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UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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

COMPLAINT COUNSEL'S PRE-TRIAL BRIEF

Leonard L. Gordon (212) 607-2801
Theodore Zang, Jr. (212) 607-2816
Carole A. Paynter (212) 607-2813
David W. Dulabon (212) 607-2814
Elizabeth K. Nach (202) 326-2611
Counsel Supporting the Complaint

Federal Trade Commission
Alexander Hamilton U.S. Custom House
One Bowling Green, Suite 318
New York, NY 10004

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I. INTRODUCTION

The evidence at trial will demonstrate that Respondents Daniel Chapter One ("DCO") and James Feijo violated Sections 5(a) and 12 of the Federal Trade Commission Act (the "FTC Act") when marketing their Bio*Shark, 7 Herb Formula, GDU, and BioMixx products (collectively, the "DCO Products"). Respondents represented in their advertisements and promotional materials that the DCO Products were effective in preventing, treating, or curing cancer or tumors without competent and reliable scientific evidence to support such claims. Respondents preyed upon desperate, sick consumers "suffer[ing] from any type of cancer." Respondents touted the DCO Products as "Cancer solutions" that would "stop tumor growth," "fight[] tumor formation," and otherwise "battle[] cancer." At the time they made these serious health claims, Respondents lacked a reasonable basis for their representations, making them unsubstantiated and misleading.

At trial, Complaint Counsel will present overwhelming evidence that Respondents made

the alleged claims and lacked adequate substantiation for these representations.

II. STATEMENT OF FACTS[1]

A. DCO and the Feijos Have Long Sold Various Products to Consumers.

In 1986, James Feijo and his wife Patricia started DCO as a health food store. CCPF ¶¶ 4 and 6. Then, in 2002, James Feijo organized DCO as a corporation sole under Washington state laws. CCPF ¶ 1. DCO currently offers consumers 150 to 200 products. CCPF ¶ 7. James Feijo serves as DCO's Overseer, trustee for all DCO assets, and custodian of DCO's financial records. CCPF ¶¶ 2, 9, and 13-14. Patricia Feijo is DCO's Secretary. CCPF ¶ 3. Neither James nor Patricia Feijo is a doctor or research scientist. CCPF ¶¶ 114 and 116.

Respondents' principal office and place of business is located in Portsmouth, Rhode Island, where the Feijos live. CCPF ¶ 5. DCO's two Rhode Island buildings contain an Order Center and a warehouse for the products that DCO offers to the public. CCPF ¶ 17. James Feijo established another Washington corporation sole -- Messiah Y'Shua Shalom -- which he uses to own the Rhode Island property. CCPF ¶¶ 19-20. DCO also owns a three-bedroom property in Deerfield Beach, Florida, where the Feijos stay, as well as two Cadillacs which the Feijos use. CCPF ¶¶ 22-24. DCO pays for all the Feijos' expenses. CCPF ¶¶ 15, 23, and 25.

[1] Pursuant to the Court's Scheduling Order, Complaint Counsel have submitted the accompanying Proposed Findings of Fact ("CCPF") as a separate document.

B. The Feijos are Responsible for the Development and Price of the DCO Products.

1. The Feijos Developed the DCO Products and Their Labels.

James Feijo developed, created, and produced the DCO Products. CCPF ¶ 8. He established the DCO Products' price. CCPF ¶ 37. He and Patricia Feijo have been solely responsible for creating, drafting, and approving the DCO Products' directions and recommended usages. CCPF ¶ 95. They also developed the suggested dosages. CCPF ¶¶ 95, 98, 100, and 102. The identity and amount of each ingredient is contained on the product labels. CCPF ¶ 96. DCO contracts with Universal Nutrition to manufacture approximately 35-40 products, including Bio*Shark, GDU, and BioMixx. CCPF ¶ 82.

2. Respondents Sell Products to Consumers.

Over one thousand consumers have purchased DCO's products. CCPF ¶ 46. DCO has generated approximately $2 million in annual sales for 2006, 2007, and 2008. CCPF ¶ 47. DCO offers consumers coupons for their next on-line store order. CCPF ¶ 60. Respondents run promotions from time to time to "give [consumers] more of an opportunity to . . . get things at a lower rate." CCPF ¶ 61. For example, consumers can buy multiple bottles and get a bottle free. CCPF ¶ 62. DCO charges shipping and handling fees of $20.95. CCPF ¶ 59. Doctors and stores that carry DCO's product line purchase the products at a lesser price. CCPF ¶ 64. DCO sells its products in a number of stores nationally, including stores in Georgia and Pennsylvania. CCPF ¶ 63.

The DCO Products are expensive. An FTC investigator, Michael Marino, purchased one bottle of each of the four DCO Products, which together cost $175.75. CCPF ¶¶ 52 and 58. With his purchase, he received a product catalog, a blank purchase order form, and an invoice

form. CCPF ¶ 55. At least one consumer pleaded for prices to be lowered: "There should be discounts for customers who have referred lots of people and for those customers who consume lots of product monthly." CCPF ¶ 73. To counter such complaints, on their Web site, Respondents post "testimonials" to convince consumers to pay their high prices: "[i]t wasn't cheap but it was the best money I ever spent"; "I then proceeded to reduce my 7 Herb Formula to a maintenance dosage. Tricia & Jim Feijo did not agree with my decision. They felt I should stay on the maximum dosage to be safe, but I was having financial problems, and could not afford the cost." CCPF ¶¶ 71-72.

3. The DCO Products.

a. Bio*Shark

Bio*Shark contains, among other ingredients, Shark Cartilage. CCPF ¶ 76. Each Bio*Shark label directs users to take 2-3 capsules three times a day or as directed by a physician or by a "BioMolecular Nutrition health care professional." CCPF ¶ 97. Respondents invented the term "BioMolecular Nutrition" to describe "the spiritual and physical" aspects of their products. CCPF ¶¶ 26-27. Respondents offer one bottle of Bio*Shark for $30.95 (100 capsules) and $65.95 (300 capsules), but only pay Universal Nutrition, their manufacturer, $3.15 per unit for the 100-capsule and $8.75 per unit for the 300-capsule bottle of Bio*Shark. CCPF ¶¶ 77-78. Thus, their acquisition cost for the 100-capsule bottle is approximately 10 percent of what Respondents charge consumers. During 2008, Respondents paid Universal Nutrition approximately $1,437 to manufacture 479 100-capsules bottles of Bio*Shark and approximately $6,256 to manufacture 782 300-capsule bottles of Bio*Shark. CCPF ¶ 79.

b. 7 Herb Formula

7 Herb Formula, a liquid tea concentrate, contains, among other ingredients, distilled water, Cat's Claw, Burdock Root, Siberian Ginseng, Sheep Sorrel, Slippery Elm, Watercress, and Turkey Rhubarb Root. CCPF ¶ 84. Respondents' label directs users to take 1-2 ounces of 7 Herb Formula with 2-4 ounces of hot or cold filtered or distilled water. CCPF ¶ 99. The label further directs users to take 7 Herb Formula twice daily or as directed by a BioMolecular Nutrition health care professional. CCPF ¶ 99.

Respondents offer one 32-ounce bottle of 7 Herb Formula for $70.95. CCPF ¶ 85. Their acquisition cost for 7 Herb Formula is approximately 30 percent of the price they charge to consumers. CCPF ¶ 45.

c. GDU

GDU contains, among other ingredients, Bromelain, Turmeric, Quercetin, Feverfew, and Boron. CCPF ¶ 87. Respondents' label directs users to take 3-6 capsules 2 to 4 times per day or as directed by a physician or by a BioMolecular Nutrition health care professional. CCPF ¶ 101.

Respondents offer GDU for $29.95 (120 capsules) and $45.95 (300 capsules) but only pay Universal Nutrition $3.28 for the 120-capsule bottle and $7.07 for the 300-capsule bottle of GDU. CCPF ¶¶ 88-89. Thus, their acquisition cost for the 120-capsule bottle is slightly over 10 percent of what they charge consumers. During 2008, Respondents paid Universal Nutrition approximately $5,127 to manufacture 1,709 of the 120-capsule bottles and approximately $52,661 to manufacture 7,523 of the 300-capsule bottles of GDU. CCPF ¶ 90.

d. BioMixx

BioMixx contains, among other ingredients, Goldenseal, Echinacea, and Ginseng. CCPF ¶ 91. Respondents' label for BioMixx directs users to take five scoops daily. CCPF ¶ 103.

Respondents offer BioMixx for $22.95 (1 lb. powder) and $40.95 (3 lb. powder), but only pay Universal Nutrition $11.50 for the 3-pound bottle of BioMixx, CCPF ¶¶ 92-93, approximately 35% of what they charge consumers. During 2008, Respondents paid Universal Nutrition approximately $8,778 to manufacture 798 3-pound bottles of BioMixx. CCPF ¶ 94.

C. Respondents Disseminate Claims That the DCO Products "Fight Cancer," "Stop Tumor Growth," and Are a "Cancer Solution" For All Types of Cancer.

Respondents' Web sites www.danielchapterone.com, dc1pages.com, www.7herbformula.com, www.gdu2000.com, and dc1store.com provide information on the DCO Products. CCPF ¶¶ 141-42. Consumers can locate the Web site www.danielchapterone.com by entering the term "cancer" in a Google search. CCPF ¶ 144. Respondents also disseminate information about the DCO Products through written materials, including the BioGuide, the Cancer Newsletter, and the radio program "Daniel Chapter One Health Watch." CCPF ¶ 142. The Feijos are responsible for the information disseminated about the DCO Products. CCPF ¶ 143. James and Patricia Feijo also co-host DCO's radio program for two hours a day, Monday through Friday. CCPF ¶ 146. They have counseled cancer patients who have called into the radio program about taking the DCO Products. CCPF ¶ 147. Respondents purposefully use the DCO radio program and the DCO Web sites to reach out to consumers. CCPF ¶ 148.

On their Web sites, radio program, and in their print publications, Respondents make numerous claims about how their products are a "Cancer Solution," a "Cancer Treatment," or can be used for "all types of cancer" to "fight cancer," "stop tumor growth," "fight tumor formation," "battles cancer," and "digest . . . unwanted tumors." CCPF ¶¶ 104-06, 124-25, 132.

1. Claims That the DCO Products Are For All Types of Cancer.

Respondents recommend taking the DCO Products "**If you suffer from any type of cancer**," CCPF ¶¶ 120, 124, 133, and 138 (emphasis added) and, in their *The Most Simple Guide to the Most Difficult Diseases: The Doctors' How-To Quick Reference Guide*, recommend the DCO Products for "***All types of Cancer***:" CCPF ¶ 106. Respondents reinforce this claim by listing at least ten different types of cancer with consumer "testimonials." CCPF ¶ 107.

2. Claims That the DCO Products Will Fight Cancer.

The DCO Products all appear in Respondents' Cancer Newsletter, *How to Fight Cancer is Your Choice!!!*. CCPF ¶ 111. Respondents describe the DCO Products as a "Cancer solution" and specifically advise consumers to take the DCO Products to "fight" or "battle" cancer:

> **If you suffer from any type of cancer, Daniel Chapter One suggests taking this products [sic], to fight it:** [emphasis added]
> 7*Herb Formula ™. . .
> Bio*Shark ™. . .
> BioMixx ™. . .
> GDU Caps ™. . .
> [depiction of bottles of BioMixx, 7 Herb Formula, Bio*Shark, and GDU]
> **Daniel Chapter One's Cancer solutions**
> To Buy the products click here
> **How to fight cancer is your choice!**. . . [emphasis added]
> CCPF ¶ 124.

Respondents use testimonials to convince consumers that the DCO Products will help them "fight" and "battle" cancer and end up in remission, claiming that one consumer had "three inoperable tumors," and that, when she "decided not to do chemotherapy or radiation, my *father sent me Bio*Mixx and 7 Herb Formula. Each day as I took it and got it into my system more and more, the better I felt. Then I added Garlic Pur, Siberian Ginseng and BioShark.*'" "*I am now in complete remission. . .*" CCPF ¶ 108 (*italics added).* Similarly, another testimonial

claimed that 7 Herb Formula "did such a good job fighting cancer," "I plan to stay on that forever!" CCPF ¶ 127.

On their radio program, "Daniel Chapter One Health Watch," Respondents tout the DCO Products. By example, on one show Patricia Feijo urged consumers:

> "[W]hile the FTC does not want us saying that anything natural can be used to treat cancer and that nothing certainly can cure cancer, we know that the truth is different than what they want us to say. **The truth is God has given us herbs in His creation and nutrients that can heal cancer, even cure cancer.**" CCPF ¶ 118 (emphasis added).

3. Claims that the DCO Products will Fight and Stop Tumors.

Respondents also specifically claim that the DCO Products will "battle tumors," "stop tumor growth," "fight tumor formation," and "digest . . . unwanted tumors." CCPF ¶¶ 122, 124, 128, and 132. On danielchapterone.com and dc1pages.com, Respondents advise consumers that: "With Jim Feijo's addition to the [7 Herb] formula, **we now have the most effective and potent formula available in the battle against tumors.**" CCPF ¶ 128 (emphasis added). In their product catalog and on their Web site, Respondents claim that the 7 Herb Formula will "fight pathogenic bacteria and tumor formation." CCPF ¶¶ 124 and 126. Similarly, in their product catalog, Respondents claim that GDU "[c]ontains natural proteolytic enzymes (from pineapple source bromelain) to help digest protein, ***even that of unwanted tumors*** and cysts. Helps to relieve pain, inflammation, and as ***an adjunct to cancer therapy***." CCPF ¶¶ 132 and 134 (emphasis added). They likewise claimed that their "**Bio*Shark Shark Cartilage** Stops tumor growth in its tracks," (emphasis in original), a claim repeated in their product catalog. CCPF ¶¶ 121-22. Respondents also used a testimonial in their product catalog to claim that BioMixx, 7 Herb Formula, and Bio*Shark worked on "three inoperable tumors" so well that one "just above the brain stem . . . has completely disappeared," one on the liver "is shrinking," and one

behind the heart "has shrunk over 50%." CCPF ¶ 108.

III. RESPONDENTS DISTRIBUTE THEIR PRODUCTS IN COMMERCE

Respondents admit that they distribute the DCO Products in commerce, CCPF ¶ 30, an admission borne out by their activities. Nationwide advertising, marketing, or sales activity constitutes "commerce" under the FTC Act. *See, e.g., P.F. Collier & Son Corp. v. FTC*, 427 F.2d 261, 272 (6th Cir. 1970); *see, e.g., Ford Motor Co. v. FTC*, 120 F.2d 175, 183 (6th Cir. 1941) (noting that commerce also includes the actions, communications, and other acts or practices that are incident to those activities). Respondents engage in nationwide advertising, marketing, *and* sales activity.

Respondents advertise their products on their Web sites and on their radio show. CCPF ¶¶ 104-05, 117-18, 122, 128-31, and 136. DCO has a toll-free telephone number and a call center for consumers to purchase the DCO Products. CCPF ¶ 31. DCO's toll-free number is advertised on DCO's Web site, "BioGuide," radio program, and on the front page of DCO's BioMolecular Nutrition Product Catalog, where Respondents inform consumers to "Call Toll FREE 1-800-504-5511 or shop online at www.danielchapterone.com." CCPF ¶¶ 31-33, and 36. DCO's Order Center is open Monday through Friday from 9:00 a.m. to 8:00 p.m., and receives payments through credit card and COD. CCPF ¶¶ 40-41. DCO also accepts consumers' orders on the Internet. CCPF ¶ 42. DCO's Web site invites consumers to shop at DCO's "On-Line Store" and to "Buy Now." CCPF ¶¶ 43-44. In addition, a number of stores nationally sell DCO's products. CCPF ¶ 63. Over one thousand consumers have purchased DCO's products. CCPF ¶ 46. DCO has generated $2 million in annual gross sales for each of the last several years. CCPF ¶ 47.

IV. RESPONDENTS' DECEPTIVE ADVERTISING VIOLATES SECTIONS 5 AND 12 OF THE FTC ACT.

The undisputed evidence shows that Respondents engaged in unfair or deceptive acts or practices prohibited by Sections 5 and 12 of the FTC Act. Section 5(a) provides that "unfair or deceptive acts or practices in or affecting commerce are hereby declared unlawful." 15 U.S.C. § 45(a)(1). Section 12 prohibits the dissemination of "any false advertisement" in order to induce the purchase of "food, drugs, devices, or cosmetics." 15 U.S.C. § 52(a)(2).[2]

An advertisement is deceptive under the FTC Act if it is likely to mislead consumers, acting reasonably under the circumstances, in a material respect. *Kraft, Inc. v. FTC*, 970 F.2d 311, 314 (citing Sections 5 and 12); *FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285, 297 (D.Mass 2000); *Telebrands Corp.*, 140 F.T.C. 278, 290 (2005), *aff'd*, 457 F.3d 354 (4th Cir. 2006); *In re Thompson Medical Co.*, 104 F.T.C. 648, 788 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987); *Cliffdale Assocs. Inc.*, 103 F.T.C. 110, 164-66 (1984); *FTC Policy Statement on Deception*, 103 F.T.C. 174 (1984) (appended to *Cliffdale Assocs.*).

In implementing the "likely to mislead" standard, "the [FTC] examines the overall net impression of an ad[vertisement] and engages in a three-part inquiry: (1) what claims are conveyed in the advertisement; (2) are those claims false or misleading; and (3) are those claims material to prospective consumers." *Kraft*, 970 F.2d at 314.

A. Respondents Represented in Their Advertisements that Their Products Prevent, Treat, and/or Cure Cancer.

[2] For the purposes of Section 12, the DCO Products are "food" or "drugs." 15 U.S.C. § 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"). Section 12 defines "false advertisement" as "an advertisement, other than labeling, which is misleading in a material respect." 15 U.S.C. § 55.

1. The Appropriate Legal Standard Is the Overall Net Impression Created by the Advertisement.

The FTC may use its own reasoned analysis to determine what claims an advertisement conveys. *See Kraft*, 970 F.2d at 318 ("[i]n determining what claims are conveyed by a challenged advertisement, the [FTC] relies on . . . its own viewing of the ad"); *see also FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 385 (1965). In determining whether an advertisement conveys a claim, the Commission looks to the overall, net impression created by the advertisement, through the interaction of different elements in the advertisement, rather than focusing on the individual elements in isolation. *Stouffer Foods Corp.*,118 F.T.C. 746, 799 (1994); *Kraft*, 114 F.T.C. 40 at 122 (1991); *American Home Prods. Corp. v. FTC*, 695 F.2d 681, 688 (3d Cir. 1982); *FTC Policy Statement on Deception*, 103 F.T.C. 174, 179 (1984) (appended to *Cliffdale Assocs.*) (emphasizing importance of considering "the entire mosaic, rather than each tile separately"). Features of an advertisement such as a product name, visual images, and the use of testimonials may imply claims. *Jacob Siegel v. FTC*, 327 U.S. 608, 609 (1946); *Kraft*, 114 F.T.C. at 322; *Thompson Medical*, 104 F.T.C. at 793 and 811-12; *Porter & Dietsch, Inc. v. FTC*, 605 F.2d 294, 301, 303 (7th Cir. 1979). To determine how "reasonable consumers" interpret a claim, the Commission considers the target market for the advertisement. When the target market consists of "desperate consumers with terminal illnesses," the FTC has shown particular care in evaluating deceptive acts or practices. *FTC v. Travel King, Inc.*, 86 F.T.C. 715 (1975).

Advertising claims may be express or implied. *Kraft,* 970 F.2d at 318. Express claims directly state the representation at issue, while implied claims make representations without direct statements. *Id.* at 318 and 319 n.4; *Thompson Medical*, 104 F.T.C. at 788-89. The courts

and the FTC have recognized consistently that implied claims fall along a continuum, from those which are so conspicuous as to be virtually synonymous with express claims, to those which are barely discernible. *See, e.g., Kraft*, 970 F.2d at 319; *FTC v. Febre*, No. 94 C 3625, 1996 WL 396117, at *4 (N.D. Ill. July 2, 1996) (magistrate judge recommendation), adopted by 1996 WL 556957 (N.D. Ill. Sept. 25, 1996), *aff'd*, 128 F.3d 530 (7th Cir. 1997); *see also Bronson Partners*, 564 F. Supp. at 127-28 (an advertisement's statements were "so clear, repetitive, and unambiguous that they constitute[d] the functional equivalent of express claims"). Moreover, Commission law recognizes that advertisements may be susceptible to more than one reasonable interpretation. *Kraft*, 114 F.T.C. at 120 n.8. "Statements susceptible of both a misleading and a truthful interpretation will be construed against the advertiser." *Bronson Partners*, 564 F. Supp. 2d 119, 127 n.6 (D. Conn. 2008) (quoting *Country Tweeds, Inc. v. FTC*, 326 F.2d 144, 148 (2d Cir. 1964)).

If the facial analysis demonstrates that the claims were conveyed in the advertisements and promotional materials, the Court need not consider extrinsic evidence even if such evidence is offered. *Novartis*, 127 F.T.C. 580, 680 (1996); *Stouffer*, 118 F.T.C. at 798; *Kraft, Inc.*, 114 F.T.C. at 121; *Thompson Medical*, 104 F.T.C. at 789.

2. Respondents Claimed that the DCO Products Could Prevent, Treat, and/or Cure Cancer.

The Complaint alleges that Respondents represented in their advertising and promotional materials that the DCO Products were effective in preventing, treating, and/or curing cancer. As the Court noted in its February 2, 2009 Order Denying Respondents' Motion to Dismiss Complaint, Respondents admit in their Answer that they made such claims. Order Den. Resp'ts' Mot. to Dismiss, at 2; Answer ¶ 14.

In addition to Respondents' admissions, a facial analysis of the challenged DCO Products' advertisements and promotional materials establishes that the alleged representations are a reasonable interpretation. Respondents' advertisements and promotional materials for the DCO Products, which include, but are not limited to, Exhibits A-D of the Complaint, convey bold promises of cancer prevention, treatment, and cure that, if not express, are so strongly implied as to be virtually express.

a. Respondents' Advertising Represented that Bio*Shark Inhibits Tumor Growth and Is Effective in Treating Cancer.

Respondents' Web page for Bio*Shark contains both express and strongly implied representations that create the net impression that Bio*Shark inhibits tumor growth, as alleged in ¶14 a of the Complaint. Complaint Counsel's Trial Exhibit (hereinafter referred to as CX ___) 12 at FTC-DCO 0011. In the Web page's center, in bold type, appears the headline "**Bio*Shark: Tumors & Cysts.**" Respondents' decision to tie unequivocally its product with tumors and cysts carries the strong implication that Bio*Shark is intended to be used on tumors. Immediately beneath this statement, the representation is stated virtually expressly: "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 . . .". *Id.* (emphasis added); CCPF ¶ 119. The claim is restated even more succinctly in an underlined link near the bottom of the Web page: "**Stop Tumor Growth & Cysts**." CX 12 at FTC-DCO 0011; CCPF ¶ 119. Another link on the same page reinforces this claim, inviting consumers to "Read our clients [*sic*] testimonials on Bio Shark & Tumors." CX 12 at FTC-DCO 0011; CCPF ¶ 119. The link appears directly below the "BUY NOW" link through which consumers may purchase the product. CX 12 at FTC-DCO 0011; CCPF ¶¶ 44 and 119.

Respondents make numerous strongly implied representations that Bio*Shark is effective in the treatment of cancer as alleged in ¶ 14b of the Complaint. Respondents' representations about stopping tumor growth also support the allegation that Bio*Shark is effective in the treatment of cancer. Respondents tout Bio*Shark a "Cancer solution." CCPF ¶ 104. Respondents also state on their Web site:

> **"If you suffer from any type of cancer, Daniel Chapter One suggests taking this products[*sic*], to fight it:** . . . Bio*Shark TM. . . **How to fight cancer is your choice!"** CCPF ¶ 120 [emphasis added]

Respondents also used testimonials on their Web site and during the DCO Healthwatch radio program to make representations to consumers that Bio*Shark cured cancer or resulted in a cancer patient's remission. For example, they represented that Bio*Shark, in conjunction with 7 Herb Formula and GDU, cured someone's skin cancer so that "there was no trace of cancer," CCPF ¶ 130, very strongly implying, if not expressly stating, that Bio*Shark is effective in treating cancer. Similarly, Respondents represented that Bio*Shark, with BioMixx and 7 Herb Formula, cured three inoperable tumors, resulting in the patient's "complete remission." CCPF ¶ 125. Patricia Feijo also specifically advised a consumer who called the radio program, and whose father was diagnosed with colon cancer, that she should order Bio*Shark and the other DCO Products for her father, and a copy of the DCO publication *How To Fight Cancer Is Your Choice.* CCPF ¶¶ 36, 147.

b. Respondents Represented that 7 Herb Formula Is Effective in the Treatment or Cure of Cancer and Inhibits Tumor Formation.

As alleged in ¶¶14 c and d of the Complaint, Respondents expressly claim or very strongly imply that 7 Herb Formula is effective in the treatment or cure of cancer and inhibits tumor formation. As with Bio*Shark, Respondents claim on their Web site that 7 Herb Formula

is a "Cancer solution" and that **"If you suffer from any type of cancer, Daniel Chapter One suggests taking this products[*sic*], to fight it:** . . . 7 Herb Formula. . . **How to fight cancer is your choice!,"** CCPF ¶ 104 and 124 (emphasis added), thus strongly implying, if not explicitly stating, that 7 Herb Formula is effective in the treatment or cure of cancer.

Respondents also use testimonials on their Web site and in their radio program to convince consumers that 7 Herb Formula (and some combination of the other three DCO Products): (1) "battles cancer," resulting in a patient's "complete remission" despite "inoperable tumors"; (2) does "such a good job fighting cancer" that a patient "plan[s] to stay on [7 Herb Formula] forever" because it is a "good prophylaxis," or (3) cured someone's skin cancer so that "there was no trace of cancer," thus strongly implying, if not expressly stating, that 7 Herb Formula effectively treats, cures, or prevents cancer. CX 12, 21, and 8; CCPF ¶¶ 125, 127, and 130.

On their Web sites, Respondents advise consumers that: "With Jim Feijo's addition to the [7 Herb] formula, **we now have the most effective and potent formula available in the battle against tumors**." CCPF ¶ 128 (emphasis added). In their product catalog and Web site, Respondents claim that the 7 Herb Formula will "fight . . . tumor formation," CCPF ¶¶ 124 and 126, (under the heading "Cancer News"), thus strongly implying, if not explicitly stating, that 7 Herb Formula inhibits tumor formation (and thus prevents cancer or the recurrence of cancer).

Respondents also strongly imply, if not explicitly claim, that 7 Herb Formula (and other DCO Products) inhibit tumor formation when they use a testimonial in their product catalog to claim that BioMixx, 7 Herb Formula, and Bio*Shark worked on "three inoperable tumors" so well that one "just above the brain stem . . . has completely disappeared," one on the liver "is shrinking," and one behind the heart "has shrunk over 50%." CCPF ¶ 108.

c. Respondents Represented that GDU Eliminates Tumors and Is Effective in the Treatment of Cancer.

As alleged in ¶¶14 e and f of the Complaint, Respondents expressly claim or very strongly imply that GDU eliminates tumors and is effective in the treatment of cancer. Respondents' description of GDU on the DCO Web site leads with the statement "[GDU] [c]ontains natural proteolytic enzymes (from pineapple source bromelain) **to help digest** protein – even that of **unwanted tumors** and cysts." CCPF ¶ 132 (emphasis added). This statement strongly implies that GDU's enzymes eliminate tumors by eroding their protein. In addition, the advertisement expressly states that "GDU is also used . . . as an adjunct to cancer therapy." CCPF ¶ 132. The Web page also features a link to "[r]ead our clients[*sic*] testimonials," which include stories about sufferers of prostate cancer and a breast mass. CX 14 at FTC-DCO 0029.

As with DCO's other Products, Respondents claim on their Web site that GDU is a "Cancer solution" and that **"If you suffer from any type of cancer, Daniel Chapter One suggests taking this products [*sic*], to fight it:** . . . GDU. . . **How to fight cancer is your choice!,"** CCPF ¶¶ 104, 133 (emphasis added), thus strongly implying, if not explicitly stating, that GDU effectively treats cancer.

d. Respondents Represented that BioMixx Is Effective in the Treatment of Cancer and Heals the Destructive Effects of Radiation and Chemotherapy.

As alleged in ¶14 g and h of the Complaint, Respondents expressly claim or very strongly imply that BioMixx effectively treats cancer and heals the destructive effects of radiation and chemotherapy. As with DCO's other Products, Respondents claim on their Web site that BioMixx is a "Cancer solution" and that **"If you suffer from any type of cancer, Daniel Chapter One suggests taking this products [*sic*], to fight it:** . . . BioMixx. . . **How to**

fight cancer is your choice!," CCPF ¶¶ 104, 138 (emphasis added), thus strongly implying, if not explicitly stating, that BioMixx effectively treats cancer. DCO's "Cancer Newsletter" contains both express claims and claims so strongly implied as to be virtually express. CCPF ¶¶ 111-12. The cover displays the following:

how to

fight

cancer is

your

choice!!!

CCPF ¶ 111; CX 15 at FTC-DCO 0031; CX 23 at FTC-DCO 0390. Inside, Respondents printed an anecdote about a man who, after taking a combination of DCO products including 7 Herb Formula, Bio*Shark, and BioMixx, made a full recovery from bladder cancer and emphysema. CX 15 at FTC-DCO 0032. The newsletter also describes the BioMixx product, stating expressly that BioMixx **"is used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatments."** CCPF ¶ 140 (emphasis added); CX 15 at FTC-DCO 0032.

In Respondents' *BioGuide*, they use a consumer testimonial which claimed that a cancer patient had three inoperable tumors and decided not to take radiation or chemotherapy but used BioMixx and other DCO Products, which resulted in "complete remission," thus making an express, or strongly implied, claim that BioMixx effectively treats cancer:

> "When I decided not to do chemotherapy or radiation, my father sent me ***BIOMIXX*** and *7 HERB FORMULA*. Each day as I took it and got it into my system more and more, the better I felt. Then I added Garlic, Siberian Ginseng, and Bio*Shark. **I am now in complete remission. The cancer cell count has dropped, the doctors tell me.** I had a tumor just above the brain stem in my brain that has completely disappeared. The tumor

on my liver is shrinking and the tumor behind my heart has shrunk over 50%. . ." CCPF ¶ 108 (emphasis in bold added) .

3. Respondents' DSHEA Arguments

Respondents have argued that their representations, including those stated above, were "structure/function" claims rather than health claims. *See Respondents' Mot. for Summ. Decision* at 15. Respondents also have attempted to minimize the impact of their cancer claims by asserting that their representations were accompanied by appropriate disclaimers under the Dietary Supplements Health and Education Act (DSHEA).

Respondents' argument that their advertisements contain merely "structure/function" claims, and not health claims, simply ignores the advertisements themselves. As detailed above, Respondents' advertisements and promotional material are replete with serious disease claims about the efficacy of the DCO Products in preventing, treating, or curing cancer. 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" could not be any more express. CCPF ¶¶ 122, 125, 133, 137. If there is any doubt that Respondents are addressing serious diseases and health conditions in their advertising, one need only refer to Respondents' publication entitled "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 ¶¶ 68, 106.

Had Respondents even made legitimate "structure/function" claims, the FDA's

regulatory distinctions between "structure/function" claims and health claims under DSHEA do not apply to Section 5 of the FTC Act. As noted in the FTC staff's guide, *Dietary Supplements: An Advertising Guide for Industry* (hereinafter 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). Respondents never adequately supported their cancer claims, as they were required to do.

DSHEA in no way altered the FTC's approach to truth in advertising, and, in fact, as Respondents acknowledged in their Motion for Summary Decision, DSHEA is fully consistent with this approach. *See* 21 U.S.C. § 343(r)(6); *Respondents' Mot. for Summ. Decision* at 15. FTC staff explained in the *Dietary Supplements Guide* that "a statement about a product's effect on a normal 'structure or function' of the body may also convey to consumers an implied claim that the product is beneficial for the treatment of a disease. If elements of the ad imply that the product also provides a disease benefit, the advertiser must be able to substantiate the implied disease claim even if the ad contains no express reference to disease." *Dietary Supplements Guide* at 4. Respondents cannot explain how their "Disease Guide," "Cancer Newsletter," and other cancer-related advertisements do not make disease claims. As detailed above, there are express references to disease, and the net impressions conveyed by both the express and implied claims – that the DCO Products can treat, prevent, or cure cancer or tumors – must be substantiated by competent and reliable scientific evidence. This year, the FDA even 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.cfsan.fda.gov/~dms/dsclmgu2.html.

Respondents' reliance on disclaimers also is unavailing. One only needs to review the attachments to the Complaint to see that Respondents' advertisements do not even contain the DSHEA disclaimer that "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent disease," a disclaimer that must be "prominently displayed and in boldface type." *See* 21 U.S.C. § 343(r)(6). Instead, any disclaimers Respondents do make, where they do appear, are in fine-print. For example, at the bottom of their product pages on the DCO Web site, under the copyright line, Respondents simply state: "The information on this website is . . . not intended to diagnose a disease." Such disclaimers are inadequate to cure Respondents' deceptive claims, which are prominently featured on the Web site. It is well-established that advertisers cannot use fine print to contradict other statements in an advertisement or to clear up misimpressions the advertisement would otherwise leave. *Deception Policy Statement*, 103 F.T.C. at 180-81. To be effective, disclosures must be clear and conspicuous. *See, e.g., Thompson Med.*, 104 F.T.C. at 842-43 (1984). *U.S. v. Lane Labs* makes it clear that any such disclaimer also must be in boldface type and is permissible only if the claim is properly substantiated. *U.S. v. Lane Labs, Inc.*, 324 F. Supp. 2d 547. 564 (D.N.J. 2004) (stating that "[t]hese types of claims are permissible under DSHEA **only if the**

manufacturer of the dietary supplement has "substantiation" that the "statement is truthful and not misleading" and if the label contains the following disclaimer in boldface type: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease") (emphasis added). Even if a prominent, bold-type DSHEA disclaimer had been used, that could not cure Respondents' deceptive statements. As the *Dietary Supplements Guide* states, "the inclusion of the DSHEA disclaimer is not likely to negate the explicit disease claims made in the ad, and will not cure the fact that the claims are not substantiated." *Dietary Supplements Guide* at 24 (quoting "Example 34").

B. Respondents' Representations That The DCO Products Prevent, Treat, or Cure Cancer Are Misleading.

1. Unsubstantiated Claims Are Misleading.

The Commission may prove an advertisement is deceptive or misleading by showing that an express or implied claim is false, or by showing that a claim is unsubstantiated because Respondents lacked a reasonable basis for asserting that the claim was true. *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1096 (9th Cir. 1994); *FTC v. Sabal*, 32 F. Supp. 2d 1004, 1007 (N.D. Ill. 1998). Proof of intent to deceive is not required, and "the subjective good faith of the advertiser is not a valid defense to an enforcement action brought under section 5(a)." *Sabal*, 32 F. at 1007; *see also FTC v. World Travel Vacation Brokers, Inc.*, 861 F.2d 1020, 1029 (7th Cir. 1988).

The "reasonable basis" test is an objective standard. Advertisers must possess at least the level of substantiation expressly or impliedly claimed in the advertisement. *See Honeywell, Inc.*, 126 F.T.C. 202 (1998); *FTC v. Natural Solution, Inc.*, No. CV 06-6112-JFW, 2007 U.S. Dist.

LEXIS 60783, at *10 (C.D. Cal. Aug. 7, 2007) (citing *FTC v. U.S. Sales Corp.*, 785 F. Supp. 737, 748 (N.D. Ill. 1992)). The Commission has the burden of proving that Respondents' purported substantiation is inadequate, but is not required to conduct or present clinical studies showing that the products do not perform as claimed. *See FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 959 (N.D. Ill. 2006) *aff'd* 512 F.3d 858 (7th Cir. 2008), (citing *Sabal,* 32 F. Supp. 2d at 1008-09).

For health and safety claims, advertisers must possess "competent and reliable scientific evidence" substantiating their claims in order to have a "reasonable basis" for such claims. *See FTC v. National Urological Group, Inc.*, No. 1:04-CV-3294-CAP, 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"); *Natural Solution*, 2007 U.S. Dist. LEXIS 60783, at *11-13 (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); *FTC v. QT, Inc.*, 448 F. Supp. at 961 ("Reasonable basis" required defendants to have "competent and reliable scientific evidence" when they made the claim that the Q-Ray bracelet provides immediate, significant, or complete pain relief).

"Competent and reliable scientific evidence" is typically defined as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." *See, e.g., Brake Guard Products, Inc.*, 125 F.T.C. 138 (1998); *ABS Tech Sciences, Inc.*, 126 F.T.C. 229 (1998).

Courts have consistently found or upheld that double-blind, placebo-controlled studies are required to provide adequate substantiation for the truthfulness of various health-related efficacy claims. *See, e.g., FTC v. SlimAmerica, Inc.*, 77 F.Supp. 2d 1263, 1274 (S.D. Fla. 1999) ("Scientific validation of the defendants' product claims requires a double blind study of the combination of ingredients used in [the product formula]."); *Sabal*, 32 F.Supp. 2d at 1008-09 (rejecting study as valid substantiation, in part, because it was not blinded or placebo-controlled); *FTC v. Cal. Pac. Research, Inc.*, 1991 U.S. Dist. LEXIS 12967, at *12-13 (D. Nev. Aug. 27, 1991) (only placebo-controlled, double-blind clinical studies meet "the most basic and fundamental requirements for scientific validity and reliability"); *FTC v. QT, Inc.*, 448 F. Supp. 2d at 962 ("[W]ith medical, health-related claims, a well-conducted, placebo-controlled, randomized, double-blind study, the gold standard, should have been conducted. . . . Defendants would not be required to have a gold-standard study to substantiate the Q-Ray bracelet if they did not make such a strong, medical claim").

Respondents use testimonials to make representations to consumers, but courts consistently have found such anecdotal testimonial evidence inadequate to support such claims. *See, e.g., Direct Marketing Concepts*, 569 F. Supp. 2d at 304 (entering summary judgment for FTC where it was undisputed that respondents had no scientific studies supporting health-related efficacy claims, despite testimonials from customers); *FTC v. Simeon Mgmt. Corp.*, 579 F.2d 1137, 1143-44 (9th Cir. 1978) (anecdotal evidence of weight loss insufficient to support weight loss claims); *Koch v. FTC*, 206 F.2d 311, 316 (6th Cir. 1953) (evidence regarding case histories did not support cancer claims); *FTC v. QT, Inc.*, 512 F.3d 858, 862 (7th Cir. 2008) ("a person who promotes a product that contemporary technology does not understand must establish that this 'magic' actually works"; "[p]roof is what separates an effect new to science from a swindle"

and testimonials "are not a form of proof because most testimonials represent a logical fallacy: *post hoc ergo propter hoc.* (A person who experiences a reduction in pain after donning the [Q-Ray] bracelet may have enjoyed the same reduction without it. That's why the 'testimonial' of someone who keeps elephants off the streets of a large city by snapping his fingers is the basis of a joke rather than proof of cause and effect)").

Respondents' purported substantiation is a far cry from "competent and reliable scientific evidence." Thus, Respondents did not possess a reasonable basis for their advertising representations and such representations are misleading.

2. Respondents Did Not Possess a Reasonable Basis for Their Advertising Representations that the DCO Products Prevent, Treat and/or Cure Cancer.

Respondents admit in their Answer that they represented that they possessed and relied upon a reasonable basis that substantiated the claims at issue in the Complaint. Answer ¶ 15. However, the evidence reveals that Respondents did not have a reasonable basis for their advertising claims.

a. Respondents Never Conducted Any Tests or Studies on the DCO Products.

Respondents have failed to produce any competent and reliable scientific evidence to substantiate their claims that Bio*Shark, 7 Herb Formula, GDU, and/or BioMixx prevent, treat, or cure cancer or tumors. They have conducted no scientific testing on any of the DCO Products, and no person or entity, including Universal Nutrition, has been involved in the scientific testing, research, substantiation, or clinical trials of the DCO Products. CCPF ¶¶ 149-152, 159, 162-63, 168-69, 171. Respondents have no documents relating to their policies, procedures, or requirements for evaluating or reviewing the safety, efficacy, or bioavailability for the DCO Products. CCPF ¶ 153.

b. Dr. Miller, an Expert Oncologist, Confirms that No Competent and Reliable Scientific Evidence Exists with Regard to the DCO Products.

At trial, Complaint Counsel will submit the Expert Report and testimony of Denis R. Miller, M.D., a board-certified pediatric hematologist/oncologist, which confirms that no competent and reliable scientific evidence substantiates Respondents' claims concerning cancer. CCPF ¶¶ 172-194. For over 40 years, Dr. Miller has directed clinical care, education, laboratory and clinical research, and administration, heading divisions or departments at University of Rochester Medical Center, New York Hospital-Cornell Medical Center, Memorial Sloan Kettering Cancer Center, and Northwestern University Medical School. CCPF ¶ 173. Dr. Miller has supervised numerous clinical studies of cancer treatments and authored hundreds of book chapters and peer reviewed articles on cancer. CCPF ¶¶ 175-76.

Dr. Miller noted that "to constitute competent and reliable scientific evidence, a product that purports to treat, cure, or prevent cancer must have its efficacy and safety demonstrated through controlled clinical studies." CCPF ¶ 178. He stated that "only data from well-designed, controlled, clinical trials will substantiate claims that a new therapy . . . is safe and effective to treat, cure, or prevent cancer." CCPF ¶ 179. Dr. Miller also noted that anecdotal reports are "the weakest form of evidence supporting the anticancer activity of a new agent," and that testimonials "do not substitute for a well-designed clinical trial." CCPF ¶¶ 180-81.

Dr. Miller concluded that "[a] thorough review of peer-reviewed literature and all of the documents produced by DCO indicates that there is no competent and reliable scientific evidence that [the DCO Products] are effective either alone or in combination with other DCO products in the treatment or cure of cancer, in inhibiting tumor formation, and in preventing the destructive effects of radiation and chemotherapy." CCPF ¶ 182. None of the purported experts

put forth by Respondents contradicted Dr. Miller's findings.

i. Respondents' Claims that Bio*Shark Inhibits Tumor Growth and Effectively Treats Cancer Are Unsubstantiated.

After reviewing the peer-reviewed literature and all of the documents Respondents submitted as substantiation, Dr. Miller concluded that there was no competent and reliable scientific evidence that Bio*Shark inhibits tumor growth in humans or that it is effective in the treatment of cancer in humans. CCPF ¶ 183. He stated that there were no adequate and well-controlled studies demonstrating that Bio*Shark is antiangiogenic or is effective in the treatment of cancer, and even supporting non-clinical studies of crude or partially-purified shark cartilage products were extremely limited, particularly with regard to mechanisms of action, pharmacokinetics, pharmacodynamics, and dose response. CCPF ¶ 184. In addition, Dr. Miller noted that Respondents' reliance on Dr. I. William Lane's book, *Sharks Don't Get Cancer*, was misplaced, as studies at Johns Hopkins University indicate that sharks do indeed get cancer. CCPF ¶ 185. [3]

ii. Respondents' Claims that 7 Herb Formula Inhibits Tumor Formation and Effectively Treats or Cures Cancer Are Unsubstantiated.

After reviewing the peer-reviewed literature and all of the documents Respondents submitted as substantiation, Dr. Miller concluded that there was no competent and reliable scientific evidence that 7 Herb Formula inhibits tumor formation and is effective in the treatment or cure of cancer in humans. CCPF ¶ 186. He found neither non-clinical nor clinical studies supporting claims that 7 Herb Formula or any of its individual ingredients are effective

[3] In 2000, I. William Lane and his company Cartilage Consultants, Inc., as well as Andrew J. Lane and his company Lane Labs-USA, Inc., entered into orders to settle FTC charges that they made unsubstantiated claims about the efficacy of the products BeneFin (a shark cartilage product) and Skin Answer (a glycoalkoid product) in the prevention, treatment, and cure of cancer. *See FTC v. Lane Labs-USA, Inc.*, No. 00-CV-3174 (D. N.J. June 30, 200) (contempt motion pending).

anticancer agents or inhibit tumor formation. CCFS ¶ 187. Moreover, any relevant studies on the ingredients Burdock root, Cat's Claw, Sheep Sorrel, Slippery Elm Bark, Turkish Rhubarb Root, Siberian Ginseng, and Watercress were performed either in vitro or on animals, not on humans with cancer. CCPF ¶ 188.

iii. Respondents' Claims that GDU Eliminates Tumors and Effectively Treats Cancer Are Unsubstantiated.

After reviewing the peer-reviewed literature and all of the documents Respondents submitted as substantiation, Dr. Miller concluded that there was no competent and reliable scientific evidence that GDU eliminates tumors and is effective in the treatment of cancer in humans. CCPF ¶ 189. He found no randomized, controlled clinical trials of any of the individual components of GDU or of GDU itself in patients with cancer. CCPF ¶ 190.

However, Dr. Miller did note that curcumin (tumeric), one of GDU's ingredients, is currently being evaluated in controlled clinical trials to determine its potential as a chemoprotective and cancer preventive agent. CCPF ¶ 191. Animal studies have suggested that curcumin may have activity as a cancer preventive and therapeutic agent. CCPF ¶ 192. Nevertheless, he cautioned that some studies have suggested that curcumin may actually inhibit the anticancer activity of some approved anticancer agents as well as exacerbate iron deficiency. CCPF ¶ 193. Thus, Dr. Miller advised that further research on curcumin was necessary. CCPF ¶ 194.

iv. Respondents' Claims that BioMixx Effectively Treats Cancer and Heals the Destructive Effects of Radiation and Chemotherapy Are Unsubstantiated.

After reviewing the peer-reviewed literature and all of the documents Respondents submitted as substantiation, Dr. Miller concluded that there was no competent and reliable

scientific evidence that BioMixx is effective in the treatment of cancer and heals the destructive effects of radiation and chemotherapy. CCPF ¶ 195. According to Dr. Miller, there are no reported studies of goldenseal in cancer patients. CCPF ¶ 196. BioMixx's other principal ingredients -- ginseng, shark cartilage, bromelain, and boron – appear in the other three DCO Products discussed above and were not supported by clinical data for cancer treatment. CCPF ¶ 196.

Dr. Miller also stated that "absolutely no data" supports the claim that BioMixx is used to heal the destructive effects of radiation and chemotherapy treatments. CCPF ¶ 197.

C. Respondents' Advertising Representations That the DCO Products Prevent, Treat, or Cure Cancer Are Material.

"A 'material' misrepresentation is one that involves information that is important to consumers, and that is therefore likely to affect a consumer's choice of or conduct regarding a product. Proof of actual consumer injury is not required." *Kraft, Inc.*, 114 F.T.C. 40, 1991 FTC LEXIS 38, *38 (1991). Courts have interpreted the *FTC Deception Policy Statement* to "presume[] materiality for express claims and claims that significantly involve health, safety, or other issues that would concern reasonable consumer[s]." *QT, Inc.*, 448 F. Supp. 2d, at 965-66 (citing *Kraft, Inc.*, 970 F.2d at 322); *see also FTC v. Cliffdale Assocs.*, 103 F.T.C. at 176-84 (1984) (claims involving "health, safety, or other areas with which the reasonable consumer would be concerned, [such as] . . . the purpose, safety, efficacy, or cost of the product . . . [or] its durability, performance, warranties or quality" are material as a matter of law). 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*, 564 F. Supp. 2d at 135-36.

In this case, Respondents' serious health claims were both express and so strongly implied as to be virtually express that they should be presumed material. Moreover, 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.

V. THE FTC IS NOT VIOLATING THE RESPONDENTS' FIRST AMENDMENT RIGHTS.

A. The Filing of the Instant Suit Does Not Infringe Respondents' First Amendment Rights.

Throughout this proceeding Respondents have argued that their advertising representations are constitutionally protected religious and political speech that is immune to the FTC Act's prohibition against unfair and deceptive practices. Respondents first raised their First Amendment argument in their January 13, 2009 Motion to Dismiss. The Court denied Respondents' Motion to Dismiss in its February 2, 2009, Order, and stated:

> The Complaint contains sufficient allegations that respondents are engaging in deceptive commercial speech, including allegations that the Respondents promote and advertise the Challenged Products, that the Challenged products are offered for sale at not insignificant prices, and that the advertisements refer to specific products and attributes. These allegations, and the content of the exhibits to the Complaint, are more than sufficient for a reasonable fact-finder to infer that the speech proposes a commercial transaction, refers to specific products and is economically or commercially motivated. Respondents point to no facts that would dispute such an inference. *Feb. 2 Order* at 8 (citing *In re R.J. Reynolds*, 1998 WL 490114, *4 (1998)).

The Court explained that commercial speech – speech proposing a commercial transaction – that is false or misleading can be suppressed, and that "[t]he more limited

protection accorded commercial speech permits the FTC to act when necessary to challenge false or deceptive advertising." Feb. 2 Order at 7 (citing *In re R.J. Reynolds*, 1998 WL 490114, *4 (1998)).

To date, Respondents are still unable to point to any facts that would dispute the inference that their representations constitute commercial speech. As detailed in this brief, the evidence in this case clearly demonstrates that Respondents have not only engaged in commercial speech in advertising and selling the DCO Products, but their commercial speech is deceptive. Thus, FTC action is not only appropriate, but necessary in this matter.

B. The First Amendment Does Not Protect Deceptive Commercial Speech.

The speech at issue in this case is commercial speech, not political or religious speech as Respondents argue. The determination of whether speech is commercial speech "rests heavily on 'the common sense distinction between speech proposing a commercial transaction. . . . and other varieties of speech.'" *Zauderer v. Office of Disciplinary Council*, 471 U.S. 626, 637-38 (1985). As a result, the determinant factor is whether the speech at issue "propose[s] a commercial transaction." *Bd. of Trustees of State Univ. of New York v. Fox*, 492 U.S. 469, 473-74 (1989). As noted above, the Respondents make the claims at issue in the context of a Web site and other promotional material used to promote and sell their products. The speech at issue proposes a commercial transaction – the purchase of Respondents' products – and is commercial speech.

The Supreme Court has long held that "the Constitution accords less protection to

commercial speech than to other constitutionally safeguarded forms of expression." *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 64 (1983). Commercial speech receives less protection than other forms of expression under the First Amendment because "commercial speech may be more durable than other kinds. Since advertising is the sine qua non of commercial profits, there is little likelihood of its being chilled by proper regulation and foregone entirely." *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 772 (1976). In addition, "commercial speakers have extensive knowledge of both the market and their products. Thus, they are well suited to evaluate the accuracy of their messages and the lawfulness of the underlying activity." *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 564 (1980) (citing *Bates v. State Bar of Arizona*, 433 U.S. 350, 381 (1977)). For commercial speech to receive the protections of the First Amendment, the commercial speech "at least must concern lawful activity and not be misleading." *Id.* at 566. Moreover, the government may prohibit false or misleading commercial speech entirely. *See In re R. M. J.*, 455 U.S. 191, 203 (1982) ("Misleading speech may be prohibited entirely"). Thus, *deceptive* commercial speech, as Complaint Counsel alleges is at issue in this case, is not protected by the First Amendment. *See Zauderer*, 471 U.S. at 638 ("The States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading"); *National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *29-30 (citing *Bristol-Myers Co. v. FTC*, 738 F.2d 554, 562 (2d Cir. 1984) ("[D]eceptive advertising enjoys no constitutional protection")).

Although Respondents assert that their products "cannot be isolated from their overall religious ministry of health freedom and healing," this purported link does not

change the commercial nature of the speech. *Respondents' Motion to Dismiss and Supporting Memorandum* at 13. In *Bolger v. Youngs Drug Products Corporation*, the Supreme Court concluded that advertisements were commercial speech, "notwithstanding the fact that they contain discussions of important public issues." 463 U.S. 60, 67-68 (1983). Indeed, to find otherwise would allow advertisers to "immunize false or misleading product information from government regulation simply by including references to public issues." *Id.* at 68.4 Respondents "ha[ve] the full panoply of protections available to [their] direct comments on public [or religious] issues, so there is no reason for providing them similar constitutional protections when such statements are made in the context of commercial transactions." *Id.*

Thus, Respondents can comment on public and religious issues freely. Respondents cannot, however, make deceptive statements in connection with the sale of the Challenged Products and protect that deception through flawed invocations of the First Amendment.

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[4] Respondents seek to draw parallels between the instant case and the seminal civil rights era case of *New York Times v. Sullivan* to support their assertion that they are engaged in protected political speech. 376 U.S. 254 (1964). This comparison is unavailing as *Sullivan* centered on the issues of libel and defamation, not advertising for the sale of products. Moreover, Respondents' efforts to apply the *Sullivan* "malice standard" in asserting that Complaint Counsel be required to establish proof of intent to deceive when challenging advertising claims is unsupported by long-standing case law. Courts have consistently held that the FTC is not required to prove intent to deceive in an action for violation under Section 5 of the FTC Act. *See Amy Travel Serv.*, 875 F.2d at 574 ("We find that imposing a requirement that the FTC prove subjective intent to defraud on the part of the defendants would be inconsistent with the policies behind the FTC Act and place too great a burden on the FTC"); *Orkin Exterminating Co.*, 849 F.2d at 1368 ("intent has no bearing on the question whether a Section 5 violation has occurred").

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

Respondents assert that "[t]he FTC administrative process imposes an unconstitutional prior restraint in violation of the freedoms of speech and press . . . [and] empowers the FTC to impose censorship settlements without evidence that such censorship powers are necessary to protect a government interest." *Respondents' Motion to Dismiss and Supporting Memorandum* at 21. Respondents misapply the concept of "prior restraint." "The term 'prior restraint' is used 'to describe administrative and judicial orders forbidding certain communications when issued in advance of the time that such communications are to occur,'" and include regulatory schemes where the permitting authority enjoys "unbridled discretion" over whether to permit future speech. *Alexander v. United States*, 509 U.S. 544, 550 (1993) (citations omitted); *see also FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 225-26 (1990); *Granite State Outdoor Adver. Inc. v. City of Clearwater, Fl.*, 351 F.3d 1112, 1117-18 (11th Cir. 2003). The FTC brings this case using its law enforcement authority to challenge advertising that has already been disseminated by Respondents. There has been no prior restriction on Respondents' advertisements. Moreover, Respondents are in no way compelled to discontinue claims in already-disseminated advertisements that they believe to be truthful until the FTC has proven that the claims are deceptive and a final order is issued prohibiting the claims. Of course, if such claims are unsubstantiated and thus false and misleading, Respondents ultimately may need to provide monetary relief to consumers for their already-disseminated claims.

The instant action also does not infringe on Respondents' right to free exercise of religion. Although they may not make deceptive claims to sell products, Respondents are

otherwise free to believe whatever they want and to practice their faith as they see fit. *Church of Scientology v. Richardson*, 437 F.2d 214, 217 (9th Cir. 1971) (stating that "the exercise of religious freedom does *not* include the freedom to violate the Federal Food, Drug, and Cosmetic Act") (emphasis in original). The fact that Respondents purport to have a religious motivation in making the claims at issue is irrelevant. Subjective intent is not an issue in a claim brought under Section 5 of the FTC Act. *See FTC v. Amy Travel Serv., Inc.*, 875 F.2d 564, 574 (7th Cir. 1989); *Orkin Exterminating Co. v. FTC*, 849 F.2d 1354, 1368 (11th Cir. 1988) ("intent has no bearing on the question whether a section 5 violation has occurred"); *Sabal,* 32 F. Supp. 2d at 1007.

VI. JAMES FEIJO IS INDIVIDUALLY LIABLE

An individual may be held liable under the FTC Act for the violations of his corporation when the individual either participated directly in or had the authority to control the deceptive acts or practices. *FTC v. Amy Travel Serv., Inc.*, 875 F.2d 564, 573 (7th Cir. 1989). Authority to control can be established by an individual's "active involvement in business affairs and the making of corporate policy, including assuming the duties of a corporate officer." *Id.* "An individual's status as a corporate officer gives rise to a presumption of ability to control a small, closely-held corporation. 'A heavy burden of exculpation rests on the chief executive and shareholder of a closely-held corporation whose stock-in-trade is overreaching and deception.'" *Windward Marketing*, 1997 U.S. Dist. LEXIS 17114, at *38 (quoting *Standard Educ., Inc. v. FTC*, 475 F.2d 401, 403 (D.C. Cir. 1973)).

Respondent James Feijo both participated directly in and had the authority to

control the deceptive representations at issue in this case. CCPF ¶¶ 2, 95, 109, 143. Respondents admit that Respondent Feijo is responsible for the activities of Respondent DCO as its Overseer. CCPF ¶ 2. The activities for which he is responsible include the development, creation, and production of the DCO Products; the creation, management, and maintenance of DCO's toll-free telephone number by which consumers may order the DCO Products; the setting of prices for the DCO Products; and the creation, drafting, and approval of the directions for usage and the recommended usages of the DCO Products. CCPF ¶¶ 8, 32, 37, 95. Respondent Feijo and his wife Patricia Feijo, are also responsible for the information contained in DCO's advertising and promotional materials, including the BioGuide, the Cancer Newsletter, the websites www.danielchapterone.com, www.7herbformula.com, www.gdu2000.com. CCPF ¶ 143. In addition, Respondent Feijo and his wife co-host the DCO radio program, "Daniel Chapter One Health Watch," for two hours daily, Monday through Friday, on which they have counseled cancer patients who have called into the radio program about taking the DCO Products. CCPF ¶¶ 146-147. Finally, Respondent Feijo is the trustee for all DCO assets, including all funds which are held in trust. CCPF ¶ 9. He receives all bank statements and maintains DCO's financial records. CCPF ¶¶ 13-14.

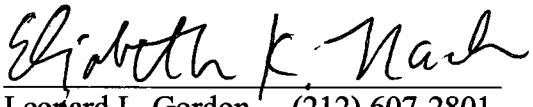
Thus, Respondent Feijo is the driving force behind DCO's operations, and the evidence is uncontroverted that he participated directly in and had the authority to control the deceptive acts or practices at issue in this case.

VII. CONCLUSION

The evidence at trial will show that Respondents have violated Sections 5 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 an appropriate order.

Respectfully submitted,



Leonard L. Gordon (212) 607-2801
Theodore Zang, Jr. (212) 607-2816
Carole A. Paynter (212) 607-2813
David W. Dulabon (212) 607-2814
Elizabeth K. Nach (202) 326-2611

Federal Trade Commission
Alexander Hamilton U.S. Custom House
One Bowling Green, Suite 318
New York, NY 10004

Dated: March 30, 2009

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 PROPOSED
FINDINGS OF FACT AND CONCLUSIONS OF LAW

Pursuant to the Court's October 28th, 2008 Scheduling Order, Complaint Counsel submit their *Proposed Findings of Fact and Conclusions of Law*, supported by citations to documentary materials, deposition testimony, and/or legal authority as appropriate.

Respectfully submitted,

Leonard L. Gordon (212) 607-2801
Theodore Zang, Jr. (212) 607-2816
Carole A. Paynter (212) 607-2813
David W. Dulabon (212) 607-2814
Elizabeth K. Nach (202) 326-2611
Counsel Supporting the Complaint

Federal Trade Commission
Alexander Hamilton U.S. Custom House
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New York, NY 10004

Dated: March 30, 2009

I. COMPLAINT COUNSEL'S PROPOSED FINDINGS OF FACT

A. Daniel Chapter One And The Feijos.

1. Respondent Daniel Chapter One ("DCO") is a corporation sole organized in 2002 under the laws of the state of Washington. Respondents' Answer to FTC's Compl., dated Oct. 14, 2008 (hereinafter referred to as the "Answer) at ¶ 1; *see also* Complaint Counsel's Trial Exhibit (hereinafter referred to as CX ___) 35.

2. Respondent James Feijo is responsible for the activities of Respondent DCO as its Overseer. Answer ¶ 2.

3. Patricia Feijo, Respondent James Feijo's wife, is the secretary for DCO. Deposition of Patricia Feijo, January 14, 2009, (hereinafter referred to as *P. Feijo Dep. Tr.*) at 10, l. 17-21; 52, l. 3-16.

4. Respondent James Feijo and his wife, Patricia, originally started DCO as a health food store in 1986. *P. Feijo Dep. Tr.* at 39, l. 14-25 - 40, l. 1-20.

5. Respondents' principal office and place of business is located at 1028 East Main Road, Portsmouth, Rhode Island 02871. Answer ¶ 1; Deposition of James D. Feijo, January 13, 2009, (hereinafter referred to as *J. Feijo Dep. Tr.*) at 99, l. 10-18.

6. James Feijo sold DCO products prior to registering as a corporation sole. *J. Feijo Dep. Tr.* at 224, l. 4-6.

7. DCO offers 150 to 200 products today. *J. Feijo Dep. Tr.* at 37, l. 11-13.

8. Respondent James Feijo is responsible for the development, creation, and production of Bio*Shark, 7 Herb Formula, GDU, and BioMixx (collectively, the "DCO Products"). CX 39 (Resp. to Interrog. No. 2); *J. Feijo Dep. Tr.* at 116, l. 17-21.

9. Respondent James Feijo is the trustee for all Daniel Chapter One assets, including all funds which are held in trust. CX 39 (Resp. to Interrog. No. 9).

10. Daniel Chapter One has a bank account with Citizens Bank. Deposition of Jill Susan Feijo, January 22, 2009, (hereinafter referred to as *Jill Feijo Dep. Tr.*) at 33, l. 19-23.

11. Patricia Feijo is a signatory to DCO's bank account and writes checks on behalf of the DCO account. *P. Feijo Dep. Tr.* at 54, l. 8-19.

12. Jill Feijo, James Feijo's daughter and Respondents' corporate representative, also has authority to write checks on behalf of the DCO account. *Jill Feijo Dep. Tr.* at 34, l. 15-17.

13. Respondent James Feijo receives all the bank statements for the DCO account. *Jill Feijo Dep. Tr.* at 34, l. 10-11.

14. Respondent James Feijo maintains the financial records for DCO. *Jill Feijo Dep. Tr.* at 47, l. 6-8.

15. Respondent DCO defrays James Feijo's expenses as Overseer and provides for his support. CX 39 (Resp. to Interrog. No. 3).

16. Respondent James Feijo pays his daughter Jill $700 per week cash for her work at Daniel Chapter One. *Jill Feijo Dep. Tr.* at 13, l. 3-9.

17. DCO has two buildings in Portsmouth, Rhode Island – one contains the office with the Order Center and the other contains the products that DCO offers to the public. *Jill Feijo Dep. Tr.* at 20, l. 9-24.

18. DCO is not registered with the Internal Revenue Service as a charity. *J. Feijo Dep. Tr.* at 45, l. 11-13.

19. Messiah Y'Shua Shalom, a Washington corporation sole, owns the property that Respondents use in Rhode Island. *J. Feijo Dep. Tr.* at 72, l. 7-25 - 73, l. 1-3; CX 35.

20. Respondent James Feijo is the overseer for Messiah Y'Shua Shalom. *J. Feijo Dep. Tr.* at 72, l. 7-25 - 73, l. 1-3; CX 35.

21. Messiah Y'Shua Shalom houses the buildings where Respondents perform their ministry of Daniel Chapter One. *J. Feijo Dep. Tr.* at 72, l. 7-25 - 73, l. 1-3.

22. Daniel Chapter One owns a three-bedroom property in Deerfield Beach, Florida. *J. Feijo Dep. Tr.* at 70, l. 22-25 - 71, l. 1-15.

23. James and Patricia Feijo live in the properties owned by Messiah Y'Shua Shalom and DCO. *J. Feijo Dep. Tr.* at 70, l. 25 - 71, l. 1-2; 78, l. 20-25 - 79, l. 1.

24. Daniel Chapter One owns two cars - a 2003 Cadillac and a 2004 Cadillac. DCO purchased one Cadillac new and the other Cadillac used. *J. Feijo Dep. Tr.* at 71, l. 16-23.

25. Respondent James Feijo uses the two Cadillacs owned by DCO. *J. Feijo Dep. Tr.* at 96, l. 9-10, 14-16; 97, l. 7-13.

26. Respondents practice a science they call BioMolecular Nutrition. CX 21.

27. According to Respondents, "[t]here are two aspects of BioMolecular Nutrition, the spiritual and the physical." CX 21.

28. "The principles of BioMolecular Nutrition were those missing principles needed to bind together those of the nutritionists and the biochemists." CX 21.

29. According to Respondents, "[b]ecause of BioMolecular nutritional products developed at that time, we've been able to support other naturopathic disciplines – chiropractic, acupuncture, herbology, and homeopathy – and using the principles of BioMolecular Nutrition has allowed many natural health practitioners to be complete." CX 21.

B. Respondents Distribute Their Products in Commerce to Consumers.

30. Respondents distribute the DCO Products in commerce. Answer ¶ 4; *J. Feijo Dep. Tr.* at 102, l. 13-16.

31. Respondent DCO has an 800 number and a call center for consumers to purchase the DCO Products. *P. Feijo Dep. Tr.* at 67, l. 7-13; *Jill Feijo Dep. Tr.* at 15, l. 5-14.

32. Respondent James Feijo created, managed, and maintained the toll-free telephone number, designed so that consumers can order the DCO Products. CX 39 (Resp. to Interrog. No. 33).

33. On the front page of their BioMolecular Nutrition Product Catalog, Respondents inform consumers to "Call Toll FREE 1-800-504-5511 or shop online at www.danielchapterone.com." CX 17 (at FTC-DCO 0060).

34. Respondents operate the website www.danielchapterone.com. Answer ¶ 5; *J. Feijo Dep. Tr.* at 62, l. 10-13.

35. DCO also operates the Web sites dc1pages.com and dcstore.com. *J. Feijo Dep. Tr.* at 232, l. 21-25 - 233, l. 1-19.

36. Consumers learn of DCO's 800 number from the DCO Web site, the BioGuide, and the radio program. *Jill Feijo Dep. Tr.* at 15, l. 15-25.

37. Respondent James Feijo established the price of the DCO Products. CX 39 (Resp. to Interrog. No. 25); *P. Feijo Dep. Tr.* at 77, l. 13-16.

38. Jill Feijo has supervised Respondent DCO's Order Center for the past nine years and has taken telephone orders. CX 39 (Resp. to Interrog. No. 30).

39. DCO employs Kevin Vandeburg, Axel Busche, and Jay Butler to work in the building that contains the DCO Products and to ship the DCO Products ordered by consumers. *Jill Feijo Dep. Tr.* at 21, l. 7-22.

40. DCO's Order Center is open Monday through Friday from 9:00 a.m. to 8:00 p.m. *Jill Feijo Dep. Tr.* at 16, l. 5-10.

41. DCO receives payments through its Order Center through credit card and COD. *Jill Feijo Dep. Tr.* at 18, l. 6-10.

42. DCO also accepts consumers' orders on the Internet. *Jill Feijo Dep. Tr.* at 18, l. 11-13.

43. DCO's Web site contains a tab inviting consumers to shop at DCO's "On-Line Store." CX 12, CX 13, CX 14, CX 15 (at FTC-DCO 0011), CX 43.

44. DCO's Web site contains an icon inviting consumers to "Buy Now." CX 12, CX 13, CX 14, CX 15 (at FTC-DCO 0011), CX 43.

45. Respondents' acquisition costs for the products they sell is 30 percent of the price Respondents charge to consumers for products such as 7 Herb Formula. *J. Feijo Dep. Tr.* at 232, l. 3-8.

46. Over a thousand consumers have purchased DCO's products. *P. Feijo Dep. Tr.* at 57, l. 13-18.

47. Respondents have generated approximately $2 million in annual sales for the years 2006, 2007, and 2008 for all of DCO's two-hundred products. *J. Feijo Dep. Tr.* at 206, l. 18-20; 212, l. 14-24; CX 44.

48. There is no indication in the BioMolecular Nutrition Product Catalog that the price listed is for a donation. *J. Feijo Dep. Tr.* at 158, l. 11-17; *P. Feijo Dep. Tr.* at 76, l. 11-17; 77, l. 5-12.

49. There is no mention of the DCO ministry in the BioMolecular Nutrition Product Catalog. *J. Feijo Dep. Tr.* at 161, l. 4-10.

50. Jill Feijo does not recall whether there is anything in writing regarding any alleged "donation policy." *Jill Feijo Dep. Tr.* at 22, l. 25 - 23, l. 1-3.

51. Most consumers pay DCO's alleged "suggested donation" price and "not many" people per day ask Jill Feijo to pay a lowered amount. *Jill Feijo Dep. Tr.* at 23, l. 14-21.

52. On January 3, 2008, FTC investigator Michael Marino ("Marino") purchased the DCO Products from Respondents' Web site. CX 10.

53. Prior to making the purchase, Marino created an undercover e-mail account to confirm and monitor the progress of the purchase and received four emails from Respondents relating to the purchase of the DCO Products. CX 33.

54. On or about January 24, 2008, Marino received the DCO Products. CX 34.

55. Included in the shipment of the DCO Products ordered by Marino were the following: (a) BioGuide 3: The BioMolecular Nutrition Guide to Natural Health 3; (b) "BioMolecular Nutrition Product Catalog;" (c) a blank purchase order form; and (d) an invoice form. CX 34.

56. According to the UPS Ground shipping label attached to the package containing the DCO Products and the DCO materials, the shipment originated from Daniel Chapter One, 822 Anthony Road, Portsmouth Rhode Island 02871-5604 and was sent to an FTC undercover address in a state other than Rhode Island in the United States. CX 34.

57. Marino inspected the contents of the shipment of the DCO Products and did not observe a separate document indicating that the purchase was a "donation" or thanking the purchaser for making a "donation" to Daniel Chapter One. CX 34.

58. According to Commission records, the amount charged to the undercover credit card used for the purchase of the DCO Products was $175.75. These records also indicate that this charged was made by "DANIEL CHAPTER ONE." CX 34.

59. DCO's shipping and handling fees for its products are $20.95. *J. Feijo Dep. Tr.* at 152, l. 22-25 - 153, l. 1-3.

60. DCO offers coupons to consumers for their next online store order. *J. Feijo Dep. Tr.* at 154, l. 2-7.

61. Respondents run promotions from time to time to "give [consumers] more of an opportunity to . . . get things at a lower rate." *J. Feijo Dep. Tr.* at 154, l. 8-24.

62. For example, consumers can buy multiple bottles and get a bottle free. *J. Feijo Dep. Tr.* at 232, l. 16-20.

63. A number of stores nationally sell DCO's products, including stores in Georgia and a store in Pennsylvania. *P. Feijo Dep. Tr.* at 72, l. 16-24.

64. Doctors and stores that carry DCO's product line get the product at a lesser price because they are going to be selling it. *P. Feijo Dep. Tr.* at 71, l. 3-9.

65. Respondents' Cancer Newsletter, entitled How to Fight Cancer is Your Choice!!!, costs $5.95. CX 23 (at FTC-DCO 0405).

66. In their Cancer Newsletter, Respondents instruct consumers to call "1-800-504-5511" to order their products. CX 23 (at FTC-DCO 0405).

67. In their Cancer Newsletter, entitled How to Fight Cancer is Your Choice!!!, Respondents state that their "[l]atest Bioguide" is "[o]nly $9.95." CX 23 (at FTC-DCO 0397).

68. Respondents' publication entitled The Most Simple Guide to the Most Difficult Diseases: The Doctors' How-To Quick Reference Guide costs $12.95. CX 20 (at FTC-DCO 2825).

69. On their Web site dc1store.com, Respondents state: "For Information on Special offers for ***purchasing*** multiple bottles of 7-Herb call 1-800-504-5511 between 9-6 EST Mon-Fri." CX 17 (at FTC-DCO 0084) (emphasis added).

70. On their Web site dc1store.com, Respondents state the following regarding their affiliate program: "**Welcome to the DC1 Affiliate Program!** Our program is free to join, it's easy to sign-up and requires no technical knowledge. Affiliate programs are common throughout the Internet *and offer website owners a means of profiting from their websites. Affiliates generate sales for commercial websites* and in return receive a percentage of the value of those sales. **How Does It Work?** When you join the DC1 Affiliate Program, you will be supplied with a range of banners and textual links that you place within your site. When a user clicks on one of your links to the DC1 Affiliate Program, their activity will be tracked by our affiliate software. You will earn a commission based on your commission type. **Real-Time Statistics and Reporting!** Login 24 hours a day to check your sales, traffic, account balance and see how your banners are performing. You can even test conversion performance by creating your own custom links! Affiliate Program Details. Pay-Per-Sale: 10% of all sales you deliver. $100.00 USD - Minimum balance required . . . . Payments are made on the 1st of each month, for the previous month." CX 29 (at FTC-DCO 0461 - 0462) (emphasis in bold in original; emphasis in italics supplied).

71. When discussing the cost of DCO's products generally, Terry Brotherton, a consumer whose testimonial was provided by Respondents in discovery, stated "***[i]t wasn't cheap but it was the best money I ever spent.***" (*Terry Brotherton Statement produced by Respondents as DCO 0156*) (emphasis added).

72. When discussing the cost of 7 Herb Formula specifically, Charlotte Rice, a consumer whose testimonial was provided by Respondents in discovery, stated, "I then proceeded to reduce my 7 Herb Formula to a maintenance dosage. Tricia & Jim Feijo did not agree with my decision. They felt I should stay on the maximum dosage to be safe, ***but I was having financial problems, and could not afford the cost.***" (*Charlotte Rice Statement produced by Respondents as DCO 0170 - 0171* at DCO 0170) (emphasis added).

73. When discussing the cost of 7 Herb Formula, GDU, Bio*Shark, and other DCO products, Earl Davis, a consumer whose testimonial was provided by Respondents in discovery, stated, "***[t]he only drawback that we've experienced is the pricing of the products. There should be discounts for customers who have referred lots of people and for those customers who consume lots of product monthly*** because alternative therapy is expensive. . . ." (*Earl Davis Statement produced by Respondents as DCO 0187*) (emphasis added).

74. When discussing the cost of 7 Herb Formula, Ernie Jensen, a consumer whose testimonial was provided by Respondents in discovery, stated "I could not afford the 7 Herb [Formula]." (*Ernie Jenson Statement produced by Respondents as DCO 0189 - 0193* at DCO 0189).

75. The trademark symbol appears next to Respondents' term "BioMolecular Nutrition" and Respondents' products 7 Herb Formula, GDU, and BioMixx. CX 17 (at FTC-DCO 0060 - 0061).

Bio*Shark

76. Bio*Shark is a product that contains, among other ingredients, Shark Cartilage. Answer ¶ 6.

77. Respondents offer one bottle of Bio*Shark for $65.95 (300 of the 800 mg capsules) and $30.95 (100 of the 800 mg capsules). Answer ¶ 6.

78. Respondents pay Universal Nutrition $3.15 per unit for the 100 capsule bottle of Bio*Shark and $8.75 per unit for the 300 capsule bottle of Bio*Shark. Deposition of Claudia Petra Bauhoffer-Kinney, January 15, 2009, (hereinafter referred to as *Kinney Dep. Tr.*) at 44, l. 15-19.

79. During 2008, Respondents paid Universal Nutrition approximately $1,437 to manufacture 479 units of the 100 capsule bottle of Bio*Shark and approximately $6,256 to manufacture 782 units of the 300 capsule bottle of Bio*Shark. *Kinney Dep. Tr.* at 45, l. 3-10.

80. Universal Nutrition does two things - it has its own brand of products, and it also is a private label manufacturer. *Kinney Dep. Tr.* at 17, l. 10-23.

81. DCO falls under the private label part of Universal Nutrition. *Kinney Dep. Tr.* at 17, l. 24-25.

82. Universal Nutrition makes approximately 35-40 products for DCO, including Bio*Shark, GDU, and BioMixx. *Kinney Dep. Tr.* at 21, l. 1-19.

83. Universal Nutrition started manufacturing Bio*Shark for Respondents approximately eight to ten years ago. *Kinney Dep. Tr.* at 42, l. 23-25 - 43, l. 1.

7 Herb Formula

84. 7 Herb Formula is a liquid tea concentrate product that contains, among other ingredients, distilled water, Cat's Claw, Burdock Root, Siberian Ginseng, Sheep Sorrel, Slippery Elm, Watercress, and Turkey Rhubarb Root. Answer ¶ 8.

85. Respondents offer one 32-ounce bottle of 7 Herb Formula for $70.95. Answer ¶ 8.

86. On their Web sites danielchapterone.com and dc1pages.com, Respondents state the following regarding 7 Herb Formula: "I think it costs too much: Essiac formulas normally retail for $45 to $69 per bottle. If you compare that to the cost of a hospital stay and drug treatment, this is cheap! ***Daniel Chapter One's 7 Herb Formula is equally priced with most other brands but with ours you get a great deal more***. Remember you are not only getting 32 ounces per bottle, when some of the other brands are only 16 ounces; you are also getting 2 more expensive herbs (Cat's Claw and Siberian Ginseng). We use 3 times the herbs and prepare each individually using a double water filtering process. If that is the case you must at least double the price they are asking to get equal price comparison." CX 18 (at FTC-DCO 0159 - 0160 and at FTC-DCO 0495) (emphasis added).

GDU

87. GDU is a product that contains, among other ingredients, Bromelain, Turmeric, Quercetin, Feverfew, and Boron. Answer ¶ 10.

88. Respondents offer GDU for $45.95 (300 capsules) and $29.95 (120 capsules). Answer ¶ 10.

89. Respondents pay Universal Nutrition $3.28 per unit for the 120 tablet [sic] bottle of GDU and $7.07 per unit for the 300 tablet [sic] bottle of GDU. *Kinney Dep. Tr.* at 34, l. 21-25 - 35, l. 1-4.

90. During 2008, Respondents paid Universal Nutrition approximately $5,127 to manufacture 1,709 units of the 120 tablet [sic] bottle of GDU and approximately $52,661 to manufacture 7,523 units of the 300 tablet [sic] bottle of GDU. *Kinney Dep. Tr.* at 34, l. 5-25 - 35, l. 1-4.

BioMixx

91. BioMixx is a product that contains, among other ingredients, Goldenseal, Echinacea, and Ginseng. Answer ¶ 12.

92. Respondents offer BioMixx for $40.95 (3 lb. powder) and $22.95 (1 lb. powder). Answer ¶ 12.

93. Respondents pay Universal Nutrition $11.50 per unit for the 3 pound bottle of BioMixx. *Kinney Dep. Tr.* at 46, l. 8-16.

94. During 2008, Respondents paid Universal Nutrition approximately $8,778 to manufacture 798 units of the 3 pound bottle of BioMixx. *Kinney Dep. Tr.* at 46, l. 8-16.

C. Respondents Direct Consumers On How To Take Their Products.

95. Respondent James Feijo and his wife, Patricia Feijo, have been solely responsible for creating, drafting, and approving the directions for usage and the recommended usages of the DCO Products. CX 39 (Resp. to Interrog. No. 16).

96. There only has been one version of each of the DCO Products, and the information relating to the identity of each ingredient and the amount of each ingredient is contained on the labels for the DCO Products. CX 39 (Resp. to Interrog. No. 17).

97. Each Bio*Shark product label directs users to take 2-3 capsules three times a day or as directed by a physician or by a BioMolecular Nutrition health care professional. Answer ¶ 6; CX 17 (FTC-DCO 0065 - 0066 and 0122 - 0123).

98. Respondent James Feijo and his wife developed the suggested dosage for Bio*Shark, and the suggested dosage was based on their "reading and from experience." *P. Feijo Dep. Tr.* at 166, l. 19-25 - 167, l. 1-4.

99. Respondents' product label directs users to take 1-2 ounces of 7 Herb Formula with 2-4 ounces of hot or cold filtered or distilled water. The label further directs users to take 7 Herb Formula twice daily or as directed by a BioMolecular Nutrition Health care professional. Answer ¶ 8; CX 17 (at FTC-DCO 0064 and 0124).

100. Respondent James Feijo and his wife developed the suggested dosage for 7 Herb Formula. *P. Feijo Dep. Tr.* at 175, l. 13-16.

101. Respondents' GDU product label directs users to take 3-6 capsules 2 to 4 times per day or as directed by a physician or by a BioMolecular Nutrition health care professional. Answer ¶ 10; CX 17 (at FTC-DCO 0125 - 0126 and 0067 - 0068).

102. Respondent James Feijo and his wife developed the suggested dosage for GDU. *P. Feijo Dep. Tr.* at 192, l. 20-23.

103. Respondents' product label for BioMixx directs users to take five scoops daily. Answer ¶ 12; CX 17 (at FTC-DCO 0127 - 0128).

D. Respondents Claim That Their Products Cure, Mitigate, Treat, Or Prevent Cancer Or Tumors.

104. DCO's Web site depicts pictures of the DCO Products next to the statement "Daniel Chapter One's Cancer Solutions." *P. Feijo Dep. Tr.* at 176, l. 20-25 - 177, l. 1-19; CX 12, CX 13, CX 14, CX 15 (at FTC-DCO 0014); CX 43.

105. On their Web site dc1pages.com, Respondents publish information about the DCO Products, including, but not limited to, the following:

Supporting Products

To enhance 7 Herb Formula's healing quantities Daniel Chapter One advises [sic] to get familiar with the supporting products below:

CANCER
TREATMENT:

7Herb Formula
Bio*Shark
BioMixx
GDU Caps

also

Ezekiel Oil
topically

CX 18 (at FTC-DCO 0190).

106. In DCO's The Most Simple Guide to the Most Difficult Diseases: The Doctors' How-To Quick Reference Guide, DCO recommends the following products for cancer:

CANCER
All types of Cancer

7*Herb Formula ™
2 ounces in juice or water
(minimum intake)
2 times daily

Bio*Shark ™**(for tumors only)**
2 - 4 capsules
3 times daily with meals

BioMixx ™ (Boosts immune system)
4 - 5 scoops in soy milk
2 times daily

GDU Caps ™

3 - 6 capsules
3 times daily; ½ hr.
BEFORE meals

CX 20 (at FTC-DCO 2739).

107. Through the "Testimonies" tab on the danielchapterone.com Web site, Respondents provide the following titles for testimonials from their customers, who claim that DCO's Products were effective in the cure, mitigation, treatment, or prevention of cancer or tumors:

Cancer, Bladder (Drew Dellinger)
Cancer, Breast Mass (Deloris Winter)
Cancer, Cancerous Lung Tumor (Douglas Meeks)
Cancer, Cancerous Tumor (Joe Rocha)
Cancer, Leukemia, Brain Tumor (Tracey Kulikowski)
Cancer, Prostate (Jim Givens)
Cancer, Prostate Cancer (Joe)
Special Forces Officer Overcomes Prostate Cancer
Cancer, Prostate (Sherman "Red" Smith)
Cancer, Renal Cell (Jim Hatfield)
Cancer, Skin (Pastor Wayne Harms)
Cancer, Stage 4 (Joseph Jungles)

CX 17 (at FTC-DCO 0100 - 0119).

108. In Respondents' BioGuide: The BioMolecular Nutrition Guide to Natural Health 3, Respondents published the following testimonial from Tracey Kulikowski that states: "I had contracted leukemia and had three inoperable tumors. When I decided not to do chemotherapy or radiation, my father sent me ***BIOMIXX*** and ***7 HERB FORMULA***. Each day as I took it and got it into my system more and more, the better I felt. Then I added Garlic, Siberian Ginseng, and **Bio*Shark**. I am now in complete remission. The cancer cell count has dropped, the doctors tell me. I had a tumor just above the brain stem in my brain that has completely disappeared. The tumor on my liver is shrinking and the tumor behind my heart has shrunk over 50%. . . . There are alternatives besides chemo and radiation!" CX 21 (at FTC-DCO 0353)(emphasis in bold added).

109. Respondent James Feijo was responsible for putting together BioGuide 3. *J. Feijo Dep. Tr.* at 243, l. 12-21.

110. Patricia Feijo was responsible for writing the BioGuide. *P. Feijo Dep. Tr.* at 20, l. 15-25.

111. Bio*Shark, 7 Herb Formula, GDU, and BioMixx all appear in Respondents' Cancer Newsletter, entitled How to Fight Cancer is Your Choice!!!. CX 23 (at FTC-DCO 0390 - 405).

112. The Cancer Newsletter is "strictly all about the products for cancer." *J. Feijo Dep. Tr.* at 143, l. 17-22.

113. Patricia Feijo was responsible for writing the Cancer Newsletter. *P. Feijo Dep. Tr.* at 26, l. 23-25 - 27, l. 1-19; 28, l. 5-10.

114. James and Patricia Feijo are not doctors. *P. Feijo Dep. Tr.* at 114, l. 15-16.

115. James Feijo never held a position where he had to use any skills involving medicine. *J. Feijo Dep. Tr.* at 47, l. 12-17.

116. James and Patricia Feijo are not research scientists. *P. Feijo Dep. Tr.* at 114, l. 16.

117. During the July 8, 2008 DCO Healthwatch radio program, James Feijo stated that "the FTC, the FDA, the Canadian Government don't like the fact that we've told people about what to do about natural methods of health and healing, especially cancer." CX 5 (at FTC-DCO 0506).

118. During the July 14, 2008 DCO Healthwatch radio program, Patricia Feijo stated the following: "And while the FTC does not want us saying that anything natural can be used to treat cancer and that nothing certainly can cure cancer, we know that the truth is different than what they want us to say. The truth is God has given us herbs in His creation and nutrients that can heal cancer, even cure cancer." CX 8 (at FTC-DCO 0612).

BioShark

119. Respondents publish information about Bio*Shark, including, but not limited to, the following:

PRODUCTS
Bio*Shark: Tumors & Cysts
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 such as diabetic retinopathy and macular degeneration. . .

Answer ¶ 7; CX 43; J. Feijo Dep. Tr. at 61, l. 11-14; 100, l. 24-25 - 101, l. 1; 107, l. 15-18; *P. Feijo Dep. Tr.* at 156, l. 14-25 - 157, l. 1-7.

120. Respondents publish information about Bio*Shark, including, but not limited to the following:

If you suffer from any type of cancer, Daniel Chapter One suggests taking this products [sic], to fight it: [emphasis added]
7*Herb Formula ™. . .
Bio*Shark ™. . . [emphasis added]
BioMixx ™. . .
GDU Caps ™. . .
[depiction of bottles of BioMixx, 7 Herb Formula, Bio*Shark, and GDU]
Daniel Chapter One's Cancer solutions
To Buy the products click here
How to fight cancer is your choice!. . . [emphasis added]

Answer ¶ 9; CX 43; *J. Feijo Dep. Tr. at 61, l. 11-14; 100, l. 24-25 - 101, l.1; 110, l. 23-25 - 111, l. 13-20.*

121. In their BioMolecular Nutrition Product Catalog, next to the pictures of the BioShark bottles, Respondents state that "Shark Cartilage protein inhibits angiogenesis, stops tumor growth, and halts eye disease." CX 17 (at FTC-DCO 0061).

122. On a prior Daniel Chapter One Web site, Respondents stated "**Bio*Shark Shark Cartilage** Stops tumor growth in its tracks." CX 18 (at FTC-DCO 2032) (emphasis in original).

7 Herb Formula

123. 7 Herb Formula is a product that can be used by a person who is suffering from cancer. *P. Feijo Dep. Tr.* at 171, l. 4-8.

124. Respondents publish information about 7 Herb Formula, including, but not limited to, the following:

INFO CENTER
Cancer News.
7 Herb Formula
- purifies the blood
- promotes cell repair
- **fights tumor formation** [emphasis in original]
- fights pathogenic bacteria

. . .

If you suffer from any type of cancer, Daniel Chapter One suggests taking this products [sic], to fight it: [emphasis added]
7*Herb Formula ™. . . [emphasis added]
Bio*Shark ™. . .
BioMixx ™. . .
GDU Caps ™. . .
[depiction of bottles of BioMixx, 7 Herb Formula, Bio*Shark, and GDU]
Daniel Chapter One's Cancer solutions
To Buy the products click here
How to fight cancer is your choice!. . . [emphasis added]

Answer ¶ 9; CX 43; *see also J. Feijo Dep. Tr.* at 60, l. 17-22; 101, l. 2-6; 110, l. 23-25; 111, l. 13-20.

125. Respondents publish information about 7 Herb Formula, including, but not limited to, the following:

7 Herb Formula battles cancer.
Tracey was given no hope!
The doctors had pretty much given up on Tracey. She had leukemia and tumors on the brain, behind the heart and on her liver. . .

This is Tracey's story in her own words as told in 1997: 'I had contracted leukemia and had three inoperable tumors. When I decided not to do chemotherapy or radiation, my father sent me Bio*Mixx and 7 Herb Formula. Each day as I took it and got it into my system more and more, the better I felt. Then I added Garlic Pur, Siberian Ginseng and BioShark." "I am now in complete remission. . .'

Answer ¶ 9; CX 43; *see also J. Feijo Dep. Tr.* at 60, l. 17-22; 101, l. 2-6; 110, l. 23-25; 111, l. 13-20.

126. In their BioMolecular Nutrition Product Catalog, next to the picture of the 7 Herb Formula bottle, Respondents state that the herbs in 7 Herb Formula "purify the blood and promote cell repair, clear skin, cleanse the liver, decrease cell mutation, fight pathogenic bacteria and ***tumor formation***." CX 17 (at FTC-DCO 0061) (emphasis added).

127. In Respondents' BioGuide: The BioMolecular Nutrition Guide to Natural Health 3, Respondents published the following testimonial from Buzz McKay: "I had beam radiation for ***prostate cancer***. I also took 7 Herb Formula, 6 ounces a day, and BioMixx; I never had a bad day, never felt sick. When my PSA went from 7.6 to 0.5 in the month after I finished radiation, my doctor was surprised. Several months later, it was down to 0.16! 7 Herb Formula is extremely well done - fantastic. I still take 2 ounces of ***7 Herb Formula*** every morning; I plan to stay on that forever! ***I figure 6 ounces (2 morning, 2 afternoon, 2 evening) did such a good job fighting cancer***, 2 ounces is a good prophylaxis!" CX 21 (at FTC-DCO 0330) (emphasis added).

128. On their Web sites danielchapterone.com and dc1pages.com, Respondents publish information about 7 Herb Formula, including, but not limited to, the following: "With Jim Feijo's addition to the [7 Herb] formula, we now have the most effective and potent formula available in the battle against tumors." CX 18 (at FTC-DCO 0142, and CX 30 (at FTC-DCO 0493).

129. On their Web site dc1pages.com, Respondents publish information about 7 Herb Formula, including, but not limited to, the following: "The 7 Herb Formula has been used by patients involved in clinical studies in cancer clinics and sold in doctor's offices around the country." CX 18 (at FTC-DCO 0157).

130. During the July 8, 2008 DCO Healthwatch radio program, James Feijo stated the following: "Here's a testimony from Pastor Wayne Hamm, Henderson, Nevada. He had the Gulf War illness. He was told that he needed surgery and radiation treatment for his cancer, that he developed skin cancer because of the Gulf War, he was exposed out there. He didn't take it. He decided to use Daniel Chapter One 7 Herb Formula, internally and topically. He also used Ezekiel Oil topically, BioShark and GDU. My skin cleared up after a few months in the late 1980s, early '99, I was told there was no trace of cancer. The FDA does not want us to let you know about this." CX 5 (at FTC-DCO 0603)).

131. During the July 14, 2008 DCO Healthwatch radio program, Patricia Feijo stated that 7 Herb Formula is "great for cancer." CX 8 (at FTC-DCO 0691).

GDU

132. Respondents publish information about GDU, including, but not limited to, the following:

PRODUCTS
. . .
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. . . .and as an adjunct to **cancer** therapy. [emphasis added]

Answer ¶ 11; CX 43; *see also J. Feijo Dep. Tr.* at 101, l. 7-9; 138 l. 22-25 - 139, l. 1-2; *P. Feijo Dep. Tr.* at 185, l. 24-25 - 186, l. 1-16.

133. Respondents publish information about GDU, including, but not limited to, the following:

If you suffer from any type of cancer, Daniel Chapter One suggests taking this products [sic], to fight it: [emphasis added]
7*Herb Formula ™. . .
Bio*Shark ™. . .
BioMixx ™. . .
GDU Caps ™. . . [emphasis added]
[depiction of bottles of BioMixx, 7 Herb Formula, Bio*Shark, and GDU]
Daniel Chapter One's Cancer solutions
To Buy the products click here
How to fight cancer is your choice!. . . [emphasis added]

Answer ¶ 9; CX 43; *see also J. Feijo Dep. Tr.* at 101, l. 7-9; 110, l. 23-25; 111, l. 13-20.

134. In their BioMolecular Nutrition Product Catalog, next to the pictures of the GDU bottles, Respondents state that GDU "[c]ontains natural proteolytic enzymes (from pineapple source bromelain) to help digest protein, ***even that of unwanted tumors*** and cysts. Helps to relieve pain, inflammation, and as ***an adjunct to cancer therapy***." CX 17 (at FTC-DCO 0062) (emphasis added).

135. In Respondents' BioGuide: The BioMolecular Nutrition Guide to Natural Health 3, Respondents published the following testimonial from Deloris Winter: "I went in for a breast examination by mammography. On 10/8/01 they said they found a mass that they believed was not cancerous, but benign. I began taking GDU six times a day: 2 before breakfast, 2 before lunch, and 2 before dinner, and in a month I went to my doctor for the breast examination, and he found nothing on either breast." CX 21 (at FTC-DCO 0331); *see also P. Feijo Dep. Tr.* at 190, l. 5-19.

136. During the July 14, 2008 DCO Healthwatch radio program, Patricia Feijo advised a consumer whose father was diagnosed with colon cancer that she should get her father "on . . . GDU, BioShark and 7 Herb Formula. And if you can get him to, you know, go right now to the website, How To Fight Cancer Is Your Choice, or you can get him a hard copy from our order center, while we have them. It's what the FTC wants to shut us down over and they certainly want us to, you know, crash the website and they want to,

you know, burn our material. They don't want us circulating How To Fight Cancer Is Your Choice." CX 8 (at FTC-DCO 0693 - 0694).

BioMixx

137. Respondents publish information about BioMixx, including, but not limited to, the following:

Bio*Mixx 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. [emphasis added]

Answer ¶ 13; CX 8; *see also J. Feijo Dep. Tr.* at 101, l. 10-11.

138. Respondents publish information about BioMixx, including, but not limited to the following:

If you suffer from any type of cancer, Daniel Chapter One suggests taking this products [sic], to fight it: [emphasis added]
7*Herb Formula ™. . .
Bio*Shark ™. . .
BioMixx ™. . . [emphasis added]
GDU Caps ™. . .
[depiction of bottles of BioMixx, 7 Herb Formula, Bio*Shark, and GDU]
Daniel Chapter One's Cancer solutions
To Buy the products click here
How to fight cancer is your choice!. . . [emphasis added]

Answer ¶ 9; CX 43; *see also J. Feijo Dep. Tr.* at 101, l. 10-11; 110, l. 23-25; 111, l. 13-20.

139. In Respondents' BioGuide: The BioMolecular Nutrition Guide to Natural Health 3, Respondents state the following regarding BioMixx: "What separates BioMixx is that it was developed specifically to maximize the immune system, particularly for those individuals whose immune systems were compromised through chemotherapy and radiation." CX 21 (at FTC-DCO 0334).

140. In their Cancer Newsletter, entitled How To Fight Cancer is Your Choice!!!, Respondents state that BioMixx "is used to assist the body in **fighting cancer** and in healing the destructive effects of **radiation** and **chemotherapy** treatments." CX 23 (at FTC-DCO 0400) (emphasis added).

E. Respondents Disseminate Claims About Their Products to Consumers.

141. Respondents operate the Web sites www.danielchapterone.com, dc1pages.com, and dc1store.com that provide information on the DCO Products. Answer ¶ 5; *J. Feijo Dep. Tr.* at 62, l. 10-13; *see also J. Feijo Dep. Tr.* at 232, l. 21-25 - 233, l. 1-19.

142. Respondents disseminate information about the DCO Products through written materials, including, but not limited to, the BioGuide, the Cancer Newsletter, the websites www.danielchapterone.com, www.7herbformula.com, www.gdu2000.com, and the radio program, "Daniel Chapter One Health Watch." CX 39 (Resp. to Interrog. No. 11); *see also J. Feijo Dep. Tr.* at 103, l. 19-21.

143. Respondent James Feijo and his wife, Patricia Feijo, are responsible for the information contained in the written materials, including the BioGuide, the Cancer Newsletter, the websites www.danielchapterone.com, www.7herbformula.com, www.gdu2000.com, and the radio program, "Daniel Chapter One Health Watch," that describe the DCO Products. CX 39 (Resp. to Interrog. No. 12); *J. Feijo Dep. Tr.* at 62, l. 10-13.

144. Consumers can locate Respondents' Web site by entering the term "cancer" in a Google search. *J. Feijo Dep. Tr.* at 136, l. 12-17.

145. FTC Investigator Michael Marino found and accessed DCO's Web site www.danielchapterone.com through Microsoft Internet Explorer. CX 1.

146. Respondent James Feijo and his wife, Patricia Feijo, co-host the Daniel Chapter One radio program for two hours a day, Monday through Friday. CX 39 (Resp. to Interrog. No. 5); *J. Feijo Dep. Tr.* at 16, l. 25 - 17, l. 4.

147. Respondents have counseled cancer patients who have called into the Daniel Chapter One radio program about taking the DCO Products. *P. Feijo Dep. Tr.* at 96, l. 10-25 - 97, l. 1-8.

148. The DCO radio program and the DCO Web site were the natural vehicle for Respondents to reach out to people in other states. *P. Feijo Dep. Tr.* at 62, l. 3-8.

F. Respondents Did Not Possess Substantiation For Such Claims At the Time They Were Made.

149. Respondents conducted no scientific testing on any of the DCO Products. *P. Feijo Dep. Tr.* at 161, l. 12-16; *see also J. Feijo Dep. Tr.* at 201, l. 22-25 - 201, l. 1-3.

150. Respondents have not conducted any double-blind studies on the DCO Products. *J. Feijo Dep. Tr.* at 58, l. 17-22; *see also J. Feijo Dep. Tr.* at 205, l. 25 - 206, l. 1-10.

151. Respondents' have not conducted any controlled studies on any of the DCO Products. *J. Feijo Dep. Tr.* at 54, l. 23-25; 55, l. 11.

152. No person has been involved in the scientific testing, research, substantiation, or clinical trials of the DCO Products. CX 39 (Resp. to Interrog. No. 15).

153. Respondents have no documents relating to their policies, procedures, or requirements for evaluating or reviewing each safety, efficacy, or bioavailability representation made for the DCO Products. CX 38 (Resp. to Req. No. 6).

154. It was not Respondents' practice to obtain scientific studies about any of the components in their products. *P. Feijo Dep. Tr.* at 120, l. 9-19.

155. Respondents did not search for scientific studies regarding the components in their products because "[w]e're working with people, and again, it's experiential and it's working with the whole person." *P. Feijo Dep. Tr.* at 120, l. 20-22.

156. James Feijo agrees that individual results may vary and that what one person says in her testimonial may not apply to other people. *J. Feijo Dep. Tr.* at 141, l. 19-25 - 142, l. 1-8.

157. According to Patricia Feijo, "only God can cure cancer." *P. Feijo Dep. Tr.* at 115, l. 19-20.

158. According to Patricia Feijo, "We [James and Patricia Feijo] do have knowledge that is experiential. We have seen how these products work. God has shown us [James and Patricia Feijo] and given us a wealth of knowledge and information that - - and we felt it is very truthful and actually our duty to share with people." *P. Feijo Dep. Tr.* at 116, l. 12-26.

BioShark

159. Respondents conducted no scientific testing on Bio*Shark. *P. Feijo Dep. Tr.* at 161, l. 12-16.

160. Respondents' substantiation for the statement that "[p]ure skeletal tissue of sharks . . . can stop tumor growth" is "from the material that [they] had read that shark cartilage provides a protein that inhibits angiogenesis and the information [they] have that [they] have . . . read and complied for many years now." *P. Feijo Dep. Tr.* at 157, l. 16-20.

161. Patricia Feijo is not aware of any other studies that might have been done on Bio*Shark or shark cartilage other than Dr. Lane's studies. *P. Feijo Dep. Tr.* at 162, l. 5-16.

162. Universal Nutrition did not conduct any testing, quality or otherwise, on Bio*Shark. *Kinney Dep. Tr.* at 45, l. 19-25 - 46, l. 1.

7 Herb Formula

163. Respondents never had an outside lab study the components of 7 Herb Formula to see whether its components actually have the effect that Respondents believe it has. *P. Feijo Dep. Tr.* at 132, l. 11-15.

164. Rather than having an outside lab study the components of 7 Herb Formula to determine whether its components were actually having the effect Respondents believe, Respondents have "experiential information [and] many testimonies, many hundreds if not thousands of testimonies." *P. Feijo Dep. Tr.* at 132, l. 16-18.

165. Respondents' basis for asserting that using 7 Herb Formula will help someone with any type of cancer is "their knowledge about the structure/function of the separate ingredients and the history of the herbal formally, so experientially . . . [they] can say generally that if you suffer from any type of cancer that [Respondents] suggest taking [7 Herb Formula]." *P. Feijo Dep. Tr.* at 175, l. 23-25 - 176, l. 1-7.

GDU

166. GDU was never subjected to clinical trials. *P. Feijo Dep. Tr.* at 190, l. 20-21.

167. Respondents have not done any studies to know whether GDU would counteract with any conventional cancer medicine someone was taking. *P. Feijo Dep. Tr.* at 194, l. 11-14.

BioMixx

168. Respondents did not conduct any tests or clinical studies on BioMixx. *P. Feijo Dep. Tr.* at 199, l. 15-18.

169. Respondents did not engage anybody else to do any kind of clinical tests on BioMixx. *P. Feijo Dep. Tr.* at 199, l. 19-21.

170. Respondents' basis for asserting that BioMixx fights cancer is "[b]ased on the structure of the ingredients, what we know that to be, and based on the function of those ingredients, what we know that to be, and based on the experiential evidence, the witness of many." *P. Feijo Dep. Tr.* at 199, l. 22-25 - 200, l. 1-4.

171. Universal Nutrition has not conducted any testing on BioMixx. *Kinney Dep. Tr.* at 50, l. 8-9.

G. Dr. Miller Confirms That There Is No Competent And Reliable Scientific Evidence To Substantiate The Claims That DCO'S Products Treat, Cure, Or Prevent Cancer.

Introduction

172. Denis R. Miller, M.D. is a board-certified pediatric hematologist/oncologist. Expert Report of Denis R. Miller, M.D., dated January 28, 2009, (hereinafter referred to as *D. Miller Expert Report*) at 1.

173. For over 40 years, Dr. Miller has directed clinical care, education, laboratory and clinical research, and administration, heading divisions or departments at University of Rochester Medical Center, New York Hospital-Cornell Medical Center, Memorial Sloan Kettering Cancer Center, and Northwestern University Medical School. *D. Miller Expert Report* at 1.

174. Dr. Miller also has served as Associate Medical Director of Cancer Treatment Centers of America ("CTCA") as well as Scientific Director of CTCA's Cancer Treatment Research Foundations. *D. Miller Expert Report* at 1.

175. As Scientific Director, Dr. Miller supervised the clinical research program and was principal investigator for a number of Phase I/II clinical studies involving treatments for hematological malignancies and cancers of the head and neck, lung, breast, pancreas, and colon. *D. Miller Expert Report* at 1-2.

176. Dr. Miller has authored or co-authored over 300 book chapters, peer-reviewed articles, and abstracts, and has served on the editorial boards of the British Journal of Hematology and the American Journal of Clinical Oncology. *D. Miller Expert Report* at 3.

177. Dr. Miller currently is the Oncology/Hematology Therapeutic Area Leader at PAREXEL International, a leading contract research organization, where he manages clinical trials for the pharmaceutical industry. *D. Miller Expert Report* at 2.

178. To constitute competent and reliable scientific evidence, a product that purports to treat, cure, or prevent cancer must have its efficacy and safety demonstrated through controlled clinical studies. *D. Miller Expert Report* at 7.

179. Only data from well-designed, controlled, clinical trials will substantiate claims that a new therapy is safe and effective to treat, cure, or prevent cancer. *D. Miller Expert Report* at 30.

180. Anecdotal reports of product efficacy are the weakest form of evidence supporting the anticancer activity of a new agent. *D. Miller Expert Report* at 12.

181. Testimonials do not substitute for a well-designed clinical trial in proving the efficacy of a supposed cancer fighting product. *D. Miller Expert Report* at 30.

182. Dr. Miller's thorough review of peer-reviewed literature and all of the documents produced by DCO indicates that there is no competent and reliable scientific evidence that the DCO Products are effective either alone or in combination with other DCO products in the treatment or cure of cancer, in inhibiting tumor formation, and in preventing the destructive effects of radiation and chemotherapy. *D. Miller Expert Report* at 31.

Bio*Shark

183. Dr. Miller's review of the peer-reviewed literature and all of the documents Respondents submitted as substantiation indicates that there was no competent and reliable scientific evidence that Bio*Shark inhibits tumor growth in humans or that it is effective in the treatment of cancer in humans. *D. Miller Expert Report* at 13.

184. Dr. Miller found that there were no adequate and well-controlled studies demonstrating that Bio*Shark is antiangiogenic or is effective in the treatment of cancer, and even supporting non-clinical studies of crude or partially-purified shark cartilage products were extremely limited, particularly with regard to mechanisms of action, pharmacokinetics, pharmacodynamics, and dose response. *D. Miller Expert Report* at 17.

185. Dr. Miller observed that Respondents' reliance on Dr. I. William Lane's book, "Sharks Don't Get Cancer" was misplaced, as studies at Johns Hopkins University indicate that sharks do indeed get cancer. *D. Miller Expert Report* at 16.

7 Herb Formula

186. Dr. Miller's review of the peer-reviewed literature and all of the documents Respondents submitted as substantiation indicates that there was no competent and reliable scientific evidence that 7 Herb Formula inhibits tumor formation and is effective in the treatment or cure of cancer in humans. *D. Miller Expert Report* at 18.

187. Dr. Miller found neither non-clinical nor clinical studies supporting claims that 7 Herb Formula or any of its individual ingredients are effective anticancer agents or inhibit tumor formation. *D. Miller Expert Report* at 19.

188. Any relevant studies on the ingredients Burdock root, Cat's Claw, sheep sorrel, slippery elm bark, turkish rhubarb root, Siberian ginseng, and watercress were performed either in vitro or on animals, not on humans with cancer. *D. Miller Expert Report* at 19-22.

GDU

189. Dr. Miller's review of the peer-reviewed literature and all of the documents Respondents submitted as substantiation indicates that there was no competent and reliable scientific evidence that GDU eliminates tumors and is effective in the treatment of cancer in humans. *D. Miller Expert Report* at 22.

190. Dr. Miller found no randomized, controlled clinical trials of any of the individual components of GDU or of GDU itself in patients with cancer. *D. Miller Expert Report* at 27.

191. Dr. Miller, however, did note that curcumin (tumeric), one of GDU's ingredients, is currently being evaluated in controlled clinical trials to determine its potential as a chemoprotective and cancer preventive agent. *D. Miller Expert Report* at 22 .

192. Animal studies have suggested that curcumin may have activity as a cancer preventive and therapeutic agent. *D. Miller Expert Report* at 23.

193. Nevertheless, Dr. Miller cautioned that some studies have suggested that curcumin may actually inhibit the anticancer activity of some approved anticancer agents as well as exacerbate iron deficiency. *D. Miller Expert Report* at 27.

194. Thus, Dr. Miller advised that further research on curcumin was necessary. *D. Miller Expert Report* at 27.

BioMixx

195. Dr. Miller's review of the peer-reviewed literature and all of the documents Respondents submitted as substantiation indicates that there was no competent and reliable scientific evidence that BioMixx is effective in the treatment of cancer and heals the destructive effects of radiation and chemotherapy. *D. Miller Expert Report* at 27.

196. Dr. Miller found that there are no reported studies of either BioMixx or its constituent ingredients being effective in the treatment of cancer. *D. Miller Expert Report* at 27-28.

197. Dr. Miller also found "absolutely no data" to support the claim that BioMixx is used to heal the destructive effects of radiation and chemotherapy treatments. *D. Miller Expert Report* at 29.

II. COMPLAINT COUNSEL'S PROPOSED CONCLUSIONS OF LAW

1. The acts and practices charged in the Complaint in this matter took place in or affecting commerce within the meaning of the Federal Trade Commission Act, as amended. Nationwide advertising, marketing, or sales activity of the sort that Respondents engaged in constitutes "commerce" under the FTC Act. *See, e.g., P.F. Collier & Son Corp. v. FTC*, 427 F.2d 261, 272 (6th Cir. 1970); *see, e.g., Ford Motor Co. v. FTC*, 120 F.2d 175, 183 (6th Cir. 1941) (noting that commerce also includes the actions, communications, and other acts or practices that are incident to those activities).

2. The Complaint charges Respondents with violating Sections 5 and 12 of the FTC Act. The Commission has jurisdiction over the subject matter of this proceeding pursuant to those sections of the FTC Act. Section 5(a) provides that "unfair or deceptive acts or practices in or affecting commerce are hereby declared unlawful." 15 U.S.C. § 45(a)(1). The FTC is "empowered and directed" to prevent unfair or deceptive practices in commerce by "persons, partnerships, or corporations." 15 U.S.C. § 45(a)(2).

3. The Commission has jurisdiction over persons, partnerships, and corporations. 15 U.S.C. § 45(a)(2). "Corporations" are defined in Section 4 of the FTC Act as "any company. . .which is organized to carry on business for its own profit or that of its members." 15 U.S.C. § 44. Therefore, the Commission has jurisdiction over Respondent DCO and Respondent James Feijo.

4. Section 12 prohibits the dissemination of "any false advertisement" in order to induce the purchase of "food, drugs, devices, or cosmetics." 15 U.S.C. § 52(a)(2). For the purposes of Section 12, the DCO Products are "food" or "drugs." 15 U.S.C. § 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"). Section 12 defines "false advertisement" as "an advertisement, other than labeling, which is misleading in a material respect." 15 U.S.C. § 55.

5. Respondents' speech is not protected by the First Amendment because it is deceptive commercial speech. The U.S. Supreme Court has held that when the content of commercial speech is false or misleading, it can be suppressed. "There 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 communication more likely to deceive the public than to inform it." *Central Hudson Gas & Elec. Corp. v. Public Service Commission of New York*, 447 U.S. 557, 563, 100 S.Ct. 2343, 2350 (1980) (*citing Friedman v. Rogers*, 440 U.S. 1, 99 S.Ct. 887 (1979)). Accordingly, "[t]he more limited protection accorded commercial speech permits the FTC to act when necessary to challenge false or deceptive advertising." *In re Reynolds*, 1998 WL 490114 at *4, *citing Thompson Medical Co. v. FTC*, 791 F.2d 189 (D.C.Cir. 1986), *cert. denied*, 107 S.Ct. 1289 (1987); *Sears, Roebuck & Co. v. FTC*, 676 F.2d 385 (9th Cir. 1982); *Warner-Lambert Co. v. FTC*, 562 F.2d 749 (D.C.Cir. 1977), *cert. denied*, 435 U.S. 950 (1978); *Beneficial Corp. v. FTC*, 542 F.2d 611 (3d Cir. 1976), *cert. denied*, 430 U.S. 983 (1977). Whether speech is properly deemed "commercial speech" is a question of fact, and is based on a consideration of a variety of factors, including whether the speech (1) proposes a commercial transaction, *Central Hudson Gas & Electric Corp*,

447 U.S. at 562; (2) refers to specific products, *Bolger v. Youngs Drugs Products Corp.*, 463 U.S. 60, 66-67, 103 S.Ct. 2875, 2881 (1983), *Friedman*, 440 U.S. at 11, 99 S.Ct. at 895; and (3) has an economic or commercial motivation, *Bolger*, 447 U.S. at 66-67; *In Re Primus*, 436 U.S. 412, 438, 98 S.Ct. 1893, 1908 n.32 (1978). Here, (1) Respondents are engaging in deceptive commercial speech, (2) Respondents promote and advertise the Challenged Products, (3) the Challenged Products are offered for sale at not insignificant prices, and (4) the advertisements refer to specific products and attributes.

6. Respondents' deceptive advertising that the DCO Products prevent, cure, and/or treat cancer violates Sections 5 and 12 of the FTC Act. An advertisement is deceptive under the FTC Act if it is likely to mislead consumers, acting reasonably under the circumstances, in a material respect. *Kraft, Inc. v. FTC*, 970 F.2d 311, 314 (citing Sections 5 and 12); *FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285, 297 (D.Mass 2000); *Telebrands Corp.*, 140 F.T.C. 278, 290 (2005), *aff'd*, 457 F.3d 354 (4th Cir. 2006); *In re Thompson Medical Co.*, 104 F.T.C. 648, 788 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987); *Cliffdale Assocs. Inc.*, 103 F.T.C. 110, 164-66 (1984); *FTC Policy Statement on Deception*, 103 F.T.C. 174 (1984) (appended to *Cliffdale Assocs.*).

7. In implementing the "likely to mislead" standard, "the [FTC] examines the overall net impression of an ad[vertisement] and engages in a three-part inquiry: (1) what claims are conveyed in the advertisement; (2) are those claims false or misleading; and (3) are those claims material to prospective consumers." *Kraft*, 970 F.2d at 314. The FTC may use its own reasoned analysis to determine what claims an advertisement conveys. *See Kraft*, 970 F.2d at 318 ("[i]n determining what claims are conveyed by a challenged advertisement, the [FTC] relies on . . . its own viewing of the ad"); *see also FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 385 (1965). In determining whether an advertisement conveys a claim, the Commission looks to the overall, net impression created by the advertisement, through the interaction of different elements in the advertisement, rather than focusing on the individual elements in isolation. *Stouffer Foods Corp.*,118 F.T.C. 746, 799 (1994); *Kraft*, 114 F.T.C. 40 at 122 (1991); *American Home Prods. Corp. v. FTC*, 695 F.2d 681, 688 (3d Cir. 1982); *FTC Policy Statement on Deception*, 103 F.T.C. 174, 179 (1984) (appended to *Cliffdale Assocs.*) (emphasizing importance of considering "the entire mosaic, rather than each tile separately").

8. Features of an advertisement such as a product name, visual images, and the use of testimonials may imply claims. *Jacob Siegel v. FTC*, 327 U.S. 608, 609 (1946); *Kraft*, 114 F.T.C. at 322; *Thompson Medical*, 104 F.T.C. at 793 and 811-12; *Porter & Dietsch, Inc. v. FTC*, 605 F.2d 294, 301, 303 (7th Cir. 1979).

9. To determine how "reasonable consumers" interpret a claim, the Commission considers the target market for the advertisement. When the target market consists of "desperate consumers with terminal illnesses," the FTC has shown particular care in evaluating deceptive acts or practices. *FTC v. Travel King, Inc.*, 86 F.T.C. 715 (1975).

10. Advertising claims may be express or implied. *Kraft,* 970 F.2d at 318. Express claims directly state the representation at issue, while implied claims make representations without direct statements. *Id.* at 318 and 319 n.4; *Thompson Medical*, 104 F.T.C. at 788-89. The courts and the FTC have recognized consistently that implied claims fall along a continuum, from those which are so conspicuous as to be virtually synonymous with

express claims, to those which are barely discernible. *See, e.g., Kraft*, 970 F.2d at 319; *FTC v. Febre*, No. 94 C 3625, 1996 WL 396117, at *4 (N.D. Ill. July 2, 1996) (magistrate judge recommendation), adopted by 1996 WL 556957 (N.D. Ill. Sept. 25, 1996), *aff'd*, 128 F.3d 530 (7th Cir. 1997); *see also Bronson Partners*, 564 F. Supp. at 127-28 (an advertisement's statements were "so clear, repetitive, and unambiguous that they constitute[d] the functional equivalent of express claims").

11. This Court has the authority to rule as to the conveyed meaning of advertisements and promotional materials based on a facial analysis of these advertisements or promotional materials. *Automative Breakthrough Sciences, Inc.*, Docket Nos. 9275-77, 1996 FTC LEXIS 252, at *44, (Partial Summary Decision May 22, 1996) (citing *Kroger Co.*, 98 F.T.C. at 726, 729 n.11; *Ford Motor Co.*, 87 F.T.C. 756, 794-97 (1976)).

12. Commission law recognizes that advertisements may be susceptible to more than one reasonable interpretation. *Kraft*, 114 F.T.C. at 120 n.8. "Statements susceptible of both a misleading and a truthful interpretation will be construed against the advertiser." *Bronson Partners*, 564 F. Supp. 2d 119, 127 n.6 (D. Conn. 2008) (quoting *Country Tweeds, Inc. v. FTC*, 326 F.2d 144, 148 (2d Cir. 1964)).

13. If the facial analysis demonstrates that the claims were conveyed in the advertisements and promotional materials, the Court need not consider extrinsic evidence even if such evidence is offered. *Novartis*, 127 F.T.C. 580, 680 (1996); *Stouffer*, 118 F.T.C. at 798; *Kraft, Inc.*, 114 F.T.C. at 121; *Thompson Medical*, 104 F.T.C. at 789.

14. Respondents' advertisements and promotional materials for the DCO Products, which include, but are not limited to, Exhibits A-D of the Complaint, convey bold promises of cancer prevention, treatment, and cure that, if not express, are so strongly implied as to be virtually express.

15. Respondents' representations that the DCO products prevent, treat, or cure cancer are misleading. The Commission may prove an advertisement is deceptive or misleading by showing that an express or implied claim is false, or by showing that a claim is unsubstantiated because Respondents lacked a reasonable basis for asserting that the claim was true. *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1096 (9th Cir. 1994); *FTC v. Sabal*, 32 F. Supp. 2d 1004, 1007 (N.D. Ill. 1998). Proof of intent to deceive is not required, and "the subjective good faith of the advertiser is not a valid defense to an enforcement action brought under section 5(a)." *Sabal*, 32 F. at 1007; *see also FTC v. World Travel Vacation Brokers, Inc.*, 861 F.2d 1020, 1029 (7th Cir. 1988).

16. The "reasonable basis" test is an objective standard. Advertisers must possess at least the level of substantiation expressly or impliedly claimed in the advertisement. *See Honeywell, Inc.*, 126 F.T.C. 202 (1998); *FTC v. Natural Solution, Inc.*, No. CV 06-6112-JFW, 2007 U.S. Dist. LEXIS 60783, at *10 (C.D. Cal. Aug. 7, 2007) (citing *FTC v. U.S. Sales Corp.*, 785 F. Supp. 737, 748 (N.D. Ill. 1992)).

17. The Commission has the burden of proving that Respondents' purported substantiation is inadequate, but is not required to conduct or present clinical studies showing that the products do not perform as claimed. *See FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 959 (N.D. Ill. 2006) *aff'd* 512 F.3d 858 (7th Cir. 2008), (citing *Sabal*, 32 F. Supp. 2d at 1008-09).

18. For health and safety claims, advertisers must possess "competent and reliable scientific evidence" substantiating their claims in order to have a "reasonable basis" for such claims. *See FTC v. National Urological Group, Inc.*, No. 1:04-CV-3294-CAP, 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"); *Natural Solution*, 2007 U.S. Dist. LEXIS 60783, at *11-13 (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); *FTC v. QT, Inc.*, 448 F. Supp. at 961 ("Reasonable basis" required defendants to have "competent and reliable scientific evidence" when they made the claim that the Q-Ray bracelet provides immediate, significant, or complete pain relief).

19. "Competent and reliable scientific evidence" is typically defined as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." *See, e.g., Brake Guard Products, Inc.*, 125 F.T.C. 138 (1998); *ABS Tech Sciences, Inc.*, 126 F.T.C. 229 (1998).

20. Courts have consistently found or upheld that double-blind, placebo-controlled studies are required to provide adequate substantiation for the truthfulness of various health-related efficacy claims. *See, e.g., FTC v. SlimAmerica, Inc.*, 77 F.Supp. 2d 1263, 1274 (S.D. Fla. 1999) ("Scientific validation of the defendants' product claims requires a double blind study of the combination of ingredients used in [the product formula]."); *Sabal*, 32 F.Supp. 2d at 1008-09 (rejecting study as valid substantiation, in part, because it was not blinded or placebo-controlled); *FTC v. Cal. Pac. Research, Inc.*, 1991 U.S. Dist. LEXIS 12967, at *12-13 (D. Nev. Aug. 27, 1991) (only placebo-controlled, double-blind clinical studies meet "the most basic and fundamental requirements for scientific validity and reliability"); *FTC v. QT, Inc.*, 448 F. Supp. 2d at 962 ("[W]ith medical, health-related claims, a well-conducted, placebo-controlled, randomized, double-blind study, the gold standard, should have been conducted. . . . Defendants would not be required to have a gold-standard study to substantiate the Q-Ray bracelet if they did not make such a strong, medical claim").

21. Respondents use testimonials to make representations to consumers, but courts consistently have found such anecdotal testimonial evidence inadequate to support such claims. *See, e.g., Direct Marketing Concepts*, 569 F. Supp. 2d at 304 (entering summary judgment for FTC where it was undisputed that respondents had no scientific studies supporting health-related efficacy claims, despite testimonials from customers); *FTC v. Simeon Mgmt. Corp.*, 579 F.2d 1137, 1143-44 (9th Cir. 1978) (anecdotal evidence of weight loss insufficient to support weight loss claims); *Koch v. FTC*, 206 F.2d 311, 316 (6th Cir. 1953) (evidence regarding case histories did not support cancer claims); *FTC v. QT, Inc.*, 512 F.3d 858, 862 (7th Cir. 2008) ("a person who promotes a product that contemporary technology does not understand must establish that this 'magic' actually works"; "[p]roof is what separates an effect new to science from a swindle" and testimonials "are not a form of proof because most testimonials represent a logical fallacy: *post hoc ergo propter hoc*. (A person who experiences a reduction in pain after donning the [Q-Ray] bracelet may have enjoyed the same reduction without it. That's

why the 'testimonial' of someone who keeps elephants off the streets of a large city by snapping his fingers is the basis of a joke rather than proof of cause and effect)").

22. Respondents did not possess a reasonable basis for their advertising representations that the DCO products prevent, treat, and/or cure cancer, and such representations are misleading.

23. Respondents' advertising representations that the DCO products prevent, treat, or cure cancer are material. "A 'material' misrepresentation is one that involves information that is important to consumers, and that is therefore likely to affect a consumer's choice of or conduct regarding a product. Proof of actual consumer injury is not required." *Kraft, Inc.*, 114 F.T.C. 40, 1991 FTC LEXIS 38, *38 (1991). Courts have interpreted the *FTC Deception Policy Statement* to "presume[] materiality for express claims and claims that significantly involve health, safety, or other issues that would concern reasonable consumer[s]." *QT, Inc.*, 448 F. Supp. 2d, at 965-66 (citing *Kraft, Inc.*, 970 F.2d at 322); *see also FTC v. Cliffdale Assocs.*, 103 F.T.C. at 176-84 (1984) (claims involving "health, safety, or other areas with which the reasonable consumer would be concerned, [such as] . . . the purpose, safety, efficacy, or cost of the product . . . [or] its durability, performance, warranties or quality" are material as a matter of law). 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*, 564 F. Supp. 2d at 135-36.

24. In this case, Respondents' serious health claims were both express and so strongly implied as to be virtually express that they should be presumed material. Moreover, 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.

25. Respondents did not use proper DSHEA disclaimers, but even if they did, DSHEA disclaimers cannot negate unsupported disease claims. Advertisers cannot use fine print to contradict other statements in an advertisement or to clear up misimpressions the advertisement would otherwise leave. *FTC Policy Statement on Deception*, 103 F.T.C. 110 (1984) at 180-81. To be effective, disclosures must be clear and conspicuous. *See, e.g., Thompson Med.*, 104 F.T.C. at 842-43 (1984). Any such disclaimer also must be in boldface type and is permissible only if the claim is properly substantiated. *U.S. v. Lane Labs, Inc.*, 324 F. Supp. 2d 547, 565 (D.N.J. 2004) (stating that these types of claims are permissible under DSHEA only if the manufacturer of the dietary supplement has substantiation that the statement is truthful and not misleading).

26. Therefore, Respondents violated Sections 5 and 12 of the FTC Act and Complaint Counsel is entitled to the proposed order against Respondents.

27. Individual Respondent James Feijo may be held directly liable under Sections 5 and 12 of the FTC Act for the violations of his corporation given that he participated directly in or had the authority to control the deceptive acts or practices. *FTC v. Amy Travel Serv., Inc.*, 875 F.2d 564, 573 (7th Cir. 1989). Authority to control can be established by an individual's "active involvement in business affairs and the making of corporate policy, including assuming the duties of a corporate officer." *Id.* "An individual's status as a corporate officer gives rise to a presumption of ability to control a small, closely-held corporation. 'A heavy burden of exculpation rests on the chief executive and shareholder

of a closely-held corporation whose stock-in-trade is overreaching and deception.'" *Windward Marketing*, 1997 U.S. Dist. LEXIS 17114, at *38 (quoting *Standard Educ., Inc. v. FTC*, 475 F.2d 401, 403 (D.C. Cir. 1973)). James Feijo both participated directly in and had the authority to control the deceptive representations.

28. The proposed order is appropriate for Respondents' violations. The Commission has dealt numerous times before with cancer claims for products containing various ingredients appearing in the DCO Products and these cases resulted in consent orders with requirements similar to those in the proposed order Complaint Counsel seeks here. *In re Native Essence Herb Co.*, No. 9328 (F.T.C. Jan. 29, 2009) (order withdrawing matter from adjudication for the purpose of considering a proposed consent agreement) (cat's claw); *FTC v. Westberry Enter., Inc.*, 2008 F.T.C. LEXIS 99 (F.T.C. Sept. 18, 2008) (essiac); *In re Jenks*, 2008 F.T.C. LEXIS 94 (F.T.C. Sept. 18, 2008) (essiac); *FTC v. Natural Solution, Inc.*, No. CV 06-06112-JFW (JTLx) (C.D. Cal. Sept. 4, 2007) (judgment and permanent injunction) (echinacea); *See, e.g., In re ForMor Inc.*, 132 F.T.C. 72 (2001) (shark cartilage); *In re Forrest*, 132 F.T.C. 229 (2001) (echinacea); *In re Miller*, 2000 F.T.C. LEXIS 70 (F.T.C. May 16, 2000) (essiac); *In re Body Systems Tech., Inc.*, 128 F.T.C. 299 (1999) (shark cartilage and cat's claw); *In re Nutrivida, Inc.*, 126 F.T.C. 339 (1998) (shark cartilage); *In re Am. Life Nutrition, Inc.*, 113 F.T.C. 906 (1990) (bee pollen).

29. Therefore, entering the proposed order is appropriate. The proposed order prohibits Respondents from making the types of misrepresentations challenged in the Complaint and provides fencing-in relief, requiring Respondents to possess competent and reliable scientific evidence supporting future claims about the health benefits, performance, safety, or efficacy of any dietary supplement, food, drug, or other health-related product, service, or program. The facts and the law warrant the relief sought here. *See Telebrands Corp. v. FTC*, 457 F.3d 354, 358 (4th Cir. 2006) ("Congress has given the FTC primary responsibility for devising orders to address... deceptive practices, and the FTC has broad discretion to do so"); *FTC v. Colgate-Palmolive,* 380 U.S. 374, 395 (1965) ("reasonable for the [FTC] to frame its order broadly enough to prevent respondents from engaging in similar illegal practices in future advertisements").

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on March 30, 2009, I have filed and served the attached **COMPLAINT COUNSEL'S PRE-TRIAL BRIEF, AND PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW** upon the following as set forth below:

The original and one paper copy via overnight delivery and one electronic copy via email to:

Donald S. Clark, Secretary
Federal Trade Commission
600 Pennsylvania Ave., N.W., Room H-159
Washington, DC 20580
E-mail: secretary@ftc.gov

Two paper copies via overnight delivery to:

The Honorable D. Michael Chappell
Administrative Law Judge
600 Pennsylvania Ave., N.W., Room H-528
Washington, DC 20580

One electronic copy via email and one paper copy via overnight delivery to:

James S. Turner, Esq.
Betsy Lehrfeld, Esq.
Martin Yerick, Esq.
Swankin & Turner
1400 16th St., N.W., Suite 101
Washington, D.C. 20036
jim@swankin-turner.com

One electronic copy via email to:

Michael McCormack, Esq.
M.mccormack@mac.com

Elizabeth K. Nach
Complaint Counsel