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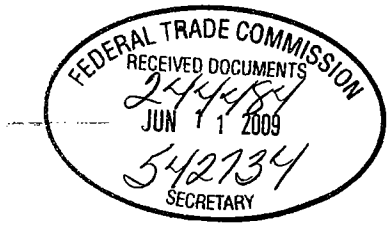
UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES



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.").