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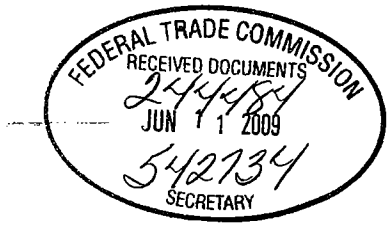
UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES



In the Matter of	)	
DANIEL CHAPTER ONE,	)	
a corporation, and	)	**Docket No. 9329**
JAMES FEIJO,	)	**Public Document**
individually, and as an officer of	)	
Daniel Chapter One	)	

COMPLAINT COUNSEL'S POST-TRIAL REPLY BRIEF

Pursuant to the Court's April 29, 2009 Order on Post Trial Briefs, Complaint Counsel submit their *Reply to Respondents' Proposed Findings of Fact* and *Post-Trial Reply Brief.*

Respectfully submitted,

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Dated: June 11, 2009

TAB 1

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COMPLAINT COUNSEL'S REPLY TO
RESPONDENTS' PROPOSED FINDINGS OF FACT

1. Respondent Daniel Chapter One (hereinafter "DCO") is a non-profit corporation sole organized under Washington State law. (CX 31; CX 35; R 1; R 2).

Response to Finding No. 1:

Although DCO is organized as a corporation sole, Respondent DCO operates as a for-profit corporation organized to carry on business for its own profit or that of its members. (Complaint Counsel's Findings of Fact (hereinafter referred to as CCPF __) ¶¶ 16-94, 109-133).

2. Respondent DCO is a religious ministry. (HOJ, ALJ, Tr. 7; R 1; Harrison, Tr. 280, 290-299; Feijo, P., Tr. 344-345, 382-384; Feijo, J., Tr. 416-417, 464).

Response to Finding No. 2:

Complaint Counsel has no specific response.

3. Corporate Respondent DCO has no for-profit members. (R 1; HOJ, Feijo, J., Tr. 181-189).

Response to Finding No. 3:

Respondents DCO and James Feijo, as well as James Feijo's wife, Patricia Feijo, profit from the sale of the DCO Products. (CCPF ¶¶ 109-133).

4. Respondent James Feijo is the overseer of DCO, and as such he holds all DCO property in trust for the ministry. (Feijo, J., Tr. 416).

Response to Finding No. 4:

Complaint Counsel does not dispute that Respondent James Feijo is the overseer of DCO or that he is legally obligated to hold DCO property in trust; however, rather than holding all DCO property in trust for the ministry, Respondent James Feijo personally profits from the sale of the DCO Products. (CCPF ¶¶ 109-133).

5. Respondent James Feijo has taken a vow of poverty as overseer of DCO's ministry. (HOJ, Feijo, J., Tr. 151).

Response to Finding No. 5:

Complaint Counsel does not dispute that Respondent James Feijo has taken a vow of poverty; however, the evidence indicates that he has not followed that vow. (CCPF ¶¶ 109-133).

6. Respondent DCO's name "Daniel Chapter One" refers to the chapter and verse of the Bible dealing with nutrition and natural healing. (Feijo, P., Tr. 327-328).

Response to Finding No. 6:

Complaint Counsel has no specific response.

7. Respondents' speech is intended to educate and inform recipients about health and healing practices that are consistent with the Book of Daniel, Chapter One, and other parts of the Bible. (Harrison, Tr. 279-284, 286-291, 298-299, 312; Feijo, P., Tr. 327-328, 337-339, 343-345, 357-358, 368-372, 382-383; Feijo, J., Tr. 416-417, 422-431, 433-436, 456-457).

Response to Finding No. 7:

Respondents' product advertisements generally do not contain any educational content. *See, e.g.*, the BioMolecular Nutrition Product Catalog. (R15 (J.Feijo, Dep. at 161)).

8. Respondents' speech is intended to reach those who are devoted to or interested in nutrition and natural healing as expressed by the DCO ministry and the Book of Daniel, Chapter One, and other parts of the Bible. (Harrison, Tr. 279-284, 286-291, 298-299, 312; Feijo, P., Tr. 327-328, 337-339, 343-345, 357-358, 368-372, 382-383; Feijo, J., Tr. 416-417, 422-431, 433-436, 456-457).

Response to Finding No. 8:

Respondents' product advertisements are broadly disseminated. The radio program "Daniel Chapter One Health Watch" is carried by an eclectic group of AM radio stations. (Harrison, Tr. 309-10). Respondents' publication, The Most Simple Guide to the Most Difficult Diseases, is available on the DCO Web site and anyone can download it. (CX 29 at FTC-DCO 0430; P. Feijo, Tr. 395; J. Feijo, Tr. 453-55). The BioGuide and the Cancer Newsletter are also available on-line through DCO's Web site. (CX 13 at FTC-DCO 0013; CX 13A at FTC-DCO 2828A; CX 29 at FTC-DCO 0430; P. Feijo, Tr. 395; J. Feijo, Tr. 453-55; Tr. 264). Consumers can locate Respondents' Web site by entering the term "cancer" in a Google search. (R15 (J. Feijo, Dep. at 136)). FTC Investigator Michael Marino found and accessed DCO's Web site www.danielchapterone.com through Microsoft Internet Explorer. (CX 1).

9. Respondents communicate the message of their ministry by traveling the world for community meetings and prayer groups, and by using the internet, live radio broadcasts and written publications, and by including a Bible verse on labels of each of the Challenged Products. (CX 18 at FTC-DCO 0122, 0124, 0125, 0127; Harrison, Tr. 279-284, 286-291, 298-299, 312; Feijo, P., Tr. 327-328, 337-339, 343-345, 357-358, 368-372, 382-383; Feijo, J., Tr. 416-417, 422-431, 433-436, 456-457).

Response to Finding No. 9:

Complaint Counsel has no specific response.

10. As part of their ministry, Respondents express opinions via their radio broadcasts and their written publications about nutrition and natural healing. (Harrison, Tr. 279-284, 286-291, 298-299, 312; Feijo, P., Tr. 327-328, 337-339, 343-345, 357-358, 368-372, 382-383; Feijo, J., Tr. 416-417, 422-431, 433-436, 456-457).

Response to Finding No. 10:

Complaint Counsel has no specific response.

11. Respondents offer dietary supplement products (DCO products), including the Challenged Products, as part of their overall ministry. (Feijo, P., Tr. 337-338; 342-343).

Response to Finding No. 11:

Respondents admit that anyone can buy and use DCO's products, including people who do not believe in God. (P. Feijo, Tr. 410-11; *see also* Marino, HOJ Tr. 55). An entity does not have to be a religious ministry to become an affiliate of Respondent DCO. (J. Feijo, HOJ Tr. 114).

Furthermore, for the purposes of Section 12, the DCO Products are "food" or "drugs." (15 U.S.C. Section 55(a), (b), (c) (defining "food" as, among other things, "articles used for food or drink for man," and defining "drug" as, among other things, "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man")).

12. The Challenged Products are four of close to 200 products offered by Respondents. (Feijo, P., Tr. 392).

Response to Finding No. 12:

Complaint Counsel has no specific response.

13. Respondents use radio broadcasting and personal appearances as the primary means of informing interested persons about DCO products. (Feijo, J., Tr. 279-280; 282-284).

Response to Finding No. 13:

The evidence cited does not support the proposition that radio broadcasting and personal appearances are the "primary means" that Respondents inform "interested persons" about DCO products.

14. Interested persons who wish to obtain DCO products do so through the website. (Feijo, J., Tr. 459-450, 464).

Response to Finding No. 14:

Complaint Counsel has no specific response.

15. Where the Challenged Products appear and are ordered on Respondents' website(s), the following language appears:

> "The information on this website is intended to provide information, record, and testimony about God and His Creation. It is not intended to diagnose a disease. The information provided on this site is designed to support, not replace, the relationship that exists between a patient/site visitor and his/her health care provider. Caution: some herbs or [nutritional] supplements should not be mixed with certain medications." (CX 11; CX 17 at FTC-DCO 0071, 0074, 0077, 0081, 0085-0086, 0090, 0093, 0096, 0099).

Response to Finding No. 15:

The language quoted above is not included on every web page where the Challenged Products appear. (See, e.g., CX 13 at FTC-DCO 0014). Moreover, the language quoted above appears in small print at the bottom of the web page where the Challenged Products are ordered. (CX 11 at FTC-DCO 0712).

16. With respect to the Challenged Products, Respondents' website(s) contain the following disclaimer:

> "These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent disease." (CX 17 at FTC-DCO 0073, 0076, 0080, 0084, 0089, 0095, 0098; Feijo, P., Tr. 382).

Response to Finding No. 16:

Complaint Counsel has no specific response.

17. The Challenged Products are intended to supplement the diet, through the use of a vitamin, mineral, herb, or other botanical, for use by man to increase the total daily intake of such ingredients. (Feijo, P., Tr. 394; Feijo, J., Tr. 442-444, 457, 459).

Response to Finding No. 17:

In their advertisements, Respondents represent that the Challenged Products cure, mitigate, treat, or prevent cancer or tumors. (CCPF ¶¶ 134-173).

18. Respondents do not claim that the Challenged Products treat disease. (Feijo, P., Tr. 442-444).

Response to Finding No. 18:

Respondents do claim that the Challenged Products cure, mitigate, treat, or prevent cancer or tumors. (CCPF ¶¶ 134-173).

19. The Challenged Products are intended for ingestion in capsule, powder, or liquid form. (Feijo, J., Tr. 446).

Response to Finding No. 19:

Complaint Counsel has no specific response.

20. The Challenged Products are not represented for use as a conventional food or as the sole item of a meal or diet. (Feijo, J., Tr. 446).

Response to Finding No. 20:

Complaint Counsel has no specific response.

21. The Challenged Products are labeled as dietary supplements. (CX 12; CX 13; CX 14; CX 15; CX 16; CX 18 at FTC-DCO 0122, 0124, 0125, 0127).

Response to Finding No. 21:

CX 12, CX 13, CX 14, and CX 15 do not contain any Challenged Product labels.

22. On their website, Respondents make the following claim about the Challenged Product Bioshark:

> "Pure skeletal tissue of sharks which provides a protein that inhibits angiogenesis -- the formation of new blood vessels. This can stop tumor growth and halt the progression of eye diseases . . ." (CX 12; Feijo, P., Tr. 341-342).

Response to Finding No. 22:

Complaint Counsel has no specific response.

23. On their website, Respondents make the following claim about the Challenged Product 7 Herb Formula:

> "purifies the blood, promotes cell repair, fights tumor formation, and fights pathogenic bacteria" (CX 13; Feijo, P., Tr. 345-346).

Response to Finding No. 23:

Complaint Counsel has no specific response.

24. On their website, Respondents make the following claim about the Challenged Product GDU:

> "contains natural proteolytic enzymes (from pineapple source bromelain to help digest protein --even that of unwanted tumors and cysts. This formula also helps to relieve pain and heal inflammation. . .GDU is also used for. . .and as an adjunct to cancer therapy. GDU possesses a wide range of actions including anti-inflammatory and antispasmodic activity. . ." (CX 14; Feijo, P., Tr. 351-352).

Response to Finding No. 24:

Complaint Counsel has no specific response.

25. On their website, Respondents make the following claim about the Challenged Product BioMixx:

> "boosts the immune system, cleanses the blood and feeds the endocrine system to allow for natural healing. It is used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatments." (CX 15; Feijo, P., Tr. 354-355).

Response to Finding No. 25:

Complaint Counsel has no specific response.

26. Respondents do not use the words *diagnose*, *mitigate*, *cure* or *prevent* in any representation they make about the Challenged Products. (Feijo, P., Tr. 338-341; 345-346; 351-352; 354-355; 412-413).

Response to Finding No. 26:

Respondents do represent that the Challenged Products cure, mitigate, treat, or prevent cancer or tumors. (CCPF ¶¶ 134-173).

27. The express statements made by DCO about the Challenged Products describe the supplement's effects on the "structure or function" of the body. (Feijo, P., Tr. 345-357; 379-392).

Response to Finding No. 27:

Respondents have admitted that they made the following claims:

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.

(Answer ¶ 14.)

28. The literature relied on by Respondents for their claims about the Challenged Products constitutes competent and reliable scientific evidence. (LaMont, Tr. 596).

Response to Finding No. 28:

This literature was not admitted for the truth of the matters asserted therein, and Patricia Feijo was unable to identify with specificity which articles she was relying upon for the specific claims that brought about the charges in this case. (Tr. 602-04; CCPF ¶ 197).

Furthermore, Respondents did not possess substantiation for their claims about the Challenged Products at the time they were made. (CCPF ¶¶ 186-211). Dr. Miller confirmed that there is no competent and reliable scientific evidence to substantiate the claims that DCO's products treat, cure, or prevent cancer. (CCPF ¶¶ 212-237). Dr. LaMont would not be comfortable with the Fiejos saying that the DCO products are going to cure cancer. (R22 (LaMont, Dep. at 53)). Until there are clinical trials, Dr. LaMont agrees that "we don't know"

whether DCO's products would be effective in battling cancer. (R22 (LaMont, Dep. at 147); LaMont, Tr. 585).

29. Respondents relied on literature consisting of articles, publications and expert analysis to substantiate their statements about the Challenged Products. (R 9; R 10; Feijo, P., Tr.. 401-402, 404-405, 605-610).

Response to Finding No. 29:

This literature was not admitted for the truth of the matters asserted therein, and Patricia Feijo was unable to identify with specificity which articles she was relying upon for the specific claims that brought about the charges in this case. (Tr. 602-04; CCPF ¶ 197).

Furthermore, Respondents did not possess substantiation for their statements about the Challenged Products at the time they were made. (CCPF ¶¶ 186-211).

30. The substantiating literature used by Respondents for their claims about the Challenged Products is consistent with the general research available about the constituent ingredients of the Challenged Products. (R 9; R 10; LaMont, Tr. 587-588).

Response to Finding No. 30:

This literature was not admitted for the truth of the matters asserted therein. (Tr., 602-04).

Furthermore, Respondents did not possess "substantiating literature" for their claims about the Challenged Products, at the time that such claims were made. (CCPF ¶¶ 186-211).

31. There is no evidence in the record that Respondents' statements about the Challenged Products caused harm or potential harm to consumers. (Entire record).

Response to Finding No. 31:

The deceptive nature of the advertisements about the Challenged Products is by its very nature likely to harm consumers. (Entire record).

32. There is no evidence in the record that the Challenged Products have caused actual harm to consumers. (Entire record).

Response to Finding No. 32:

The deceptive nature of the advertisements about the Challenged Products is by its very nature likely to harm consumers. (Entire record).

33. There is no evidence in the record that the FTC has received any complaints concerning the Challenged Products. (R 11 (Marino, Dep. at 49-51); entire record).

Response to Finding No. 33:

Complaint Counsel has no specific response.

34. There is no evidence in the record of any investigation or analysis concerning consumer expectations or perceptions about the Challenged Products. (Entire record).

Response to Finding No. 34:

Complaint Counsel has no specific response.

35. There is no evidence in the record concerning consumer expectations and perceptions about the Challenged Products. (Entire record).

Response to Finding No. 35:

Complaint Counsel has no specific response.

36. The cost to substantiate the "structure and function" claims made by the Respondents about the Challenged Products is unproven by Complaint Counsel, but is likely to be in excess of $100 million per constituent ingredient. (R 14 (Miller, Dep. at 49); Miller, Tr. 149, 181).

Response to Finding No. 36:

Complaint Counsel has no specific response.

37. The expert witness offered by Complaint Counsel did not address Respondents' express statements about the Challenged Products, but only addressed claims of cancer treatment allegedly implied by Respondents. (Miller, Tr. 150-152).

Response to Finding No. 37:

Respondents have admitted making the following claims:

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.

(Answer ¶ 14.)

Furthermore, Dr. Miller did in fact confirm that there is no competent and reliable scientific evidence to substantiate the claims that DCO's products treat, cure, or prevent cancer. (CCPF ¶¶ 212-237).

38. The expert witness offered by Complaint Counsel did not know the meaning or significance of a "structure/function" claim. (Miller, Tr. 173-174).

Response to Finding No. 38:

The evidence cited does not support the proposition that Dr. Miller did not know the meaning or significance of a "structure/function" claim. Moreover, even if the evidence cited does support the proposition, it is irrelevant to Complaint Counsel's claims in this case.

39. The expert witness offered by Complaint Counsel did not have knowledge of the type of statements for dietary supplements permitted by the FDA under DSHEA. (Miller, Tr. 150-152, 204).

Response to Finding No. 39:

The evidence cited does not support the proposition that Dr. Miller did not have knowledge of the type of statements for dietary supplements permitted by the FDA under DSHEA. Moreover, even if the evidence cited does support the proposition, it is irrelevant to Complaint Counsel's claims in this case.

40. The expert witnesses offered by Respondents did address Respondents' express statements about the Challenged Products, and concluded that those claims are accurate. (RX 3; RX 4; Duke, Tr. 519-520; LaMont, Tr. 572-574).

Response to Finding No. 40:

Respondents have admitted making the following claims:

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.

(Answer ¶ 14.)

Moreover, Respondents' purported experts did not possess any information substantiating Respondents' claims. (CCPF ¶¶ 238-472).

41. Respondents' expert witness analyzed the meaning and significance of "structure/function" claims. (R 4; LaMont, Tr. 550-551, 574-575).

Response to Finding No. 41:

Complaint Counsel has no specific response.

42. The expert witnesses offered by Respondents testified competently that the cost of substantiating "structure/function" claims for dietary supplements in the same manner as drugs is prohibitive. (Duke, Tr. 536-538; LaMont, Tr. 595-597).

Response to Finding No. 42:

Complaint Counsel has no specific response.

43. There are valid scientific, fiscal and competitive reasons for requiring lesser substantiation for dietary supplement claims as compared to pharmaceutical drug claims. (LaMont, Tr. 596-597).

Response to Finding No. 43:

Complaint Counsel has no specific response.

44. The expert witnesses offered by Respondents testified competently that the amount of substantiation that exists to support Respondents' claims about the Challenged Products is reasonable. (LaMont, Tr. 595-599).

Response to Finding No. 44:

The evidence cited does not support the proposition that the expert witnesses offered by Respondents testified competently that the amount of substantiation that exists to support Respondents' claims about the Challenged Products is reasonable. Moreover, Respondents' purported experts did not possess any information substantiating the claims Respondents have admitted making. (CCPF ¶¶ 238-472).

45. Competent and reliable scientific evidence exists for the claims made by Respondents about the Challenged Products. (LaMont, Tr. 599-600).

Response to Finding No. 45:

The evidence cited does not support the proposition that competent and reliable scientific evidence exists for the claims Respondents have admitted making about the Challenged Products. Dr. Miller confirmed that there is no competent and reliable scientific evidence to substantiate the claims that DCO's products treat, cure, or prevent cancer. (CCPF ¶¶ 212-237).

46. There is a reasonable basis for Respondents' claims about the biological mechanisms of the Challenged Products. (LaMont, Tr. 599).

Response to Finding No. 46:

The evidence cited does not support the proposition that there is a reasonable basis for Respondent's claims about the "biological mechanisms" of the Challenged Products. Moreover, as noted above, Dr. Miller confirmed that there is no competent and reliable scientific evidence to substantiate the claims that DCO's products treat, cure, or prevent cancer. (CCPF ¶¶ 212-237). Thus, Respondents lack a reasonable basis for their cancer claims.

TAB 2

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COMPLAINT COUNSEL'S POST-TRIAL REPLY BRIEF

I. INTRODUCTION

Respondents' Post-Hearing Brief, and indeed their conduct at trial, ignores that Respondents admitted in their Answer that they made the following representations in advertising the DCO 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 apparently want the Court to ignore this admission. The Court, however, has already rejected Respondents' effort to "change their mind" on this issue. *See March 3 Order Denying Respondents' Mot. to Amend Answer.* As set forth at trial, in Complaint Counsel's Post-Trial Brief, and below, Respondents' admission that they made the representations at issue in this case disposes of many of the arguments that Respondents seek to advance in their Post-Hearing Brief. Indeed, much of what Respondents claim Complaint

Counsel have improperly presumed are matters that Respondents admitted or the legal consequence of those admissions.

Respondents spend several pages arguing about the need for Complaint Counsel to introduce extrinsic evidence to prove that the advertisements in question make the representations alleged in the Complaint. *Respondents' Post-Hearing Br.* at 5-7. There is no need for any advertisement interpretation in this case, however, because Respondents have admitted making the representations alleged in the Complaint. Moreover, as set forth at trial and in Complaint Counsel's Post-Trial Brief, the representations alleged are made either expressly or by strong implication in the advertisements. *Complaint Counsel's Post-Trial Br.* at 10-15.

Respondents spend much of their Post-Hearing Brief invoking the Dietary Supplement Health and Education Act of 1994 ("DSHEA"). *Respondents' Post-Hearing Br.* at 7-12. Respondents' DSHEA arguments miss the mark for several reasons. First, to qualify as a dietary supplement under DSHEA, Respondents must not have made claims that those products diagnose, mitigate, treat, cure or prevent a disease. 21 U.S.C. § 343(r)(6). Respondents, however, have admitted making the representations that Bio*Shark, 7 Herb Formula, GDU, and BioMixx ("the DCO Products") are effective in the prevention, treatment, or cure of cancer. Respondents' admission ends their DSHEA argument. Second, whatever protection DSHEA might provide with respect to the Food, Drug, and Cosmetic Act, DSHEA is not a defense to a violation of the FTC Act.

Respondents' admission also dooms their arguments on substantiation. First, because Respondents have admitted making representations about the DCO Products being effective in preventing, treating, or curing cancer, Respondents must produce competent and reliable scientific evidence to support such representations. Respondents have not. Indeed, none of the

substantiation offered by Respondents addresses the representations that they have admitted making.

Respondents also try to make much of the fact that Complaint Counsel have purportedly failed to prove all of the necessary elements to support a claim of unfairness. Respondents ignore that Complaint Counsel have alleged and argued that Respondents' advertisements were deceptive, not that Respondents' conduct was unfair. *Complaint* ¶ 5, 14-17; *Complaint Counsel's Pre-Trial Br.* at 10-29; *Complaint Counsel's Post-Trial Br.* at 9-32.

Much of the rhetoric Respondents spend on the First Amendment is premised on their flawed arguments regarding substantiation and extrinsic evidence. Moreover, Respondents misconstrue the First Amendment issue here. In this case, there will be no restraint on Respondents' speech until Complaint Counsel prove that the Respondents' representations were deceptive, and the law is clear that there is no First Amendment protection for deceptive commercial speech.

Respondents' unsupported rhetoric and hyperbole cannot change the straight-forward nature of this case nor can it change the fact that Respondents admitted making the representations at issue. Complaint Counsel have presented overwhelming evidence that Respondents violated Sections 5(a) and 12 of the FTC Act when they: (1) distributed the DCO Products in commerce; (2) claimed that the DCO Products prevent, treat, or cure cancer or tumors; (3) disseminated these claims about the DCO Products to consumers; and (4) did not possess substantiation for such claims at the time they were made.

II. COMPLAINT COUNSEL HAVE DEMONSTRATED THAT RESPONDENTS VIOLATED SECTIONS 5(a) AND 12 OF THE FTC ACT

A. Respondents Misconstrue the FTC's Substantiation Standard

Respondents incorrectly assert that "Complaint Counsel rests its case on the presumption that only substantiation by double-blind, placebo-controlled clinical trials, as required by the US Food Drug and Cosmetic Act for approval of drugs, qualifies as reasonable substantiation for claims made by Respondents." *Respondents' Pre-Hearing Br.* at 2. Respondents mis-characterize Complaint Counsel's interpretation of the FTC's substantiation standard and misconstrue the law itself.

Well-established FTC law states that when disseminating advertisements, advertisers must have a reasonable basis for advertising claims before they are disseminated. *FTC Policy Statement Regarding Advertising Substantiation* ("Substantiation Policy Statement"), appended to *Thompson Med. Co.*, 104 F.T.C. 648, 839 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987). To have a reasonable basis for their claims, advertisers must possess at least the level of substantiation expressly or impliedly claimed in their advertising. *See Honeywell, Inc.*, 126 F.T.C. 202 (1998). Respondents have the burden of establishing what substantiation they relied on for their product claims at the time they were disseminated. *Substantiation Policy Statement*, 104 F.T.C. at 839; *see* FTC *v. Pantron I Corp.*, 33 F.3d 1088, 1096 n.23 (9th Cir. 1994); *Thompson Med.*, 791 F.2d at 193. It is the Commission's burden to prove that Respondents' purported substantiation is inadequate, but to satisfy this burden, the Commission does not need to conduct or present clinical studies showing that the product does not work or perform as claimed. *Simeon Mgmt. Corp. v. FTC*, 579 F.2d 1137, 1144-45 (9th Cir. 1978); *see FTC v. Sabal*, 32 F. Supp. 2d 1004, 1008-09 (N.D. Ill. 1998).

For health or safety claims, the FTC requires "competent and reliable scientific evidence" as substantiation for those claims. *See FTC v. Nat'l Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *77 (N.D. Ga. June 4, 2008) (granting the FTC's motion for summary judgment and finding that since all of defendants' "claims regard the safety and efficacy of dietary supplements . . . they must be substantiated with competent and reliable scientific evidence"); *FTC v. Natural Solution, Inc.*, 2007 U.S. Dist. LEXIS 60783, at *11-13 (C.D. Cal. Aug. 27, 2007) (granting the FTC's motion for summary judgment and applying the "competent and reliable scientific evidence" standard to defendants' claims that their product prevents and treats cancer). The "competent and reliable scientific evidence" standard typically is defined as "tests, analyses, research, studies, or other evidence based upon the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." *See, e.g., Brake Guard Prods., Inc.*, 125 F.T.C. 138 (1998); *Auto. Breakthrough Scis., Inc.*, 126 F.T.C. 229 (1998).

To the extent they cite to dicta in the Seventh Circuit's decision in *FTC v. QT*, Respondents fail to undercut the need for controlled, clinical studies to substantiate the cancer claims in the instant case. 512 F.3d 858, 861 (7th Cir. 2008). In fact, Respondents neglect to quote other relevant language in the Seventh Circuit's opinion, specifically that:

> [A] person who promotes a product that contemporary technology does not understand must establish that this "magic" actually works. Proof is what separates an effect new to science from a swindle. . . . A placebo-controlled, double-blind study is the best test; something less may do (for there is no point in spending $ 1 million to verify a claim worth only $ 10,000 if true); but defendants have no proof of the Q-Ray Ionized Bracelet's efficacy. The "tests" on which they relied were bunk. (We need not repeat the magistrate judge's exhaustive evaluation of this

> subject.) What remain are testimonials, which are not a form of proof because most testimonials represent a logical fallacy: post hoc ergo propter hoc. *QT*, 512 F.3d at 862.

In citing *QT*, Respondents also fail to note that the Seventh Circuit affirmed the district court's judgment that the defendants had violated the FTC Act. The district court interpreted the FTC's substantiation standard to require "competent and reliable evidence" in the form of a "well-conducted, placebo-controlled, randomized, double-blind study," as recommended by both parties' experts. *FTC v. QT*, 448 F. Supp. 2d 908, 961-62 (N.D. Ill. 2006). The district court explained that this level of substantiation was necessary given the defendants' "express, health-related claims that the Q-Ray bracelet relieves pain." *Id.*

Thus, Complaint Counsel do not disagree with the Seventh Circuit's observation that the FTC's substantiation standard is flexible, and that the level of substantiation may vary depending on the particular facts of a case. Moreover, Complaint Counsel have never asserted that double-blind, placebo-controlled studies are by default required to substantiate claims. Nevertheless, based on the seriousness of Respondents' cancer claims, and the opinion of Complaint Counsel's cancer expert on what constitutes competent and reliable scientific evidence in the instant case, Complaint Counsel assert that Respondents' claims must be substantiated with well-designed, controlled clinical trials.

Here, Complaint Counsel's expert oncologist, Denis R. Miller, M.D., testified that only data from well-designed, controlled, clinical trials will constitute "competent and reliable scientific evidence" to substantiate claims that a new therapy is safe and effective to treat, cure,

or prevent cancer. CCPF ¶¶ 218-19.[1]

Respondents assert that their purported substantiation is "more than adequate to meet the required legal standards." *Respondents' Post-Hearing Br.* at 10. Despite their rhetoric, the only support Respondents provide for this statement is a single sentence citing only two pages of the trial transcript: "As [Respondents' expert Sally LaMont, N.D.] has testified, the substantiation that Respondents used is supported by considerable literature in the field that constitutes adequate and reasonable corroboration for the claimed 'biological mechanism underlying the claimed action.' (LaMont, Tr. 587, 599)."[2] However, Respondents fail to mention that Dr. LaMont testified in her deposition and at trial that because the DCO Products have not been tested, we do not know whether these products are effective in the prevention, treatment or cure of cancer. CCPF ¶ 351. She also agreed that, until there are clinical trials, "we don't know" whether DCO's products would be effective in battling cancer. CCPF ¶ 369. Dr. LaMont acknowledged that traditional use evidence does not replace human clinical trials. CCPF ¶ 366. Further, Dr. LaMont testified that cancer patients should "follow the recommendations of their oncologist and utilize protocols that are proven to be most effective for their cancer . . . ." CCPF ¶ 355.

Similarly, Dr. Duke recognized the difference between something being efficacious in an in vitro study and something being efficacious in human beings. CCPF ¶ 271. As a matter of science, Duke did not believe that the herbal extract working in vitro proves that it would work

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[1] "CCPF" refers to Complaint Counsel's Proposed Findings of Fact, submitted to the Court on May 28, 2009.

[2] The phrase "biological mechanism underlying the claimed action" does not appear anywhere in Dr. LaMont's testimony.

in a human. CCPF ¶ 272. Indeed, rather than relying on in vitro studies, Dr. Duke recommended conducting "third arm" trials in which a given herb would be compared with a given pharmaceutical and a placebo. CCPF ¶¶ 273-74. He also testified that anecdotal reports are "even below . . . [his] lines of evidence." CCPF ¶ 280.

The uncontroverted evidence demonstrates that, even under the most generous interpretation of "competent and reliable scientific evidence," Respondents simply cannot substantiate their cancer claims. Respondents conducted no scientific testing on the DCO Products. CCPF ¶¶ 187-189, 198, 206-07, 208. Respondents have not engaged any others to conduct scientific tests on any of the DCO Products. CCPF ¶¶ 190, 202-203, 206, 209, 211. It was not Respondents' practice to obtain scientific studies about any of the components in their products. CCPF ¶ 192. Moreover, none of the four witnesses Respondents proposed as experts knew of, or had conducted, any scientific studies on the DCO Products. CCPF ¶¶ 248, 269, 279, 291, 292-94, 306, 310, 352, 365, 387, 396-401, 409, 412-13, 418-20, 423, 449, 467.

The articles Respondents offered as substantiation were not admitted for the truth of the matters asserted therein, and Patricia Feijo was unable to identify with specificity which articles she was relying upon for the specific claims that brought about the charges in this case. CCPF ¶ 197; Tr. 602-04.

Complaint Counsel's cancer expert, Dr. Miller, confirmed that there is no competent and reliable scientific evidence to substantiate the claims that the DCO Products prevent, treat, or cure cancer or tumors. CCPF ¶¶ 222-37. Indeed, in his expert report and deposition testimony, Dr. Miller even noted the potential harm to cancer patients who use complementary medicine as a substitute for traditional medicine. *See generally* (CX 52; R14 (Miller, Dep. at 90, 122, and 176)). Consistent with Dr. Miller's assessment, Dr. LaMont testified that there is a danger if

consumers do not continue with traditional cancer therapy and stated that there always is a danger that people will take DCO products and not go and see their physicians. CCPF ¶¶ 372, 374. Dr. LaMont also stated that she did not "believe that on their own across the board these [DCO] products are going to effectively treat cancer." CCPF ¶ 361.

Respondents did not ask their experts to testify that there was substantiation for the representations that Respondents admit making. Indeed, two of Respondents' experts never even reviewed the Complaint to determine what the representations at issue in this case were. CCPF ¶¶ 250, 303. However, during cross-examination and at deposition, Complaint Counsel demonstrated that Respondents' experts could not substantiate the representations made by Respondents. CCPF ¶ 352, 386, 396-402, 408-20, 421-22, 426-28, 436-442, 446-49, 467-72.

B. Complaint Counsel Have Met All Necessary Elements of Proof

1. The Applicable Standard of Proof is a Preponderance of the Evidence

Citing *Addington v. Texas*,[3] Respondents erroneously assert that the applicable standard of proof in this case is "clear, cogent and convincing evidence." *Respondents' Post-Hearing Br.* at 4. Respondents are wrong. *Addington* involved the standard of proof in an involuntary civil commitment proceeding and has nothing to do with the issues in this case.

According to well-established precedent, Complaint Counsel must satisfy the preponderance of the evidence standard, as Complaint Counsel have done in this proceeding. *See Rambus, Inc.*, No. 9302, 2006 FTC LEXIS 101, at *57 (Aug. 20, 2006) ("Complaint Counsel have the burden to prove the necessary elements of liability by a preponderance of the evidence"); *Auto. Breakthrough*, 126 F.T.C. at 306, n.45 ("To find liability . . . the Commission

[3] 441 U.S. 418 (1970).

must be persuaded that each of its findings is supported by a preponderance of the evidence on the record"); *Adventist Health Sys. West*, 117 F.T.C. 224, 297 (1994) ("Each element of the case must be established by a preponderance of the evidence"). As detailed in Complaint Counsel's Post-Trial Brief, Complaint Counsel have proven Respondents' liability by a preponderance of the evidence.

2. Complaint Counsel Have Demonstrated that Respondents Violated Sections 5(a) and 12 of the FTC Act by Engaging in Deceptive Advertising and an Unfairness Analysis Pursuant to 15 U.S.C. § 45(n) is Not Required

This is a deception case. In claiming that Complaint Counsel must also satisfy the elements of proof for unfairness under 15 U.S.C. § 45(n), Respondents confuse the legal elements governing this matter.[4] An advertisement is deceptive if it contains a representation or omission of fact that is likely to mislead a consumer acting reasonably under the circumstances, and that representation or omission is material to a consumer's purchasing decision. *Telebrands Corp.*, 104 F.T.C. 278, 290 (2005); *FTC Policy Statement on Deception*, appended to *Cliffdale Assocs., Inc.*, 103 F.T.C. 110, 174-75 (1984); *Novartis Corp.*, 127 F.T.C. 580, 679 (1999), *aff'd*, 223 F.3d 783 (D.C. Cir. 2000); *Stouffer Foods Corp.*, 118 F.T.C. 746, 798 (1994); *Kraft, Inc.*, 114 F.T.C. 40, 120 (1991), *aff'd*, 970 F.2d 311 (7th Cir. 1992), *cert. denied*, 507 U.S. 909 (1993).

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[4] In fact, deception has long been viewed as a subset of unfairness. *Int'l Harvester Co.*, 104 F.T.C. 949, 1060 (1984) ("unfairness is the set of general principles of which deception is a particularly well-established and streamlined subset."); *see also Southwest Sunsites, Inc.*, 105 F.T.C. 7, 153 (1985) ("Since deception is a means of harming consumer choice . . . such representations are unfair as well" and "[s]ince we have found the practices deceptive, it follows that they were also unfair."); *cf. Pfizer Inc.*, 81 F.T.C. 23, 25, 57 (1972) ("complaint counsel set forth charges alleging two separate and distinct violations of Section 5 . . . first, a charge of unlawful deception, and second, a charge of unlawful unfairness.").

3. Respondents Have Admitted to Making the Challenged Representations and Extrinsic Evidence Is Not Required

In Paragraph 14 of their Answer, Respondents unequivocally state: "Respondents admit making the representations contained in subparagraphs a through h of paragraph 14 [of the Complaint]." The representations in subparagraphs a through h of paragraph 14 are as follows:

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.

CCPF ¶ 135. Given these admissions, the messages conveyed by Respondents' advertising are not in dispute. Thus, the Court has no need for extrinsic evidence of consumer perceptions or expectations.

Moreover, as Complaint Counsel set forth in their Post-Trial Brief, because the advertisements in question make either express or strongly implied claims, extrinsic evidence is not required. *See Novartis*, 127 F.T.C. at 680 (1996); *Stouffer*, 118 F.T.C. at 798; *Kraft*, 114 F.T.C. at 121; *Thompson Med.*, 104 F.T.C. at 789.

Respondents also persist in arguing that "the FTC must determine the effect of the challenged claims on a reasonable member of the target group," which they identify as "individuals devoted to natural health in general and the constituents of Respondents' religious ministry in particular." *Respondents' Post-Hearing Br.* at 7. Because Respondents have admitted to making the representations at issue in this case and there is no advertising interpretation to conduct, this point is moot. In addition, Respondents' description of their target audience is inaccurate. The evidence in this case clearly shows that anyone can access

Respondents' Internet and radio advertisements. Respondents' publication, The Most Simple Guide to the Most Difficult Diseases, is available on the DCO Web site and anyone can download it. CCPF ¶ 28. The BioGuide and the Cancer Newsletter are also available on-line through DCO's Web site. CCPF ¶ 28. Consumers can locate Respondents' Web site by entering the term "cancer" in a Google search. CCPF ¶ 181. Finally, Respondents' radio program "Daniel Chapter One Health Watch" is carried by an eclectic group of AM radio stations, and anyone who can tune in to these stations can listen to the show. Harrison, Tr. 304, 309-10.

Respondents also assert that Complaint Counsel must prove harm to consumers. *Respondents' Post-Hearing Br.* at 10. 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 as detailed in their Post Trial Brief, the FTC need not prove actual injury to consumers. *See FTC Policy Statement on Deception, cited with approval in Kraft,* 970 F.2d at 314.

C. The Distinction Between "Structure/Function" Claims and "Health" Claims Is Not Relevant Under the FTC Act

Despite admitting in their Answer that they made the representations that the DCO Products are effective in the prevention, treatment or cure of cancer, Respondents insist that they have made only "structure or function" claims, and not health claims, in their advertisements. *Respondents' Post-Hearing Br.* at 2-4, 7-10. Respondents' DSHEA arguments miss the mark for several reasons. First, to qualify as a dietary supplement under DSHEA, Respondents must not have made claims that those products diagnose, mitigate, treat, cure or prevent a disease. 21 U.S.C. § 343(r)(6); *United States v. Lane Labs–USA, Inc.*, 324 F. Supp. 2d 547, 566 (D. N.J. 2004) ("If, however, this Court finds Defendants made claims that the Products diagnose,

mitigate, treat, cure, or prevent a specific disease or class of diseases, the Products must be considered drugs under the FDCA.") Here, Respondents have admitted making prevention, treatment, and cure claims, and their effort to invoke DSHEA fails.

Moreover, Respondents' argument that their advertisements contain merely "structure/function" claims, and not health claims, simply ignores the advertisements themselves. Respondents' advertisements and promotional material are replete with serious disease claims about the efficacy of the DCO Products in preventing, treating, or curing cancer. Claims such as "**Bio*Shark Shark Cartilage** Stops tumor growth in its tracks," "**7 Herb Formula battles cancer,**" "[i]f you suffer from any type of cancer, Daniel Chapter One suggests taking this products [sic], to fight it: . . . GDU Caps™," and "Bio*Mixx . . . is used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatments" are disease and health claims. CCPF ¶¶ 155, 158, 166, 170. If there is any doubt that Respondents are addressing serious diseases and health conditions in their advertising, one need only refer to Respondents' publication, The Most Simple Guide to the Most Difficult Diseases: The Doctors' How-to Quick Reference Guide, which recommends DCO products for 90 diseases, including cancer. CCPF ¶ 138; CX 20.

In addition to being contrary to the facts, Respondents' attempt to seek refuge under DSHEA misapplies the law. The FDA's regulatory distinctions between "structure or function" and "health" claims under DSHEA do not apply to the FTC Act. As noted in the FTC staff's guide, *Dietary Supplements: An Advertising Guide for Industry* (hereinafter referred to as the "*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).[5] Respondents never adequately supported their cancer claims, as they were required to do.[6]

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). This year, the FDA released guidance stating that it would adopt the FTC's substantiation standard of "competent and reliable scientific evidence":

> The FTC has typically applied a substantiation standard of "competent and reliable scientific evidence" to claims about the benefits and safety of dietary supplements and other health-related products. FDA intends to apply a standard for the substantiation of dietary supplement claims that is consistent with the FTC approach.

FDA, *Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act* (December 2008), available at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm073200.htm.

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[5] Notably, the FTC Act's definition of "drug" includes "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" as well as "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 15 U.S.C. 55(c)(1)-(2).

[6] Example 32 in the *Dietary Supplements Guide* warns that, even if a supplement advertisement claims that a particular liquid mineral solution was "a popular American folk remedy since early pioneer days for shrinking tumors," the advertisement should not be used because it "is likely to convey to consumers that the product is an effective treatment for cancer;" "[t]here is no scientific support for this disease benefit;" and "[b]ecause of the potential risks to consumers of taking a product that may or may not be effective to treat such a serious health condition, possibly without medical supervision, the advertiser should not make the claim." *Dietary Supplements Guide* at 22. The Respondents here should have heeded that advice and not made their unsubstantiated cancer claims.

III. THE FTC'S ACTION DOES NOT VIOLATE RESPONDENTS' DUE PROCESS RIGHTS

Respondents claim that Complaint Counsel are relying on presumptions and improperly shifting the burden of proof to Respondents. They further assert that "[t]his type of procedural approach absolves the government of the most basic obligation to put on a prima facie case with competent evidence," which they claim is "unconstitutional" and "violates due process in the most fundamental of ways." *Respondents' Post-Hearing Br.* at 11. Respondents' assertions are wrong and ignore both their own admissions and the overwhelming evidence in this case.

Respondents cite no relevant case authority that the way the FTC proceeds in this matter – the same way the Commission has proceeded in all advertising cases – is a violation of Respondents' Due Process rights. Contrary to Respondents' repeated protestations, the law that governs this case is FTC law. Here, Complaint Counsel simply are enforcing Sections 5(a) and 12 of the FTC Act, 15 U.S.C. § 45(a), which prohibits unfair or deceptive acts or practices in or affecting commerce.

Complaint Counsel have submitted uncontroverted evidence that (1) Respondents distribute the DCO Products in commerce; (2) Respondents claim that the DCO Products prevent, treat, or cure cancer or tumors; (3) Respondents disseminate these claims about their products to consumers; and (4) Respondents did not possess substantiation for such claims at the time they were made. The Commission is not violating Respondents' Due Process rights with this action. Rather, the Commission is enforcing the FTC Act, passed by Congress, that regulates deceptive advertising.

IV. THE FIRST AMENDMENT DOES NOT SHIELD RESPONDENTS FROM VIOLATING THE FTC ACT

Respondents' First Amendment argument ignores the facts established in, and the law

governing, this case. Respondents premise much of their First Amendment argument on their flawed interpretations regarding DSHEA, substantiation, and extrinsic evidence. Moreover, Respondents misconstrue the First Amendment issue here. In this case, there will be no restraint on Respondents' speech until Complaint Counsel prove that Respondents' representations were deceptive, and the law is clear that there is no First Amendment protection for deceptive commercial speech.

Respondents' first assertion under the First Amendment section of their Post-Hearing Brief is that their claims "qualify as religious and political speech." *Respondents' Post-Hearing Br.* at 13. This assertion is not supported by the facts adduced at trial. The evidence at trial clearly demonstrated that the challenged advertisements and promotional materials, which are broadly disseminated on the Internet to draw customers, contain little or no political or religious commentary. *See* CX 12-15; *Complaint Counsel's Post-Trial Br.* at 33. Mr. Feijo also conceded at trial that the DCO Web site constitutes advertising. J. Feijo, Tr. 459.

Respondents' fall-back position is that even if their statements "are found to be commercial speech and solely commercial speech, they are protected by the First Amendment." *Respondents' Post-Hearing Br.* at 13. As part of this argument, Respondents contend that the DCO Products are dietary supplements and not drugs. As noted above, Respondents' admission that they have represented that the DCO Products are effective in the prevention, treatment, or cure of cancer ends this discussion.

In the remainder of their "First Amendment" section to their Post-Hearing Brief, Respondents discuss burdens of proof and the *Central Hudson* test. *Respondents' Post-Hearing Br.* at 16-24. As discussed more fully below, Respondents' remaining arguments in the "First Amendment" section of their Post-Hearing Brief are wholly without merit.

A. The *Central Hudson* Test Does Not Apply to this Case

Without actually fully setting forth the test from *Central Hudson Gas & Electric Corporation v. Public Service Commission*, 447 U.S. 557 (1980) (the "*Central Hudson* test"), or even attempting to apply it to the facts of this case, Respondents make the unsupported assertion that the "FTC has not carried its burden to show that censoring Respondents' statements concerning the Challenged Products meets the three-part test of Central Hudson." *Respondents' Post-Hearing Br.* at 22. The *Central Hudson* test, however, does not apply to this case.

The Supreme Court promulgated the *Central Hudson* test to "assist courts in determining whether a regulation that limits commercial speech is constitutional." *Nat'l Urological Group,* 2008 U.S. Dist. LEXIS 44145, at *29. Under FTC law, however, "[w]hether or not the advertisements are deceptive, and thus unprotected speech, is a matter that is in the sound discretion of this court." *Id.*; *see also Kraft,* 970 F.2d at 316 (stating that "the words 'deceptive advertising' set forth a legal standard that derives its final meaning from judicial construction")(citation omitted). Therefore, the *Central Hudson* test does not apply to this deceptive advertising case. *See, e.g., Nat'l Urological Group, Inc.*, 2008 U.S. Dist. LEXIS 44145, at *30 (finding that *Central Hudson* did not apply to the FTC deceptive advertising case before the court).

Respondents proceed to cite numerous First Amendment commercial speech cases involving advertisements for accountants and attorneys to show how the Supreme Court purportedly "restated its *Central Hudson* test." *Respondents' Post-Hearing Br.* at 16-18. Respondents' use of these cases is unavailing and unpersuasive. The accountant and attorney advertisement cases to which Respondents cite all involved commercial speech that was not misleading or that did not involve unlawful activity. *See 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. and Prof'l Regulation Bd. of Accountancy*, 512 U.S. 136, 139, 142 (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 (1995) (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 v. Attorney Registration and Disciplinary Comm'n of Ill.*, 496 U.S. 91, 100, 110-11 (1990) (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. 191, 206-07 (1982) ("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").

This case, however, involves commercial speech that is misleading. Complaint Counsel submitted overwhelming evidence that Respondents' claims that the DCO Products prevent, treat, or cure cancer are unsubstantiated, and therefore deceptive. It is well-settled that "[m]isleading advertising may be prohibited entirely." *Peel*, 496 U.S. at 100; *see also Pantron I*, 33 F.3d at 1096; *Sabal*, 32 F. Supp. 2d at 1007. As this Court already explained, "[t]here can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity. The government may ban forms of communications

more likely to deceive the public than to inform it." Feb. 2, 2009 *Order Denying Respondents' Mot. to Dismiss Compl.* at 7 (quoting *Central Hudson*, 447 U.S. at 563).

In their Post-Hearing Brief, Respondents further state that "[a]lthough Complaint Counsel have not expressly argued the point, it appears that it assumes that Respondents' statements concerning the Challenged Products are 'inherently misleading' without reasonable basis, [sic] there being little or no double-blind, placebo controlled, clinical studies in evidence to support them." *Respondents' Post-Hearing Br.* at 21. Respondents also cite *Pearson v. Shalala* for the proposition that assertions claiming that "health claims lacking 'scientific agreement' are *inherently* misleading" as "almost frivolous." *See Respondents' Post-Hearing Br.* at 21-22. Respondents' argument is misplaced and the *Pearson* case is easily distinguishable from the present case on a number of grounds.

In *Pearson v. Shalala*, the marketers of dietary supplements asked the FDA to preapprove and authorize four health claims linking the consumption of a particular supplement to the reduction in risk of a particular disease for use on their labels. *Pearson v. Shalala*, 164 F.3d 650, 652 (D.C. Cir. 1999). The Court analyzed the *Pearson* case under the FDA's regulatory framework where a "health claim" is a "claim made on the label or in the labeling of . . . a dietary supplement that expressly or by implication . . . characterizes the relationship of any substance to a disease or health-related condition." *Id.* at 651 (quoting 21 C.F.R. § 101.14(a)(1) (1998)). In *Pearson*, none of the claims mentioned a specific product; rather, the claims simply referred to the underlying supplement generally, such as vitamins, fiber, omega-3 fatty acids, and folic acid. Furthermore, each of the claims stated that supplement *may* reduce the risk of certain diseases. *Id.* Here, Respondents claim that their actual products are the ones that *will* treat, cure, or prevent cancer or tumors.

The *Pearson* case also sheds light on the differences between the FDA's and FTC's regulatory framework. The FDA employs a "preapproval requirement for health claims on dietary supplements." *Id.* at 652. The *Pearson* court noted that "[t]he requirement that health claims be approved *before* added to the label of a dietary supplement constitutes the primary regulatory hurdle faced by marketers of dietary supplements." *Id.* (emphasis added). There is no such "preapproval requirement" with the FTC. Rather, advertisers are free to disseminate advertisements that they believe to be truthful, and it is the FTC's burden to prove that the claims are deceptive. Furthermore, advertisers are in no way compelled to discontinue claims in already-disseminated advertisements until a court finds that the advertisements are misleading and issues an order prohibiting such claims. Here, the evidence produced establishes that Respondents' claims are actually misleading because Respondents do not have a reasonable basis for making them.

B. Evidence of Consumers Misled by Respondents' Statements is Unnecessary to Establish a Violation of Section 5

To support their argument that Complaint Counsel somehow failed to met their burden to show that the claims at issue are misleading, Respondents assert that Complaint Counsel must produce evidence that consumers have, "in fact, been misled by Respondents' statements concerning the Challenged Products." *Respondents' Post-Hearing Br.* at 19. Once again, Respondents are wrong.

To successfully prove a claim under Sections 5(a) and 12, the FTC must establish three elements: (1) that the advertisement conveyed a representation through either express or implied claims; (2) that the representation was likely to mislead consumers; and (3) that the misleading representation was material. See *FTC v. Tashman*, 318 F.3d 1273, 1277 (11th Cir. 2003); *see*

also FTC v. Freecom Commc'ns, Inc., 401 F.3d 1192, 1203 (10th Cir. 2005); *Kraft,* 970 F.2d at 314; *FTC Policy Statement on Deception.* It is well-settled that neither proof of consumer injury nor proof of actual deception is necessary to establish a violation of Section 5. *See Freecom Commc'ns, Inc.*, 401 F.3d at 1203 (stating that "[n]either proof of consumer reliance nor consumer injury is necessary to establish a § 5 violation.") (citing *FTC v. Think Achievement Corp.*, 144 F. Supp. 2d 993, 1010 (N.D. Ind. 2000)); *FTC v. Wilcox*, 926 F. Supp. 1091, 1099 (S.D. Fla. 1995) (stating that "the FTC is only required to show that it is likely, not that it is certain, that a reasonable consumer would be mislead. Accordingly, the FTC does not need to show that every reasonable consumer would be mislead by the advertisements.") (quoting *FTC v. U.S. Sales Corp.*, 785 F. Supp. 737, 748 (N.D. Ill. 1992)); *TransWorld Accounts, Inc. v. FTC*, 594 F.2d 212, 214 (9th Cir. 1979) (stating that "[p]roof of actual deception is unnecessary to establish a violation of Section 5. Misrepresentations are condemned if they possess a tendency to deceive."). The goal of the FTC Act is to prohibit deceptive advertising "not only where there is proof of actual deception, but also when the representations made have a capacity or tendency to deceive, *i.e.*, when there is a likelihood or fair probability that the reader will be misled." *FTC v. Sterling Drug, Inc.*, 317 F.2d 669, 674 (2d Cir. 1963) ("*Sterling Drug I*")(citing cases).

The materiality prong specifically considers the well-established rule that proof of actual consumer injury is not required for an FTC cause of action. "A 'material' representation is one that involves information that is important to consumers, and that is therefore likely to affect a consumer's choice of conduct regarding a product. Proof of actual consumer injury is not required." *Kraft, Inc.*, 114 F.T.C. at 134. Courts have interpreted the *FTC Policy Statement on Deception* to "presume[] materiality for express claims and claims that significantly involve health, safety, or other issues that would concern reasonable consumer[s]." *QT*, 448 F. Supp. 2d

at 965-66 (citing *Kraft, Inc.*, 970 F.2d at 322). In addition, even implied claims that are "so unambiguous and repetitive that they were clearly intended by the advertiser to make the alleged claims . . . can be presumed material." *FTC v. Bronson Partners, LLC*, 564 F. Supp. 2d 119, 135-36 (D. Conn. 2008).

In this case, Respondents' claims are material because they contain information concerning the purpose, efficacy, and performance of the DCO Products that would likely affect a consumer's choice to purchase these products. Respondents' serious health claims were both express and so strongly implied as to be virtually express. Respondents' claims were material.

C. Congress Empowers the FTC to Protect the Consumer Public

Furthermore, Respondents claim that the "likely to mislead" standard and the role of the FTC in examining the "overall net impression" of advertisements constitutes a "paternalistic approach" that is somehow at odds with the First Amendment. *Respondents' Post-Hearing Br.* at 19-20. Respondents' suspicion of the FTC's lawful role in protecting the consumer is unavailing.

Congress defines the powers of the FTC to protect consumers from unfair and deceptive acts and practices in the marketplace. The primary purpose of Section 5 of the FTC Act is to protect the consumer public. *See Freecom Commc'ns, Inc.*, 401 F.3d at 1202. As it relates to advertising policy, the overriding purpose of the FTC Act is "to protect the consumer from being misled by governing the conditions under which goods and services are advertised and sold to individual purchasers." *Nat'l Petroleum Refiners Assoc. v. FTC*, 482 F.2d 672, 685 (D.C. Cir. 1973), *cert. denied* 415 U.S. 951 (1974). Furthermore, this Court already recognized "the FTC's authority over [] claims [of a product's 'medical effects']" and "[t]he FTC's authority to require that health-related efficacy claims be supported by 'competent and reliable scientific evidence.'"

Feb. 2, 2009 *Order Denying Respondents' Mot. to Dismiss Compl.* at 5, 6. Respondents' suggestion that a purportedly "paternalistic approach" to protecting consumers conflicts with the First Amendment ignores the well-established purpose of the FTC to safeguard the public's interest.

V. CONCLUSION

The evidence at trial demonstrated that Respondents have violated Sections 5(a) and 12 of the FTC Act through their dissemination of unsubstantiated claims that the DCO Products prevent, treat, or cure cancer or tumors. Accordingly, Complaint Counsel respectfully request that this Court enter the proposed order attached to the Complaint in this case.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on June 11, 2009, I have filed and served the attached **COMPLAINT COUNSEL'S POST-TRIAL REPLY BRIEF** as set forth below:

The original, one paper copy, and one electronic copy via email to:

Donald S. Clark, Secretary
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