. Johnson*, 221 U.S. 488, 498 (1911). Not surprisingly, in 1916, Congress amended the Food and Drugs Act to forbid "false and fraudulent" representations pertaining to curative effectiveness. *See United States v. Diapulse Mfg. Corp. of Am.*, 269 F. Supp. 162, 166-67 (D. Conn. 1967) (noting that the Supreme Court reversed course from the *Johnson* case and accorded recognition of Congress' 1916 Amendment to the Food and Drugs Act in *Seven Cases v. United States*, 239 U.S. 510 (1916)).

IV. THE REMEDY IS APPROPRIATE.

A. The Order Addresses Conduct That is Actually Misleading.

The claims the ALJ has found to be unsubstantiated are *actually* misleading, rather then merely "potentially" misleading. Where advertisers make objective product claims, they impliedly represent that they have a reasonable basis for making those claims at the time they disseminate them. *See FTC Policy Statement Regarding Advertising Substantiation, appended to In re Thompson Med. Co.*, 104 F.T.C. 648, 839 (1984) ("Objective claims for products or services represent explicitly or by implication that the advertiser has a reasonable basis for supporting these claims. These representations are material to consumers. That is, consumers would be less likely to rely on claims for products or services if they knew the advertiser did not have a reasonable basis for believing them to be true."); *In re Nat'l Dynamics Corp.*, 82 F.T.C. 488, 549 (1973) ("The record before us demonstrates that respondents employed the performance claim in advertising to inform consumers of the specific attributes of their product. In so doing, we find they represented to consumers that they had a reasonable basis for believing their claims were true."), *aff'd in relevant part*, 492 F.2d 1333 (2d Cir. 1974).

Thus, when advertisers–such as the Respondents in this case–make objective product claims without having such a reasonable basis, they actually mislead the public. *See In re Porter & Dietsch, Inc.*, 90 F.T.C. 770, 872 (1977) ("We conclude that respondents' advertising *is false and misleading*, because it implicitly represents that 'substantially all users of X-11 tablets will lose a significant amount of weight' and that respondents possess competent scientific evidence supporting that claim, even though respondents did not have a reasonable basis for making such a claim at the time the advertising was disseminated.") (emphasis added), *aff'd in relevant part*, 605 F.2d 294 (7th Cir. 1979); *Nat'l Dynamics Corp.*, 82 F.T.C. at 549-50 ("A performance claim is not a technique which can be used with impunity for ascribing specific attributes to a product based on nothing more than a guess that it will perform as represented. We find that the absence of a reasonable basis to support such claims would not only be a material fact . . . but it *would also mislead* in light of the implied representation of substantiation.") (emphasis added). The ALJ's Order properly addresses and provides an appropriate remedy for the Respondents' conduct.

B. The ALJ's Order Is An Appropriate Remedy for Respondents' Violations.

The Commission has dealt on numerous occasions with cancer claims for products containing various ingredients appearing in the Challenged Products and these cases resulted in orders with requirements similar to those in the Order the ALJ imposed here. *In re Native Essence Herb Co.*, No. 9328 (F.T.C. May 7, 2009) (cat's claw); *FTC v. Westberry Enter., Inc.*, 2008 F.T.C. LEXIS 99 (F.T.C. Sept. 18, 2008) (essiac); *In re Jenks*, 2008 F.T.C. LEXIS 94 (F.T.C. Sept. 18, 2008) (essiac); *FTC v. Natural Solution, Inc.*, No. CV 06-06112-JFW (JTLx) (C.D. Cal. Sept. 4, 2007) (judgment and permanent injunction) (echinacea); *see, e.g., In re ForMor Inc.*, 132 F.T.C. 72 (2001) (shark cartilage); *In re Forrest*, 132 F.T.C. 229 (2001)

(echinacea); *In re Miller*, 2000 F.T.C. LEXIS 70 (F.T.C. May 16, 2000) (essiac); *In re Body Sys. Tech., Inc.*, 128 F.T.C. 299 (1999) (shark cartilage and cat's claw); *In re Nutrivida, Inc.*, 126 F.T.C. 339 (1998) (shark cartilage); *In re Am. Life Nutrition, Inc.*, 113 F.T.C. 906 (1990) (bee pollen).

The undisputed facts and the law warrant the relief sought here. *See Telebrands Corp. v. FTC*, 457 F.3d at 358 ("Congress has given the FTC primary responsibility for devising orders to address . . . deceptive practices, and the FTC has broad discretion in doing so"); *FTC v. Colgate-Palmolive,* 380 U.S. 374, 395 (1965) ("reasonable for the [FTC] to frame its order broadly enough to prevent respondents from engaging in similarly illegal practices in future advertisements").

The Order prohibits Respondents from making the types of misrepresentations challenged in the Complaint and provides fencing-in relief, requiring Respondents to possess competent and reliable scientific evidence supporting future claims about the health benefits, performance, safety, or efficacy of any dietary supplement, food, drug, or other health-related product, service, or program.

While Respondents object to the letter that the Order requires Respondents to send to the purchasers of the Challenged Products, requiring such a letter to inform purchasers about the Court's findings is appropriate and standard practice in misleading advertising practices cases. *See Southwest Sunsites, Inc. v. FTC*, 785 F.2d 1431, 1438 (9th Cir. 1986) (affirming order regarding Notice to Customers to address misleading impressions that might remain from respondents' deceptive advertising); *see also, FTC v. Natural Solution, Inc.*, No. CV 06-06112-JFW (C.D. Cal. Sept. 4, 2007); *In re Native Essence Herb Company*, No. 9328 (File No. 082 3115); *In re Bioque Technologies, Inc.*, No. C-4237 (File No. 082 3095); *In the Matter of Holly A.*

Bacon, No. C-4238 (File No. 082 3119); *FTC v. Nu-Gen Nutrition, Inc.* (Stipulated Final Order, Case No. 08CV5309, Sep. 19, 2008, N.D. Ill.) (examples of recent consent orders in cases in which the FTC challenged deceptive advertising of bogus cancer cures, in which the companies were required to send out letters to consumers notifying them that there was little or no scientific evidence demonstrating the products' effectiveness for treating or curing cancer, and urging consumers to consult with their doctors about the products).

Here, the ALJ revised the proposed letter to be sent to Respondents' customers to address Respondents' concerns that Respondents not be seen as adopting statements contrary to their beliefs. Decision at 121. The letter informs past purchasers of the lack of scientific evidence regarding the Challenged Products' efficacy in preventing, treating, or curing cancer. The letter also warns purchasers to consult with their physician before using the Challenged Products. The remedy is narrow as Respondents only need to send the letter to purchasers of their product. The letter contains factual information (the lack of scientific evidence) and information that is non-controversial (the need to consult with a physician before using the Challenged Products to treat cancer).

The Order's requirement of the letter concerns commercial speech – the letter is to be sent only to purchasers of the Challenged Products. To the extent that the Respondents raise First Amendment concerns, the Order's requirement of the letter is consistent with *Central Hudson*. *See Novartis v. FTC*, 223 F.3d 783, 789 (D.C. Cir. 2000) (First Amendment challenge to FTC remedy governed by *Central Hudson*); *see also USA v. Philip Morris USA, Inc.*, 566 F.3d 1095, 1142-43 (D.C. Cir. 2009) (upholding order requiring tobacco companies to publish broad corrective statements); *Zauderer*, 471 U.S. at 651-52 (upholding mandatory disclosures regarding client's responsibility for certain costs in attorney advertising). As the Court noted in *Zauderer*,

the First Amendment interests implicated by disclosure requirements are substantially weaker than those at stake when speech is actually suppressed." *Id.* at 651 n. 14.

Under *Central Hudson*:

> The State must assert a substantial interest to be achieved by restrictions on commercial speech. Moreover, the regulatory technique must be in proportion to that interest. The limitation on expression must be designed carefully to achieve the State's goal. Compliance with this requirement may be measured by two criteria. First, the restriction must directly advance the state interest involved; the regulation may not be sustained if it provides only ineffective or remote support for the government's purpose. Second, if the governmental interest could be served as well by a more limited restriction on commercial speech, the excessive restrictions cannot survive.

447 U.S. at 563.

The ALJ explained the interest involved here:

> The evidence shows that foregoing a proven cancer treatment in favor of an ineffective treatment would be injurious to a patient's health. In addition, side effects and/or inappropriate dosings of a dietary supplement can cause harmful interactions that interfere with cancer treatments. (citations omitted).

Decision at 103.

The Order requires Respondents to send the letter only to purchasers of the Challenged Products to address the specific risks the ALJ identified. Respondents have not challenged the effectiveness of this remedy nor provided an alternative. The Order's requirement of a letter is consistent with the First Amendment.

C. The FTC's Remedy Does Not Constitute a Prior Restraint.

Respondents argue that the remedy imposes an unconstitutional prior restraint on Respondents' speech (Resp't Br. at 61). The Order simply prohibits Respondents from making claims that have been determined to be deceptive. Under *Central Hudson*, there is no First

Amendment protection for Respondents' deceptive speech and an order requiring that Respondents cease that deceptive speech does not constitute an unconstitutional prior restraint. *See also Sears, Roebuck & Co. v. FTC*, 676 F.2d 385, 399-400 (9th Cir. 1982) ("The Commission may require prior reasonable substantiation of product performance claims after finding violations of the [FTC] Act, without offending the First Amendment."); *Bristol-Myers Co. v. FTC*, 738 F.2d at 562 ("Nor is the prior substantiation doctrine as applied here in violation of the First Amendment."); *Jay Norris, Inc. v. FTC*, 598 F.2d 1244, 1252 (2d Cir. 1979) ("[W]e hold only that because the FTC here imposes the requirements of prior substantiation as a reasonable remedy for past violations of the Act, there is no constitutional prior restraint of petitioners' protected speech.").

D. The FTC's Remedy Does Not Establish Government Religious Speech.

The instant action and the ALJ's remedy also do not infringe upon Respondents' right to free exercise of religion, contrary to Respondents' assertion that the ALJ's remedy will unconstitutionally establish government religious speech. Although they may not make deceptive claims to sell products, Respondents are otherwise free to believe whatever they want and to practice their faith as they see fit. *Church of Scientology v. Richardson*, 437 F.2d 214, 217 (9th Cir. 1971) (stating that "the exercise of religious freedom does *not* include the freedom to violate the Federal Food, Drug, and Cosmetic Act") (emphasis in original).

E. The Religious Freedom Restoration Act Is Inapplicable Here.

Respondents argue that the Religious Freedom Restoration Act ("RFRA") prevents the government from substantially burdening their exercise of religion (absent a compelling government interest). However, this statute is completely inapposite here. Complaint Counsel are not attempting to stifle Respondents' ability to comment on public and religious issues freely,

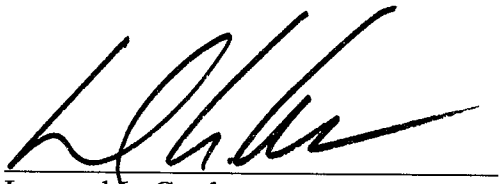
nor are Complaint Counsel challenging Respondents' ability to associate and to express religious or private association beliefs. *Cf. Boy Scouts v. Dale*, 530 U.S. 640 (2000) (protecting the Boy Scouts' rights to associate and express their association's beliefs). Respondents cannot, however, make deceptive statements in connection with the sale of the Challenged Products and protect that deception through flawed invocations of the First Amendment or RFRA.

CONCLUSION

Respondents disseminated advertisements claiming that the Challenged Products prevent, treat, or cure cancer, inhibit tumors, or ameliorate the adverse effects of radiation and chemotherapy without a reasonable basis to substantiate these claims. As the ALJ correctly found, Complaint Counsel has carried its burden of proving that Respondents are liable for their deceptive claims under Section 5(a) and Section 12 of the FTC Act. Based on the record in this proceeding, the requested Order is the appropriate relief for Respondents' violations of Sections 5 and 12. Accordingly, the Initial Decision should be affirmed in its entirety.

Dated: October 20, 2009

Respectfully submitted,



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CERTIFICATE OF SERVICE

I certify that on October 20, 2009, pursuant to Federal Trade Commission Rules of Practice 4.2(c) and 4.4(b), I caused the foregoing Answering Brief of Counsel Supporting the Complaint, to be served and filed, as follows:

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

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600 Pennsylvania Avenue, NW, Room H-135
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One paper copy via Federal Express and one electronic copy to:

Hon. D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
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Two paper copies via Federal Express for delivery the next business day, and one electronic copy to:

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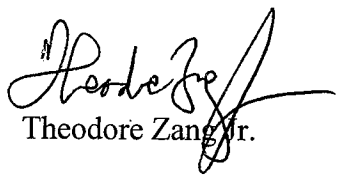
I further certify that the electronic copy sent to the Secretary of the Commission is a true and correct copy of the paper original, and that a paper copy with an original signature is being filed with the Secretary of the Commission on the same day by other means.



Theodore Zang, Jr.