

ORIGINAL

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



In the Matter of)

DANIEL CHAPTER ONE,)
a corporation, and)

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

Docket No. 9329

Public Document

COMPLAINT COUNSEL'S POST TRIAL BRIEF

Pursuant to the Court's April 29, 2009 Order on Post Trial Briefs, Complaint Counsel submit their Proposed Findings of Fact and Conclusions of Law, Post Trial Brief in support thereof, and Exhibit and Witness Indices.

Respectfully submitted,

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Dated: May 28, 2009

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TAB 1

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FINDINGS OF FACT AND CONCLUSIONS OF LAW**

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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) ¶ 1; Complaint Counsel's Trial Exhibit (hereinafter referred to as CX __) 35; J. Feijo, Hearing on Jurisdiction Transcript, April 21, 2009, (hereinafter referred to as HOJ Tr. __) at 84).
2. According to its Articles of Incorporation, Respondent DCO's mailing and principal location is 21916 Southeast 392nd Street, Enumclaw, Washington, but neither Respondent DCO nor Respondent James Feijo maintains a building at that address. (CX 31; J. Feijo, HOJ Tr. 93-94).
3. According to Respondents, their 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 R15 (J. Feijo, Dep. __)) at 99).
4. Respondent James Feijo is responsible for the activities of Respondent DCO as its Overseer. (Answer ¶ 2; J. Feijo, HOJ Tr. 70; J. Feijo, Trial Transcript (hereinafter referred to as Tr. __) at 416).
5. Patricia Feijo, Respondent James Feijo's wife, is the secretary for DCO. (Deposition of Patricia Feijo, January 14, 2009, (hereinafter referred to as R16 (P. Feijo, Dep. at __) at 10, 52; P. Feijo, HOJ Tr. 276).
6. Respondent James Feijo and his wife, Patricia, originally started DCO as a health food store in 1986. (R16 (P. Feijo, Dep. at 39-40); J. Feijo, Tr. 418).
7. Respondent James Feijo sold DCO products prior to registering as a corporation sole. (R15 (J. Feijo, Dep. at 224)).
8. Respondents offer 150 to 200 products today, including Bio*Shark, 7 Herb Formula, GDU, and BioMixx (collectively, the "DCO Products"). (R15 (J. Feijo, Dep. at 37); P. Feijo, Tr. 392; Marino, HOJ Tr. 54; J. Feijo, HOJ Tr. 314-15).
9. DCO has two buildings in Rhode Island – one is the Order Center and the other is the warehouse. (J. Feijo, HOJ Tr. 110).
10. Messiah Y'Shua Shalom, a Washington corporation sole, owns the property that Respondents use in Rhode Island. (R15 (J. Feijo, Dep. at 72-73); CX 35).
11. Respondent James Feijo is the overseer for Messiah Y'Shua Shalom. (R15 (J. Feijo, Dep. at 72-73); CX 35).
12. Respondents practice a science they call BioMolecular Nutrition. (CX 21).
13. According to Respondents, "[t]here are two aspects of BioMolecular Nutrition, the spiritual and the physical." (CX 21).

14. “The principles of BioMolecular Nutrition were those missing principles needed to bind together those of the nutritionists and the biochemists.” (CX 21).
15. 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. The FTC Has Jurisdiction Over Respondent DCO, which is a Corporation within the Meaning of Section 4 of the FTC Act, and Respondent James Feijo

16. Respondent DCO was previously incorporated as “Daniel Chapter One, Inc.,” a Rhode Island for-profit corporation, on October 30, 1990. (CX 50; J. Feijo, HOJ Tr. 101).
17. Respondent DCO’s Articles of Incorporation from 1990 state that the purposes for which Daniel Chapter One, Inc. was organized were: “To engage in the sale, retail, wholesale and distribution of health products, including but not limited to health foods and supplements, namely those with special nutritive qualities and values.” (CX 50; J. Feijo, HOJ Tr. 101-02).
18. Consistent with its status as a for-profit corporation incorporated in Rhode Island, Respondent DCO filed annual reports from 1991 through 1997, during which time the stated character of the business remained substantially similar, namely “To engage in the sale, retail, wholesale and distribution of health products, including health foods and supplements.” (CX 50; J. Feijo, HOJ Tr. 102-08).
19. Each of these for-profit corporation annual reports bears the signature of Respondent James Feijo. (J. Feijo, HOJ Tr. 102-08).
20. DCO is not registered with the Internal Revenue Service as a charity. (R15 (J. Feijo, Dep. at 45); J. Feijo, HOJ Tr. 209).

1. Respondents Are Engaged in Commerce

21. Respondents distribute the DCO Products in commerce. (Answer ¶ 4; R15 (J. Feijo, Dep. at 102); Marino, HOJ Tr. 53-55; Harrison, Tr. 295-96).
22. Anyone can buy and use DCO products, including people who do not believe in God. (Marino, HOJ Tr. 55; P. Feijo, Tr. 410-11).
23. Respondent DCO has an 800 number and a call center for consumers to purchase the DCO Products. (R16 (P. Feijo, Dep. at 67); J. Feijo, HOJ Tr. 212; P. Feijo, HOJ Tr. 273-74; J. Feijo, HOJ Tr. 168, 204, 211-12).
24. Respondent James Feijo created, managed, and maintained the toll-free telephone number, designed so that consumers can order the DCO Products. (CX 39).

25. 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).
26. Respondents operate the Web site www.danielchapterone.com. (Answer ¶ 5; R15 (J. Feijo, Dep. at 62)).
27. DCO also operates the Web sites dclpages.com and dclstore.com. (R15 (J. Feijo, Dep. at 232-33)).
28. Respondents advertise their products on the Internet through the BioGuide, the Cancer Newsletter, and The Most Simple Guide to the Most Difficult Diseases, each of which is available to read or download from the Internet. (CX 1; CX 13 at FTC-DCO 0013; CX 13A at FTC-DCO 2828A; CX 29 at FTC-DCO 0430; P. Feijo, Tr. 395; J. Feijo, Tr. 453-55; Tr. at 264).
29. Consumers learn of DCO’s 800 number from the DCO Web site, the BioGuide, and Respondents’ radio program, “Daniel Chapter One Health Watch.” (P. Feijo, HOJ Tr. 273-74; CX 21; CX 29 (FTC-DCO 0451)).
30. The “Daniel Chapter One Health Watch” radio program is broadcast on the “Accent Radio Network,” a subsidiary of Respondent DCO. (CX 32; R15 (J. Feijo, Dep. at 235)).
31. The Accent Radio Network Web site states, “Put your money where our mouth is: Accent Radio Network! We can do it for you whether you’re in a small local market or you want to hit the big time.” (CX 32). The Web site also contains an advertising schedule, which lists Accent Radio Network’s advertising rates. (CX 32; J. Feijo, HOJ Tr. 112).
32. Respondent James Feijo’s daughter, Jill Feijo, has supervised Respondent DCO’s Order Center for the past nine years and has taken telephone orders. (CX 39; J. Feijo, HOJ Tr. 204).
33. DCO also accepts consumers’ orders on the Internet. (P. Feijo, Tr. 397; Marino, HOJ Tr. 54).
34. DCO’s Web site contains a tab inviting consumers to shop at DCO’s “On-Line Store.” (CX 12-15, 43).
35. DCO’s Web site contains an icon inviting consumers to “Buy Now.” (CX 12; CX 12A; CX 13; CX 13A; CX 14; CX 14A; CX 15; CX 43; J. Feijo, HOJ Tr. 144).
36. 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. (R15 (J. Feijo, Dep. at 232)).
37. Over a thousand consumers have purchased DCO’s products. (R16 (P. Feijo, Dep. at 57)).

38. Respondents have generated approximately \$2 million in annual sales for the years 2006, 2007, and 2008 for all of DCO's two-hundred products. (CX 44; R15 (J. Feijo, Dep. at 206, 212); J. Feijo, HOJ Tr. 109, 223-24).
39. There is no indication in the BioMolecular Nutrition Product Catalog that the price listed is for a donation. (R15 (J. Feijo, Dep. at 158); R16 (P. Feijo, Dep. at 76-77); J. Feijo, HOJ Tr. 140).
40. There is no mention of the DCO ministry in the BioMolecular Nutrition Product Catalog. (R15 (J. Feijo, Dep. at 161)).
41. On January 3, 2008, FTC investigator Michael Marino ("Marino") purchased the DCO Products from Respondents' Web site. (CX 10; Marino, HOJ Tr. 53-55, 62-67).
42. At the time of Marino's purchase, each of the DCO Products was displayed on Respondents' Web site with a picture of the product, a short description of the product, and a corresponding price. (Marino, HOJ Tr. 54).
43. There were no indications on Respondents' Web site that the DCO Products could be obtained in exchange for a donation, that these products could be purchased for a reduced price, or that these products could be received for free. (Marino, HOJ Tr. 54-55).
44. 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; Marino, HOJ Tr. 56-59).
45. One of the emails Marino received, which was sent the day after he purchased the DCO Products, stated, "We appreciate your business with us," and offered a ten percent discount on a subsequent purchase. (Marino, HOJ Tr 59).
46. On or about January 24, 2008, Marino received the DCO Products. (CX 34; Marino, HOJ Tr. 60).
47. 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; Marino, HOJ Tr. 55-56, 61).
48. 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; Marino, HOJ Tr. 60).
49. The shipment of the DCO Products did not contain any documents indicating that the purchase was a "donation" or thanking the purchaser for making a "donation" to Daniel Chapter One. (CX 34; Marino, HOJ Tr. 60).
50. 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; Marino, HOJ Tr. 58, 60).
51. DCO’s shipping and handling fees for its products are \$20.95. (R15 (J. Feijo, Dep. at 152-53)).
 52. DCO offers coupons to consumers for their next online store order. (R15 (J. Feijo, Dep. at 154); Marino, HOJ Tr. 59; J. Feijo, HOJ Tr. 149-50).
 53. Respondents run promotions from time to time to “give [consumers] more of an opportunity to . . . get things at a lower rate.” (R15 (J. Feijo, Dep. at 154)).
 54. For example, consumers can buy multiple bottles and get a bottle free. (R15 (J. Feijo, Dep. at 232)).
 55. Consumers can also join DCO’s Bucket-A-Month Club to obtain volume discounts on DCO’s products. (CX 29 at FTC-DCO 0430; J. Feijo, HOJ Tr. 140-41).
 56. On their Web site dclstore.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 (emphasis added)).
 57. Respondents’ Cancer Newsletter, entitled How to Fight Cancer is Your Choice!!!, costs \$5.95. (CX 23; CX 24).
 58. In their Cancer Newsletter, Respondents instruct consumers to call “1-800-504-5511” to order their products. (CX 23; CX 24).
 59. In their Cancer Newsletter, Respondents state that their “[l]atest Bioguide” is “[o]nly \$9.95.” (CX 23; CX 24).
 60. The Cancer Newsletter is available online on DCO’s web site. (CX 13 at FTC-DCO 0013; CX 13A at FTC-DCO 2828A; Tr. 264).
 61. Respondents’ publication entitled The Most Simple Guide to the Most Difficult Diseases: The Doctors’ How-To Quick Reference Guide costs \$12.95. (CX 20).
 62. The Most Simple Guide can be accessed by anyone online. (P. Feijo, Tr. 395; J. Feijo, Tr. 453-55).
 63. A number of stores nationally sell DCO’s products, including stores in Georgia and a store in Pennsylvania. (R16 (P. Feijo, Dep. at 72)).
 64. Respondents use distributors in various states who carry DCO’s products. (J. Feijo, HOJ Tr. 132-35).
 65. Respondents have created a brochure entitled “The Truth Will Set You Free” to convince companies to become carriers of DCO products. (CX 22; J. Feijo, HOJ Tr. 135). Among the benefits listed in the brochure are financial rewards such as “boost[ed] sales” and “earnings potential.” (CX 22; J. Feijo, HOJ Tr. 136). The brochure also states that

- Respondent DCO “is the ONLY nutrition company where the owners personally tell thousands of people to visit your office or store.” (CX 22).
66. Respondent have called some distributors of DCO products “silver-line carriers” and “gold-line carriers.” (J. Feijo, HOJ Tr. 125). “Gold-line carriers” maintain a broader range of products than the “silver-line carriers.” (J. Feijo, HOJ Tr. 126).
 67. Respondents’ distributors have included stores such as Nature’s Pharmacy in Altoona, Florida; Herb Shop Unlimited, in Adel, Georgia; The Poppyseed in Peculiar, Missouri; Herbal Connection in Lake Park, Georgia; Beehive Natural Foods in Poplar Bluff, Missouri; Discount Nutrition in Monroeville, Pennsylvania; and Organic Pride in Plant City, Florida. (J. Feijo, HOJ Tr. 131-32).
 68. Respondents’ distributors have also included chiropractic centers. (J. Feijo, HOJ Tr. 134-35).
 69. Doctors and stores that carry DCO’s product line get the product at a lesser price because they are going to be selling it. (R16 (P. Feijo, Dep. at 71)).
 70. One doctor who is a distributor places about a 40 percent markup on the DCO products he sells. (Mink, HOJ Tr. 287-88; J. Feijo, HOJ Tr. 311).
 71. On their Web site dc1store.com, Respondents promote an affiliate program, stating the following: “**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 (emphasis in bold in original; emphasis in italics supplied)).
 72. An entity does not have to be a religious ministry to become an affiliate of Respondent DCO. (J. Feijo, HOJ Tr. 114).
 73. The trademark symbol appears next to Respondents’ term “BioMolecular Nutrition” and Respondents’ products 7 Herb Formula, GDU, and BioMixx. (CX 17).
 74. 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).

BioShark

75. Bio*Shark is a product that contains, among other ingredients, Shark Cartilage. (Answer ¶ 6). 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).
76. 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).
77. 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 R17 (Bauhoffer-Kinney, Dep. at ___)) at 44).
78. 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. (R17 (Bauhoffer-Kinney, Dep. at 45)).
79. Universal Nutrition does two things - it has its own brand of products, and it also is a private label manufacturer. (R17 (Bauhoffer-Kinney, Dep. at 17)).
80. DCO falls under the private label part of Universal Nutrition. (R17 (Bauhoffer-Kinney, Dep. at 17)).
81. Universal Nutrition makes approximately 35-40 products for DCO, including Bio*Shark, GDU, and BioMixx. (R17 (Bauhoffer-Kinney, Dep. at 21)).
82. Universal Nutrition started manufacturing Bio*Shark for Respondents approximately eight to ten years ago. (R17 (Bauhoffer-Kinney, Dep. at 42-43)).

7 Herb Formula

83. 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). 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).
84. 7 Herb Formula is essiac plus watercress, Cat's Claw, and Siberian Ginseng. (P. Feijo, Tr. 439).
85. Respondents offer one 32-ounce bottle of 7 Herb Formula for \$70.95. (Answer ¶ 8).
86. On their Web sites danielchapterone.com and dclpages.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 (emphasis added)).

GDU

87. GDU is a product that contains, among other ingredients, Bromelain, Turmeric, Quercetin, Feverfew, and Boron. (Answer ¶ 10). 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).
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. (R17 (Bauhoffer-Kinney, Dep. at 34-35)).
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. (R17 (Bauhoffer-Kinney, Dep. at 34-35)).

BioMixx

91. BioMixx is a product that contains, among other ingredients, Goldenseal, Echinacea, and Ginseng. (Answer ¶ 12). Respondents' product label for BioMixx directs users to take five scoops daily. (Answer ¶ 12; CX 17).
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. (R17 (Bauhoffer-Kinney, Dep. at 46)).
94. During 2008, Respondents paid Universal Nutrition approximately \$8,778 to manufacture 798 units of the 3 pound bottle of BioMixx. (R17 (Bauhoffer-Kinney, Dep. at 46)).

2. Respondent James Feijo Controls Respondent DCO's Finances and Operations

95. Respondent James Feijo is ultimately in charge of Daniel Chapter One. (J. Feijo, HOJ Tr. 112).

96. Respondent James Feijo is responsible for the development, creation, production, and pricing of the DCO Products. (CX 39; R15 (J. Feijo, Dep. at 116); R16 (P. Feijo, Dep. at 77)).
97. Respondent James Feijo and his wife, Patricia Feijo, have been solely responsible for creating, drafting, and approving the directions for usage of the DCO products. (CX 39).
98. Respondent James Feijo and Patricia Feijo developed the recommended dosages of the DCO Products. (CX 39; R16 (P. Feijo, Dep. at 117, 166-67, 192)).
99. Respondent James Feijo is the trustee for all Daniel Chapter One assets, including all funds, which are to be held in trust. (CX 39; J. Feijo, HOJ Tr. 73).
100. Respondent DCO has bank accounts with Citizens Bank. (CX 49).
101. All of the revenue earned by Respondent DCO is deposited in the DCO bank account before being distributed, at Respondent James Feijo's discretion, to other bank accounts such as a "Creation Science Funding," "Radio Leasing International," "Business Partners Checking," and "Business Partners Money Market Fund." (J. Feijo, HOJ Tr. 206-08, 227, 230).
102. Patricia Feijo is a signatory to DCO's bank account and writes checks on behalf of the DCO account. (R16 (P. Feijo, Dep. at 54); P. Feijo, HOJ Tr. 276).
103. Jill Feijo, James Feijo's daughter, pays DCO's bills. (J. Feijo, HOJ Tr. 204).

3. Respondents Do Not Maintain Records

104. DCO has a policy of not maintaining records. (J. Feijo, HOJ Tr. 73, 83).
105. Respondent James Feijo did not change DCO's document retention policies after learning that the FTC had brought a proceeding against him and DCO. (J. Feijo, HOJ Tr. 80).
106. DCO did not change its document retention policies after receiving the Court's first and second orders to produce certain documents to Complaint Counsel. (J. Feijo, HOJ Tr. 81-83).
107. Respondent James Feijo had the authority to change DCO's document retention policy after receiving the Court's orders to produce certain documents to Complaint Counsel if he thought the records would show that DCO was a nonprofit corporation. (J. Feijo, HOJ Tr. 83).
108. DCO continued to throw out documents, including Marino's purchase order form, even after receiving the Court's orders to produce certain documents to Complaint Counsel. (J. Feijo, HOJ Tr. 83).

4. Respondents Profit from the Sale of the DCO Products

109. James and Patricia Feijo live in the Portsmouth, Rhode Island property owned by Messiah Y'Shua Shalom as well as in a three-bedroom property in Deerfield Beach,

- Florida, which Respondent DCO owns. (R15 (J. Feijo, Dep. at 70-71; 78-79); J. Feijo, HOJ Tr. 160, 204).
110. Respondent DCO owns two cars - a 2003 Cadillac and a 2004 Cadillac. DCO purchased one Cadillac new and the other Cadillac used. (R15 (J. Feijo, Dep. at 71); J. Feijo, HOJ Tr. 160).
 111. Respondent James Feijo uses the two Cadillacs owned by DCO. (R15 (J. Feijo, Dep. at 96-97); J. Feijo, HOJ Tr. 160).
 112. Respondent DCO pays for all of the Feijos' living expenses. (CX 39; J. Feijo, HOJ Tr. 206; P. Feijo, HOJ Tr. 276).
 113. Respondents do not maintain any records on how much DCO money is spent on the Feijos' living expenses. (P. Feijo, HOJ Tr. 277).
 114. The Feijos do not file any tax returns with regard to the money they receive from Respondent DCO. (P. Feijo, HOJ Tr. 278).
 115. Respondent DCO pays for pool and gardening services rendered on the "Feijo house" in Florida. (CX 49 at FTC-DCO 3443, 3457).
 116. Respondent DCO pays for Patricia Feijo's tennis club membership. (P. Feijo, HOJ Tr. 278).
 117. Respondent DCO paid for Respondent James Feijo's membership at the Green Valley Country Club in Rhode Island. (J. Feijo, HOJ Tr. 154-55).
 118. Respondent DCO paid for Respondent James Feijo to play golf at the Deer Creek Golf Course located behind his Deerfield Beach, Florida home. (CX 49; J. Feijo, HOJ Tr. 155).
 119. Respondent DCO has an American Express Business Gold Card, which is also in Patricia Feijo's name, and to which Respondent James Feijo is a signatory. (CX 48).
 120. Respondent James Feijo has frequently used the American Express Business Gold Card to eat at restaurants, play golf, buy cigars, and other retail items. (CX 48; J. Feijo, HOJ Tr. 151-60).
 121. According to American Express statements for DCO's American Express Business Gold Card, approximately \$11,358 was charged for golf expenses during the period December 2005 - March 2009. (CX 48 at FTC-DCO 2985, 2995, 3003, 3004, 3011, 3039, 3049, 3081, 3082, 3091, 3092, 3103, 3104, 3111, 3113, 3119, 3129, 3171, 3174, 3181, 3182, 3189, 3208B, 3208C, 3208M, 3210, 3237, 3264, 3297).
 122. According to American Express statements for DCO's American Express Business Gold Card, approximately \$14,024 was charged for restaurant expenses during the period December 2005 - March 2009. (CX 48 at FTC-DCO 2966, 2975, 2985, 2995, 2996, 3003, 3011, 3012, 3019, 3027, 3028, 3039, 3040, 3049, 3057, 3058, 3059, 3067, 3068, 3081, 3091, 3103, 3113, 3129, 3137, 3181, 3182, 3197, 3208A, 3208B, 3208K, 3208M,

- 3209, 3210, 3217, 3218, 3225, 3235, 3238, 3245, 3251, 3255, 3264, 3265, 3274, 3275, 3284).
123. According to American Express statements for DCO's American Express Business Gold Card, approximately \$28,582 was charged for automobile expenses during the period December 2005 - March 2009. (CX 48 at FTC-DCO 2966, 2975, 3003, 3011, 3019, 3027, 3039, 3049, 3050, 3057, 3065, 3068, 3082, 3103, 3105, 3113, 3127, 3129, 3165, 3173, 3181, 3189, 3208B, 3231, 3238, 3245, 3264, 3265, 3271, 3273, 3284).
 124. According to American Express statements for DCO's American Express Business Gold Card, approximately \$1,077 was charged for cigar expenses during the period December 2005 - March 2009. (CX 48 at FTC-DCO 3113, 3121, 3181, 3197, 3208M, 3245, 3264, 3273).
 125. Respondent DCO also has credit cards with Bank of America and Chase Bank. (J. Feijo, HOJ Tr. 161).
 126. According to Citizens Bank statements for DCO's and related entities' checking accounts, approximately \$51,087 was electronically transferred from these checking accounts to Bank of America during the period February 2007 - March 2009. (CX 49 at FTC-DCO 3352, 3359, 3363, 3367, 3674, 3680, 3685, 3701, 3706, 3726, 3733, 3741, 3750).
 127. According to Citizens Bank statements for DCO's and related entities' checking accounts, approximately \$30,277 was paid by check from DCO's Creation Science Funding account to Bank of America during the period January 2007 - April 2007. (CX 49 at FTC-DCO 3448, 3456, 3470, 3472, 3498).
 128. According to Citizens Bank statements for DCO's and related entities' checking accounts, approximately \$25,837 was paid by check from DCO's Creation Science Funding account to Chase Card Services during the period January 2007 - April 2007. (CX 49 at FTC-DCO 3441, 3464, 3470, 3493, 3497).
 129. Respondent James Feijo does not retain any receipts for his credit card purchases and credit card payments are automatically debited. (J. Feijo, HOJ Tr. 163-64).
 130. Respondent James Feijo does not have his own individual bank account. (J. Feijo, HOJ Tr. 208).
 131. Respondent James Feijo pays his daughter Jill \$700 per week for her work at Daniel Chapter One. (J. Feijo, HOJ Tr. 204-05).
 132. Although he personally paid income taxes prior to DCO's incorporation as a corporation sole, Respondent James Feijo has since stopped personally paying income taxes. (J. Feijo, HOJ Tr. 86).
 133. Respondents do not pay any state sales tax based on the sale of DCO products through the DCO Web site. (J. Feijo, HOJ Tr. 210).

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

134. Respondents advertise their products on the Internet. (J. Feijo, Tr. 459, 464).

135. Respondents admit that they make the following representations:

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

(Answer ¶ 14.)

136. DCO's Web site depicts pictures of the DCO Products next to the statement "Daniel Chapter One's Cancer Solutions." (R16 (P. Feijo, Dep. at 176-77); CX 12-15, CX 12A, CX 13A, CX 14A, CX 43).

137. 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).

138. 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).

139. 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).

140. 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 (emphasis in bold added)).

141. Respondent James Feijo was responsible for putting together BioGuide 3. (R15 (J. Feijo, Dep. at 243)).
142. Patricia Feijo was responsible for writing the BioGuide. (R16 (P. Feijo, Dep. at 20)).
143. Bio*Shark, 7 Herb Formula, GDU, and BioMixx all appear in Respondents’ Cancer Newsletter, entitled How to Fight Cancer is Your Choice!!!. (CX 23; CX 24).
144. The Cancer Newsletter is “strictly all about the products for cancer.” (R15 (J. Feijo, Dep. at 143)).
145. The Cancer Newsletter contains descriptions of various DCO products that “a person can choose to use to help them fight cancer.” (P. Feijo, Tr. 399). These products include Bio*Shark, GDU, BioMixx, and 7 Herb Formula. (P. Feijo, Tr. 402-04).
146. Patricia Feijo was responsible for writing the Cancer Newsletter. (R16 (P. Feijo, Dep. at 26-28); P. Feijo, Tr. 395-96).
147. James and Patricia Feijo are not doctors. (R16 (P. Feijo, Dep. at 114); P. Feijo, Tr. 404; J. Feijo, Tr. 416).
148. James Feijo never held a position where he had to use any skills involving medicine. (R15 (J. Feijo, Dep. at 47)).
149. James and Patricia Feijo are not research scientists. (R16 (P. Feijo, Dep. at 114); P. Feijo, Tr. 405).
150. 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).
151. 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

152. 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 12; CX 12A; CX 43; R15 (J. Feijo, Dep. at 61, 100-101, 107); R16 (P. Feijo, Dep. at 156-57); P. Feijo, Tr. 341).

153. 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 TM . . .

Bio*Shark TM . . . [emphasis added]

BioMixx TM . . .

GDU Caps TM . . .

[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 13; CX 13A; CX 43; R15 (J. Feijo, Dep. at 61, 100-101, 110-111)).

154. 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).

155. 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

156. 7 Herb Formula is a product that can be used by a person who is suffering from cancer. (R16 (P. Feijo, Dep. at 171)).

157. 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
- **fight 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 TM . . . [emphasis added]

Bio*Shark TM . . .

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 13; CX 13A; CX 43; R15 (J. Feijo, Dep. at 60, 101, 110-11); P. Feijo, Tr. 345).

158. 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 13; CX 13A; CX 43; R15 (J. Feijo, Dep. at 60, 101, 110-11)).

159. 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)).
160. 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)).
161. 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; CX 30 at FTC-DCO 0493).
162. 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).

163. 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).
164. 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

165. 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 14; CX 14A; CX 43; R15 (J. Feijo, Dep. at 101, 138-39); R16 (P. Feijo, Dep. at 185-86); P. Feijo, Tr. 351).

166. 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 13; CX 13A; CX 43; R15 (J. Feijo, Dep. at 101, 110-11)).

167. 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)).
168. 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; R16 (P. Feijo, Dep. at 190)).

169. 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

170. 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 15; R15 (J. Feijo, Dep. at 101); P. Feijo, Tr. 354-55).

171. 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 13; CX 13A; CX 43; R15 (J. Feijo, Dep. at 101, 110-11)).

172. 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).

173. 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)).

D. Respondents Disseminate Claims About Their Products to Consumers

174. Respondents operate the Web sites www.danielchapterone.com, dc1pages.com, and dc1store.com that provide information on the DCO Products. (Answer ¶ 5; R15 (J. Feijo, Dep. at 62, 232-33)).

175. DCO advertises its products on the DCO Web site. (J. Feijo, Tr. 459, 464).

176. Respondents disseminate information about the DCO Products through written materials, including, but not limited to, the BioGuide, the Cancer Newsletter, the Web sites www.danielchapterone.com, www.7herbformula.com, www.gdu2000.com, and the radio program, “Daniel Chapter One Health Watch.” (CX 39; R15 (J. Feijo, Dep. at 103); Harrison, Tr. 303, 305, 309-10; P. Feijo, Tr. 325, 350, 380; J. Feijo, Tr. 452-54).

177. The radio program “Daniel Chapter One Health Watch” is carried by an eclectic group of AM radio stations. (Harrison, Tr. 309-10).

178. Respondents’ publication, The Most Simple Guide to the Most Difficult Diseases, is available on the DCO Web site and anyone can still download it. (CX 29 at FTC-DCO 0430; P. Feijo, Tr. 395; J. Feijo, Tr. 453-55).

179. The BioGuide and the Cancer Newsletter are also available on-line through DCO’s Web site. (CX 13 at FTC-DCO 0013; CX 13A at FTC-DCO 2828A; CX 29 at FTC-DCO 0430; P. Feijo, Tr. 395; J. Feijo, Tr. 453-55; Tr. 264).

180. 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 Web sites 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; R15 (J. Feijo, Dep. at 62); P. Feijo, Tr. 350, 380, 395-96).

181. Consumers can locate Respondents’ Web site by entering the term “cancer” in a Google search. (R15 (J. Feijo, Dep. at 136)).

182. FTC Investigator Michael Marino found and accessed DCO’s Web site www.danielchapterone.com through Microsoft Internet Explorer. (CX 1).

183. 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; R15 (J. Feijo, Dep. at 16-17); Harrison, Tr. 303; P. Feijo, Tr. 324; J. Feijo, Tr. 450-51).

184. Respondents have counseled cancer patients who have called into the Daniel Chapter One radio program about taking the DCO Products. (R16 (P. Feijo, Dep. at 96-97); J. Feijo, HOJ Tr. 221-22; P. Feijo, Tr. 360-64).

185. The DCO radio program and the DCO Web site were the natural vehicle for Respondents to reach out to people in other states. (R16 (P. Feijo, Dep. at 62)).

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

186. Respondents represented to consumers that they possessed and relied upon a reasonable basis that substantiated the representations set forth in the FTC's Complaint. (Answer ¶ 15.)

187. Respondents conducted no scientific testing on any of the DCO Products. (R16 (P. Feijo, Dep. at 161); R15 (J. Feijo, Dep. at 201-02); P. Feijo, Tr. 405).

188. Respondents have not conducted any double-blind studies on the DCO Products. (R15 (J. Feijo, Dep. at 58, 205-06)).

189. Respondents' have not conducted any controlled studies on any of the DCO Products. (R15 (J. Feijo, Dep. at 54-55)).

190. No person has been involved in the scientific testing, research, substantiation, or clinical trials of the DCO Products. (CX 39).

191. 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).

192. It was not Respondents' practice to obtain scientific studies about any of the components in their products. (R16 (P. Feijo, Dep. at 120)).

193. 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." (R16 (P. Feijo, Dep. at 120)).

194. James Feijo agrees that individual results may vary and that what one person says in her testimonial may not apply to other people. (R15 (J. Feijo, Dep. at 141-42)).

195. According to Patricia Feijo, "only God can cure cancer." (R16 (P. Feijo, Dep. at 115)).

196. 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." (R16 (P. Feijo, Dep. at 116)).

197. Patricia Feijo was unable to identify with specificity which articles she was relying upon specifically for the specific claims that brought about the charges in this case. (P. Feijo, Tr. 607-08).

BioShark

198. Respondents conducted no scientific testing on Bio*Shark. (R16 (P. Feijo, Dep. at 161)).

199. 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." (R16 (P. Feijo, Dep. at 157)).
200. 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. (R16 (P. Feijo, Dep. at 162)).
201. Although Respondents relied upon Dr. Lane's book, "Sharks Don't Get Cancer," for substantiation, Respondent James Feijo never read it. (J. Feijo, Tr. 449).
202. Universal Nutrition did not conduct any testing, quality or otherwise, on Bio*Shark. (R17 (Bauhoffer-Kinney, Dep. at 45-46)).

7 Herb Formula

203. 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. (R16 (P. Feijo, Dep. at 132)).
204. 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." (R16 (P. Feijo, Dep. at 132)).
205. 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]." (R16 (P. Feijo, Dep. at 175-76)).

GDU

206. GDU was never subjected to clinical trials. (R16 (P. Feijo, Dep. at 190)).
207. Respondents have not done any studies to know whether GDU would counteract with any conventional cancer medicine someone was taking. (R16 (P. Feijo, Dep. at 194)).

BioMixx

208. Respondents did not conduct any tests or clinical studies on BioMixx. (R16 (P. Feijo, Dep. at 199)).
209. Respondents did not engage anybody else to do any kind of clinical tests on BioMixx. (R16 (P. Feijo, Dep. at 199)).
210. 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." (R16 (P. Feijo, Dep. at 199-200)).

211. Universal Nutrition has not conducted any testing on BioMixx. (R17 (Bauhoffer-Kinney, Dep. at 50)).

F. 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

212. 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 CX 52 at __) at 1.

213. 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. (CX 52 at 1).

214. 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. (CX 52 at 1).

215. 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. (CX 52 at 1-2).

216. 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. (CX 52 at 3.)

217. 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. (CX 52 at 2).

218. 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. (CX 52 at 7).

219. 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. (CX 52 at 30).

220. Anecdotal reports of product efficacy are the weakest form of evidence supporting the anticancer activity of a new agent. (CX 52 at 12).

221. Testimonials do not substitute for a well-designed clinical trial in proving the efficacy of a supposed cancer fighting product. (CX 52 at 30).

222. 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. (CX 52 at 31).

Bio*Shark

223. 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. (CX 52 at 13).
224. 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. (CX 52 at 17).
225. 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. (CX 52 at 16).

7 Herb Formula

226. 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. (CX 52 at 18).
227. 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. (CX 52 at 19).
228. 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. (CX 52 at 19-22).

GDU

229. 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. (CX 52 at 22).
230. Dr. Miller found no randomized, controlled clinical trials of any of the individual components of GDU or of GDU itself in patients with cancer. (CX 52 at 27).
231. 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. (CX 52 at 22).
232. Animal studies have suggested that curcumin may have activity as a cancer preventive and therapeutic agent. (CX 52 at 23).

233. 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. (CX 52 at 27).
234. Thus, Dr. Miller advised that further research on curcumin was necessary. (CX 52 at 27).

BioMixx

235. 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. (CX 52 at 27).
236. Dr. Miller found that there are no reported studies of either BioMixx or its constituent ingredients being effective in the treatment of cancer. (CX 52 at 27-28).
237. 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. (CX 52 at 29).

G. Respondents' Purported Experts Do Not Possess Any Information Substantiating Respondents' Claims and Reinforce Dr. Miller's Conclusion that No Competent and Reliable Scientific Evidence Exists to Support Respondents' Claims

Introduction

James Duke, Ph.D.

238. James Duke, Ph.D. ("Duke") has never met Jim and Patricia Feijo. (Deposition of James Duke, Ph.D. (hereinafter referred to as R18 (Duke, Dep. at __)) at 8).
239. Duke is not a medical doctor. (R18 (Duke, Dep. at 56); Duke, Tr. 521).
240. Duke is not licensed to practice medicine in any state. (R18 (Duke, Dep. at 56); Duke, Tr. 521).
241. Duke is not a board-certified oncologist. (R18 (Duke, Dep. at 56); Duke, Tr. 521).
242. Duke does not recall ever publishing any articles in any peer-reviewed medical journals. (R18 (Duke, Dep. at 56); Duke, Tr. 521).
243. Duke has never practiced medicine. (R18 (Duke, Dep. at 18)).
244. Duke would not recommend that people self-medicate with herbal remedies in treating cancer. (R18 (Duke, Dep. at 135)).
245. Duke is sure that there is a risk that some people will pursue herbal medications instead of effective pharmaceutical medications and thereby die. (R18 (Duke, Dep. at 136)).

246. Duke does not recall any holistic physicians who have consulted with him on the treatment of cancer. (R18 (Duke, Dep. at 19)).
247. Duke does not recall any homeopaths who have consulted with him on the treatment of cancer. (R18 (Duke, Dep. at 19)).
248. Duke has never managed or participated in any studies to measure the efficacy of an herb in treating cancer. (R18 (Duke, Dep. at 29); Duke, Tr. 522).
249. Duke does not remember ever being a consultant on a study where the anticancer effects of an herb were being measured on a group of patients. (R18 (Duke, Dep. at 29-30); Duke, Tr. 523).
250. Duke does not remember seeing the FTC's Complaint against Respondents. (R18 (Duke, Dep. at 36)).
251. Duke has no knowledge of any of the advertisements that the FTC has challenged as the predicate for the Complaint. (R18 (Duke, Dep. at 36-37); Duke, Tr. 534).
252. Duke was not sent any of Respondents' products and has never seen them. (R18 (Duke, Dep. at 37); Duke, Tr. 524).
253. Duke has not spoken to any persons who have taken DCO products for the treatment of cancer. (R18 (Duke, Dep. at 38)).
254. Duke has not reviewed the medical records of anyone who claims to have taken DCO products for the treatment of cancer. (R18 (Duke, Dep. at 39)).
255. Duke had never heard of DCO until this case. (R18 (Duke, Dep. at 39)).
256. Duke remembers being quite surprised when he learned that most of the list of chemicals that Respondents were studying were not biblical. (Duke, Tr. 536.)
257. Duke has never listened to the DCO Radio program. (R18 (Duke, Dep. at 39)).
258. Duke knows of no tests where the patient prays and one group of patients gets a Biblically referenced herb and the other group of patient prays and gets an allopathic treatment. (R18 (Duke, Dep. at 41-42)).
259. Duke does not think that "the FDA permits advertising for cancer unless clinically proven." (R18 (Duke, Dep. at 46)).
260. Duke's "Multiple Activity Menus" ("MAMs") are an attempt to identify herbs that show promise in fighting disease. (R18 (Duke, Dep. at 91)).
261. The MAM and the ratio that it yields does not prove that any one of these herbs is effective in fighting or treating cancer. Rather, "[i]t adds a listing of the chemicals in that herb that have been shown or assumed to help with cancer." (R18 (Duke, Dep. at 92)).

262. When entering in the MAM an activity for an herb, Duke only enters references to that source “as it may be a good source [or] it may be a bad source.” (R18 (Duke, Dep. at 93)).
263. Duke acknowledged that it is a “gut feeling” on how he makes sure that the studies he references in the MAMs are reliable. (R18 (Duke, Dep. at 108)).
264. Duke acknowledged that his MAMs have not been cited in any peer-reviewed journal. (R18 (Duke, Dep. at 113)).
265. Duke explained that his Indication Evaluations (“IE”) is where he has “gone through all these abstracts over the years [and] I’ve scored for a given indication. If it’s folklore and that’s all I have, it would receive an ‘f’; if it has a chemical or an epidemiological or an animal or an in vitro evidence, I’ve given it a 1; and then the 2, as we mentioned earlier, that means it’s either been clinically approved - - an extract of the plant has been clinically approved or it’s been approved by the Commission E or the Tramit Commission for that indication. These are lines of evidence that point to me which ones are most important and should be studied for cancer.” (R18 (Duke, Dep. at 59, 118-19)).
266. The IE is a “compendium of information.” (R18 (Duke, Dep. at 109); Duke, Tr. 526).
267. There is no relationship between the MAMs and the IE. (R18 (Duke, Dep. at 92)).
268. Neither the MAMs nor the IE reflect information that indicates that turmeric, for example, is effective in the treatment of cancer. (R18 (Duke, Dep. at 109-10)).
269. Duke has never measured the efficacy of herbs as a treatment for cancer in a controlled patient population. (R18 (Duke, Dep. at 55)).
270. Duke is not able to express opinions on what the minimum dosage would be necessary to achieve cancer-fighting. (R18 (Duke, Dep. at 67-68); Duke, Tr. 522-23).
271. Duke recognizes the difference between something being efficacious in an in vitro study and something being efficacious in human beings. (R18 (Duke, Dep. at 71); Duke, Tr. 523).
272. As a matter of science, Duke does not believe that the herbal extract working in vitro proves that it would work in a human. (R18 (Duke, Dep. at 77); Duke, Tr. 523).
273. Rather than relying solely on in vitro studies, Duke recommends “the third arm-trial where the whole plant or an extract thereof is compared with a competing pharmaceutical.” (R18 (Duke, Dep. at 77)).
274. According to Duke, “[t]he third arm would compare a given herb with a given pharmaceutical and placebo.” (R18 (Duke, Dep. at 81)).
275. Other than the St. John’s Wort trial that used a placebo and Zolofit, Duke is not aware of any other studies where an herb, a pharmaceutical, and a placebo were studied in a side-by-side manner. (R18 (Duke, Dep. at 82)).

276. Duke does not think of black cohosh as a major anticancer herb. (R18 (Duke, Dep. at 123)).
277. Duke stated that there is no reference to cancer in eleuthero because “that’s not one of the major things that are said about it.” (R18 (Duke, Dep. at 125-26)).
278. Most of the studies Duke has seen have been for preventing cancer. (R18 (Duke, Dep. at 128)).
279. Duke does not remember any studies specifically about treating cancer. (R18 (Duke, Dep. at 128-29)).
280. Duke testified that anecdotal reports are “even below . . . my lines of evidence.” (R18 (Duke, Dep. at 131)).
281. Duke attributes the increase in life expectancy in the 150 years that pharmaceuticals have been around to pharmaceuticals themselves. (R18 (Duke, Dep. at 133)).
282. Duke does not believe that homeostatic balancing has been the subject of any peer-reviewed articles in connection with the treatment or cure of cancer. (R18 (Duke, Dep. at 133-34)).
283. In Duke’s IE, there have been no clinical trials as to the efficacy of black cohosh for cancer. (R18 (Duke, Dep. at 147)).
284. There are no clinical trials regarding garlic’s efficacy as to cancer in Duke’s IE. (R18 (Duke, Dep. at 148)).
285. There are no clinical trials regarding Yellow Root’s efficacy as to cancer in Duke’s IE. (R18 (Duke, Dep. at 149)).
286. There are no clinical trials regarding eleuthero’s efficacy as to cancer in Duke’s IE. (R18 (Duke, Dep. at 153)).
287. There are no clinical trials regarding soybean’s efficacy as to cancer in Duke’s IE. (R18 (Duke, Dep. at 153-54)).
288. There are no entries for sarsaparilla in Duke’s IE indicating that it has been evaluated for its efficacy in treating cancer in clinical trials. (R18 (Duke, Dep. at 156)).
289. The editors of Duke’s book, The Green Pharmacy Guide to Healing Foods, advised Duke to “shy away from” a section on cancer treatment. (R18 (Duke, Dep. at 178)).
290. Duke does not recall seeing any articles that Mr. and Mrs. Feijo believe substantiated the claims that they made regarding the particular DCO Products. (R18 (Duke, Dep. at 185)).
291. Duke has made no effort to evaluate whether the combination of the ingredients in each of the products that DCO sells - GDU, 7 Herb Formula, and BioMixx – has any synergistic effects. (R18 (Duke, Dep. at 190); Duke, Tr. 525-26).

292. Duke made no effort to see whether there were any studies of any sort regarding the particular products that DCO sells - GDU, 7 Herb Formula, and BioMixx. (R18 (Duke, Dep. at 190-91)).
293. Duke is not familiar with any studies of GDU, 7 Herb Formula, or BioMixx. (Duke, Tr. 526).
294. Duke has not performed any tests or analyses on the DCO products himself. (Duke, Tr. 524).

James K. Dews

295. Respondents offer James K. Dews (“Dews”) as an expert in “[h]erbal formulations, specifically 7 Herb Formula.” (Deposition of James K. Dews (hereinafter referred to as R19 (Dews, Dep. at __)) at 4-5).
296. Dews attended the University of Texas at Arlington and Texas Wesleyan, but he did not finish college degrees at either institution. (R19 (Dews, Dep. at 11)).
297. According to Dews, nutraceuticals involves the merging of food supplements and pharmaceuticals. (R19 (Dews, Dep. at 17)).
298. Nutraceuticals involves the extraction of certain chemical compounds that are in many foods or herbs. (R19 (Dews, Dep. at 18)).
299. Consumers ingest nutraceuticals. (R19 (Dews, Dep. at 18)).
300. The difference between a pharmaceutical and a nutraceutical is that one can make a disease-curing claim with a pharmaceutical; one cannot make a disease-curing claim with a nutraceutical. (R19 (Dews, Dep. at 15, 62)).
301. According to Dews, animal studies cannot be extrapolated to humans. (R19 (Dews, Dep. at 63-64)).

Rustum Roy, Ph.D.

302. Respondents offer Rustum Roy, Ph.D. (“Roy”) as “an expert in the conduct of scientific research and with the focus on health and materials.” (Deposition of Rustum Roy, Ph.D. (hereinafter referred to as R20 (Roy, Dep. at __)) at 7).
303. Roy did not review the complaint that the FTC filed against Respondents. (R20 (Roy, Dep. at 7)).
304. Roy did not review any of the advertisements on which the FTC’s complaint is predicated. (R20 (Roy, Dep. at 7)).
305. Roy did not review or obtain any of the product or product labels for the products at issue in the litigation. (R20 (Roy, Dep. at 7-8)).

306. Roy did not conduct any work or tests on any product made by Respondents. (R20 (Roy, Dep. at 8)).
307. Roy is not an expert in homeopathy. (R20 (Roy, Dep. at 12)).
308. Roy and his laboratory do “zero clinical trials.” (R20 (Roy, Dep. at 13)).
309. Roy and his laboratory “have nothing to do with causing healing or not in a human being.” (R20 (Roy, Dep. at 13)).
310. Roy has not measured the efficacy of the DCO Products. (R20 (Roy, Dep. at 14)).
311. Roy has never done any experiments to measure the efficacy of any medical treatments “at the human level.” (R20 (Roy, Dep. at 14)).
312. Roy has no idea what the DCO Products contain. (R20 (Roy, Dep. at 24)).
313. Roy has not done any literature searches or any literature research concerning any of the ingredients in DCO’s products. (R20 (Roy, Dep. at 25)).
314. Roy does not have any formal training in medicine. (R20 (Roy, Dep. at 26)).
315. Roy has never treated or consulted with healers who were treating particular patients. (R20 (Roy, Dep. at 28)).
316. Roy does not know what Daniel Chapter One sells. (R20 (Roy, Dep. at 43)).
317. The practice of Daniel Chapter One selling products over the Internet to people that it had never seen, met, or examined the medical records for “obviously limits” homeopathy. (R20 (Roy, Dep. at 50)).
318. Roy’s ideal description of homeopathy would not include selling products over the Internet to persons that the seller has not met. (R20 (Roy, Dep. at 51)).
319. It is not Roy’s view that all herbal remedies are effective. (R20 (Roy, Dep. at 60-61)).
320. Roy has never been involved in trying to secure FDA approval for some medication. (R20 (Roy, Dep. at 79)).

Sally B. LaMont, N.D.

321. Respondents offer Sally B. LaMont, N.D. (“LaMont”) as “an expert in naturopathic medical, herbal medicine, functional medicine . . . [and] as an expert on nutritional supplements and botanical medicines in the prevention and treatment of illness and as an expert in reviewing the evidence that supports the functional issues of the four products that are the challenged products.” (Deposition of Sally B. LaMont, N.D. (hereinafter referred to as R22 (LaMont, Dep. at ___)) at 7-8).
322. LaMont has never previously been asked to be an expert. (R22 (LaMont, Dep. at 54)).

323. LaMont's charge from Respondents is "to provide opinions on the use of nutritional supplements and botanical medicines in the prevention and treatment of illness, including but not limited to cancer, and to review the evidence that exists regarding the mechanisms of action of the major constituents of Daniel Chapter One's products." (R22 (LaMont, Dep. at 33)).
324. LaMont is a naturopathic doctor. (R22 (LaMont, Dep. at 9, 15-16)).
325. According to LaMont, naturopathic medicine "is a primary healthcare practice that focuses on health promotion and disease prevention and the treatment of disease with an array of natural therapies that strengthen the body's innate healing capacities." (R22 (LaMont, Dep. at 9)).
326. Naturopathic doctors "provide patient-centered care and practice what would be termed functional medicine, which addresses the unique genetic, environmental and lifestyle factors that contribute to chronic disease and . . . influence our health." (R22 (LaMont, Dep. at 9)).
327. While engaged in naturopathic medicine, LaMont has worked in conjunction with traditional physicians. (R22 (LaMont, Dep. at 10)).
328. In the course of doing a workup on a patient, if LaMont finds "a diagnosis that looks like it could be cancer," she absolutely would refer the patient to a traditional physician and would comanage that patient's care with the physician. (R22 (LaMont, Dep. at 10)).
329. LaMont has not focused her naturopathic practice on naturopathic oncology; rather, she "ha[s] kept [her] practice very general." (R22 (LaMont, Dep. at 11-12); LaMont, Tr. 576).
330. LaMont does not know what additional specialized training naturopathic oncologists take. (R22 (LaMont, Dep. at 12)).
331. LaMont has not done the specialized training for naturopathic oncology. (R22 (LaMont, Dep. at 12); LaMont, Tr. 576-77).
332. If LaMont ever found, for example, an abnormal pap smear with carcinoma inside, then she "would refer that patient to a gynecologist for a comprehensive workup and recommend that [her] patients follow the advice of their oncologist." (R22 (LaMont, Dep. at 14)).
333. LaMont's understanding is that "cancer must be treated with conventional therapies." (R22 (LaMont, Dep. at 15)).
334. LaMont has seen conventional cancer therapies helpful in sometimes resolving the condition. (R22 (LaMont, Dep. at 15)).
335. LaMont would always make a referral to a cancer specialist because "it's an important part of the treatment of cancer at this point." (R22 (LaMont, Dep. at 15)).
336. Fourteen states license N.D.s. (R22 (LaMont, Dep. at 17)).

337. A licensed naturopathic doctor's responsibilities are "to diagnose and to treat disease and to promote health, which is honestly the focus of our practice, to really strengthen our body's ability to heal itself." (R22 (LaMont, Dep. at 17)).
338. The core of LaMont's practice is "[w]orking with diet and nutrition [and] nutritional supplements." (R22 (LaMont, Dep. at 20)).
339. LaMont also uses botanical medicine. (R22 (LaMont, Dep. at 20)).
340. LaMont works with mind-body therapies and regularly suggests meditation, qigong, yoga, and other biofeedback-type of therapies that would strengthen the person's connection between their mind and their immune system. (R22 (LaMont, Dep. at 20)).
341. LaMont does acupuncture on most patients. (R22 (LaMont, Dep. at 20)).
342. Nutritional supplements come from food and are an extension of food. (R22 (LaMont, Dep. at 20)).
343. Botanical medicine "comes from the plant world, and so there are phytochemicals in plants and then there's the whole plant." (R22 (LaMont, Dep. at 20-21)).
344. Almost all the patients who come to LaMont who have been diagnosed with cancer come to her with that diagnosis and are looking for supportive care. (R22 (LaMont, Dep. at 23)).
345. LaMont thinks that the amount of dosage is important to the individual taking it and their health regimen. (R22 (LaMont, Dep. at 28)).
346. For someone who is in the "throes of chemotherapy," LaMont would have them not to use many of their nutritional supplements the week that they are on chemotherapy. (R22 (LaMont, Dep. at 31)).
347. The reason why LaMont would advise someone not to use nutritional supplements during chemotherapy is because "we don't fully understand yet all of the different ways in which this and other natural therapies may interact with chemotherapy." (R22 (LaMont, Dep. at 31)).
348. LaMont only became familiar with DCO at the end of December 2008. (R22 (LaMont, Dep. at 22-23); LaMont, Tr. 577).
349. Prior to LaMont's work on this case, she had never come across Bio*Shark, 7 Herb Formula, GDU, and BioMixx. (R22 (LaMont, Dep. at 34); LaMont, Tr. 578).
350. LaMont looked at the labels for the DCO Products and did a literature search on the main constituents of each of the products. (R22 (LaMont, Dep. at 34)).
351. LaMont acknowledged that since they have not been tested, we do not know the effectiveness of GDU, BioMixx, Bio*Shark, and 7 Herb Formula in the prevention, treatment or cure of cancer. (R22 (LaMont, Dep. at 47-48); LaMont, Tr. 579-82).

352. LaMont acknowledged that there have been no clinical studies performed on the DCO Products. (R22 (LaMont, Dep. at 48); LaMont, Tr. 579).
353. The DCO products “are not silver bullets.” (R22 (LaMont, Dep. at 127)).
354. LaMont does not know the Feijos. (R22 (LaMont, Dep. at 49)).
355. LaMont thinks that it is “best that people follow the recommendations of their oncologist and utilize protocols that are proven to be most effective for their cancer and that they should be well-informed of the potential value of the array of other therapies.” (R22 (LaMont, Dep. at 49)).
356. LaMont testified that “as a doctor, if I’m working with a patient, I’m going to insist that they work with their oncologist and follow their advice and I’m going to comanage their care.” (R22 (LaMont, Dep. at 51-52)).
357. LaMont believes that “[t]he awareness of the powerful chemoprotective effects of plant foods and medicines should not influence patients with cancer and other serious diseases to abandon using the most effective methods that modern medicine has to offer.” (R22 (LaMont, Dep. at 52)).
358. LaMont would not be comfortable with the Feijos saying that the DCO products are going to cure cancer. (R22 (LaMont, Dep. at 53)).
359. LaMont can see why the Federal Trade Commission would have concerns about the statement that DCO’s products are cancer solutions. (R22 (LaMont, Dep. at 127)).
360. LaMont would not have written the text that way to include “cancer solutions” next to the DCO products. (R22 (LaMont, Dep. at 128)).
361. LaMont does not “believe that on their own across the board these [DCO] products are going to effectively treat cancer.” (R22 (LaMont, Dep. at 53)).
362. LaMont did not listen to the Feijo’s radio show nor did she have the interest in listening to their show. (R22 (LaMont, Dep. at 77)).
363. LaMont did not say that she would defend the DCO products because she has limited knowledge of their products. (R22 (LaMont, Dep. at 78)).
364. LaMont has never used the DCO products. (R22 (LaMont, Dep. at 78); LaMont, Tr. 578-79).
365. LaMont has not studied the DCO products specifically. (R22 (LaMont, Dep. at 87-88); LaMont, Tr. 579).
366. LaMont acknowledges that traditional use evidence does not replace human clinical trials. (R22 (LaMont, Dep. at 89); LaMont, Tr. 584).
367. LaMont acknowledges that it is not a common occurrence in the industry to make cancer cure or cancer treatment claims. (R22 (LaMont, Dep. at 144-45)).

368. LaMont does not know of other companies that make claims that their products treat or cure cancer. (R22 (LaMont, Dep. at 145)).
369. Until there are clinical trials, LaMont agrees that “we don’t know” whether DCO’s products would effective in battling cancer. (R22 (LaMont, Dep. at 147); LaMont, Tr. 585).
370. LaMont “wouldn’t want to have anybody say, [t]ake this, it’s going to cure your colon cancer.” (R22 (LaMont, Dep. at 161)).
371. LaMont thinks the approach of referring to some doctors as Dr. Dumb-Dumb, as James Feijo does on his radio show, is disrespectful. (R22 (LaMont, Dep. at 166)).
372. LaMont agrees that there is a danger if consumers do not continue with traditional cancer therapy. (R22 (LaMont, Dep. at 166)).
373. LaMont personally does not think that the Feijos should be suggesting that people should not get colonoscopies, as they suggest on their radio show. (R22 (LaMont, Dep. at 182)).
374. LaMont recognizes that there is always that danger that people will take DCO products and not go and see their physicians. (R22 (LaMont, Dep. at 183)).
375. LaMont has never conducted a scientific controlled study of any sort. (R22 (LaMont, Dep. at 184); LaMont, Tr. 577).
376. LaMont does not take any DCO products. (R22 (LaMont, Dep. at 184-85)).
377. LaMont has not reviewed the medical records of anyone who has taken DCO products. (R22 (LaMont, Dep. at 185); LaMont, Tr. 577-78).
378. LaMont has not spoken to any cancer patients who are or have been taking DCO products. (LaMont, Tr. 583).

BioShark

James Duke, Ph.D.

379. Duke is not offering opinions on BioShark “[b]ecause the major ingredient is an animal, and I don’t deal in animals.” (R18 (Duke, Dep. at 63)).
380. Duke was not asked to provide an opinion on BioShark. (R18 (Duke, Dep. at 64)).
381. Duke does not think highly of the studies that have been published on shark cartilage. (R18 (Duke, Dep. at 64); Duke, Tr. 527).
382. Duke “was not convinced of the efficacy of shark cartilage in the studies that [he] read.” (R18 (Duke, Dep. at 64)).

James K. Dews

383. Dews never has heard of Bio*Shark. (R19 (Dews, Dep. at 53)).
384. Dews is not familiar with the use of shark cartilage in the treatment of cancer, and he has never seen any data relating to the use of shark cartilage in the treatment of cancer. He only has heard of this. (R19 (Dews, Dep. at 54)).

Sally B. LaMont, N.D.

385. LaMont does not know whether the product Bio*Shark inhibits tumor growth. (R22 (LaMont, Dep. at 91)).
386. LaMont does not know whether Bio*Shark is effective in the prevention, treatment, or cure of cancer. (R22 (LaMont, Dep. at 92); LaMont, Tr. 580).
387. LaMont acknowledged that there are no well-controlled studies demonstrating that the product Bio*Shark is antiangiogenic. (R22 (LaMont, Dep. at 101)).
388. LaMont stated that there are no studies on Bio*Shark that are controlled clinical trials demonstrating its effectiveness. (R22 (LaMont, Dep. at 101)).
389. LaMont does not know of any good or reliable data on the amount of antiangiogenic activity per gram of shark cartilage. (R22 (LaMont, Dep. at 112)).
390. LaMont agreed that it would be ideal to study variables such as the bioavailability, the absorption, and the distribution of Bio*Shark in order to assess its effectiveness with respect to cancer. (R22 (LaMont, Dep. at 101-102)).
391. LaMont probably would not use Bio*Shark or a product like it in her practice because she thinks that there are other ways to inhibit angiogenesis that are more certain. (R22 (LaMont, Dep. at 151)).

7 Herb Formula

James Duke, Ph.D.

392. Duke has no idea how much Burdock root in vitro would be necessary to eliminate cancer. (R18 (Duke, Dep. at 72); Duke, Tr. 528).
393. Duke understands that four of the herbs in 7 Herb Formula are the “Essiac formula [that] have had both positive and negative trials published in PubMed.” (R18 (Duke, Dep. at 73)).
394. Duke does not know how much of the elements that are in 7 Herb Formula are actually in the product sold by DCO. (R18 (Duke, Dep. at 78); Duke, Tr. 528).
395. Duke acknowledged that although two of the lignans in Burdock have shown antilymphomic properties, they probably were in vitro. (R18 (Duke, Dep. at 125)).

396. There are no clinical trials regarding Burdock's efficacy as to cancer in Duke's IE. (R18 (Duke, Dep. at 148); Duke, Tr. 530).
397. There is no indication in Duke's IE that watercress has been evaluated in clinical trials for its efficacy in treating cancer. (R18 (Duke, Dep. at 154); Duke, Tr. 531).
398. There is no indication in Duke's IE that turkey rhubarb has been evaluated in clinical trials to treat cancer. (R18 (Duke, Dep. at 155); Duke, Tr. 531).
399. There is no indication in Duke's IE that sheep sorrell has been evaluated in clinical trials to measure its efficacy in treating cancer. (R18 (Duke, Dep. at 153); Duke, Tr. 532).
400. There is no indication in Duke's IE that slippery elm has been evaluated in clinical trials for its efficacy in treating cancer. (R18 (Duke, Dep. at 157); Duke, Tr. 532).
401. There is no indication in Duke's IE that Cat's Claw has been evaluated in clinical trials for its efficacy in treating cancer. (R18 (Duke, Dep. at 157); Duke, Tr. 532).
402. Duke "do[es]n't think much of the Essiac formula." (R18 (Duke, Dep. at 129); Duke, Tr. 528).
403. Duke acknowledged that sheep sorrel is "touted" for cancer in the Essiac formula. (R18 (Duke, Dep. at 129); Duke, Tr. 532).
404. Duke would recommend Slippery Elm "more for stomach problems, mucous problems. It's famous for that." (R18 (Duke, Dep. at 130); Duke, Tr. 532).
405. Slippery Elm "is not one of the first things in [Duke's] cancer category." (R18 (Duke, Dep. at 130)).

James K. Dews

406. Dews "never heard of the 7 Herb Formula until this [lawsuit]." (R19 (Dews, Dep. at 59)).
407. According to Dews, 7 Herb Formula is a neutraceutical. (R19 (Dews, Dep. at 62)).
408. Dews is not prepared to talk about how the herbs in 7 Herb Formula may or may not benefit somebody with cancer. (R19 (Dews, Dep. at 39)).
409. Dews has never seen any controlled studies regarding 7 Herb Formula and its effectiveness in treating cancer. (R19 (Dews, Dep. at 58)).
410. Dews has never seen any studies that would say that 7 Herb Formula is effective in curing cancer. (R19 (Dews, Dep. at 58-59)).
411. Dews does not know of any studies on whether 7 Herb Formula prevents cancer. (R19 (Dews, Dep. at 59)).

412. Dews is not familiar with any studies that say there is anticancer activity in any of the components from the herbs contained in 7 Herb Formula. (R19 (Dews, Dep. at 16-24)).
413. Dews is not aware of any studies showing that 7 Herb Formula inhibits tumor formation. (R19 (Dews, Dep. at 59)).
414. Other than “folk-wise” uses of the herbs contained in 7 Herb Formula as a folk remedy for cancer, there have not been any scientific studies done on the herbs found in 7 Herb Formula relating to their effectiveness as a remedy for cancer treatment. (R19 (Dews, Dep. at 45-46)).
415. Dews does not recall seeing cancer mentioned specifically in any studies relating to burdock root. (R19 (Dews, Dep. at 44)).
416. Dews has never “seen it stated that [Siberian ginseng] helps with cancer.” (R19 (Dews, Dep. at 46)).
417. Dews has not ever seen any studies that have found that Siberian ginseng reduces tumors. (R19 (Dews, Dep. at 47)).
418. Dews has never seen any studies showing that slippery elm can help with, for example, stomach cancer. (R19 (Dews, Dep. at 49)).
419. Dews has never seen any actual scientific studies done that would show that slippery elm can cure any disease. (R19 (Dews, Dep. at 50)).
420. Dews has not seen any scientific studies on rhubarb root relating to treating cancer. (R19 (Dews, Dep. at 51-52)).

Sally B. LaMont, N.D.

421. LaMont does not know whether 7 Herb Formula is effective in the prevention, treatment, or cure of cancer. (R22 (LaMont, Dep. at 105); LaMont, Tr. 579-80).
422. LaMont “do[es]n’t think that 7 Herb Formula is going to cure cancer.” (R22 (LaMont, Dep. at 205)).
423. LaMont acknowledged that there are no clinical studies on this particular [7 Herb] formula. (R22 (LaMont, Dep. at 106)).
424. LaMont does not know about the doses in 7 Herb Formula. (R22 (LaMont, Dep. at 104); LaMont, Tr. 582).
425. LaMont does not know whether essiac has ever been evaluated in clinical trials to determine if it has any anticancer activity. (R22 (LaMont, Dep. at 106-07)).
426. LaMont testified that “[i]t would be a stretch to suggest that this [7 Herb Formula] is on its own going to be effective in treating cancer.” (R22 (LaMont, Dep. at 117)).

427. LaMont “would be concerned about patients taking [7 Herb Formula] on its own and expecting their cancer to go away.” (R22 (LaMont, Dep. at 118)).
428. LaMont stated that “[i]t would be a stretch for [her] that [7 Herb Formula] is a solution to cancer.” (R22 (LaMont, Dep. at 120)).
429. Lamont “would be surprised if [7 Herb Formula] itself is the solution to cancer.” (R22 (LaMont, Dep. at 120)).
430. LaMont would have a concern if 7 Herb Formula was advertised as a cancer solution. (R22 (LaMont, Dep. at 120-21, 123)).
431. LaMont does not know whether the amount of cat’s claw in 7 Herb Formula is going to be effective. (R22 (LaMont, Dep. at 129)).
432. LaMont acknowledged that we do not know whether 7 Herb Formula as an independent agent would have any beneficial effects in respect to ovarian cancer. (R22 (LaMont, Dep. at 137)).
433. LaMont personally has never used any of the essiac tea formulas in her practice. (R22 (LaMont, Dep. at 150)).
434. LaMont does not think it is a good idea to take 7 Herb or GDU instead of having a polyp in the colon cut out. (R22 (LaMont, Dep. at 182-83)).

GDU

James Duke, Ph.D.

435. Duke does not know how much of the elements that are in GDU are actually in the product sold by DCO. (R18 (Duke, Dep. at 78); Duke, Tr. 533).
436. Duke testified that he saw two or three studies on turmeric, “but they were not conclusive.” (R18 (Duke, Dep. at 120); Duke, Tr. 533).
437. Duke is not sure whether turmeric is more effective in fighting cancer than curcumin in an isolated form. (R18 (Duke, Dep. at 137)).
438. Duke does not remember any clinical studies on Bromelain. (R18 (Duke, Dep. at 124); Duke, Tr. 533).
439. Duke testified that Feverfew is “not the first thing I think about when I’m thinking cancer.” (R18 (Duke, Dep. at 129-130)).
440. There are no clinical trials regarding pineapple Bromelain’s efficacy as to cancer in Duke’s IE. (R18 (Duke, Dep. at 148)).
441. Based on his review, there are no clinical trials regarding turmeric’s efficacy as to cancer in Duke’s IE. (R18 (Duke, Dep. at 153); Duke, Tr. 533).

442. There are no indications in Duke's IE that Feverfew has been evaluated in clinical trials for its efficacy in treating cancer. (R18 (Duke, Dep. at 157); Duke, Tr. 533-34).

James K. Dews

443. Dews is not familiar with the product GDU. In fact, he does not have a clue what GDU is. (R19 (Dews, Dep. at 55)).

444. The active chemical in turmeric is curcumin, and curcumin is "very good at reducing inflammation." (R19 (Dews, Dep. at 65)).

445. One cannot say that reducing inflammation is a cure for any particular disease. (R19 (Dews, Dep. at 66)).

Sally B. LaMont, N.D.

446. LaMont does not know whether the product GDU eliminates tumors. (R22 (LaMont, Dep. at 92)).

447. LaMont does not know whether GDU is effective in curing cancer. (R22 (LaMont, Dep. at 43); LaMont, Tr. 581-82).

448. LaMont does not know whether GDU is effective in the treatment of cancer. (R22 (LaMont, Dep. at 92); LaMont, Tr. 581).

449. LaMont is not aware of any clinical studies of GDU. (R22 (LaMont, Dep. at 42-43)).

450. LaMont agrees that it would be fair to stay that it's impossible today to state the degree to which GDU is effective in the treatment or cure of cancer. (R22 (LaMont, Dep. at 45-46)).

451. LaMont does not know whether GDU on its own at its dose would eliminate tumors. (R22 (LaMont, Dep. at 74-75)).

452. LaMont recommends curcumin to inhibit inflammation. (R22 (LaMont, Dep. at 27)).

453. LaMont recommends that her patients use turmeric in their diet and have them supplement it in a dose of around 300 milligrams a day. (R22 (LaMont, Dep. at 27)).

454. LaMont's understanding is that 300 milligrams of turmeric per day has been commonly found to be effective at reducing inflammation. (R22 (LaMont, Dep. at 28)).

455. LaMont thinks that taking turmeric in high doses can inhibit clot formation. (R22 (LaMont, Dep. at 30-31)).

456. One clinical study that LaMont can mention came out last month and involved the use of turmeric or curcumin in patients with pancreatic cancer. (R22 (LaMont, Dep. at 38-39)).

457. According to LaMont, the 2008 study involving patients with pancreatic cancer used eight grams of a curcuminoid a day. (R22 (LaMont, Dep. at 38-39)).

458. LaMont believes that GDU contains 300 milligrams of turmeric. (R22 (LaMont, Dep. at 40)).
459. LaMont does not know whether 300 milligrams of turmeric were also studied in the context of the 2008 study. (R22 (LaMont, Dep. at 41)).
460. LaMont is not familiar with any clinical studies of curcumin at 300 milligrams per day. (R22 (LaMont, Dep. at 41-42)).
461. LaMont has “no way of knowing how many milligrams [of quercetin] would produce a certain therapeutic response.” (R22 (LaMont, Dep. at 64)).
462. LaMont agreed that the dosage found in GDU is on the lower end of the therapeutic spectrum. (R22 (LaMont, Dep. at 67)).
463. LaMont agrees that there is a big difference between seeing bromelain work in the capacity of a swollen ankle and having it work in the context of cancer. (R22 (LaMont, Dep. at 71-72)).
464. LaMont does not know what dosage of feverfew was contained or used in the study from Molecular Cancer Therapies in April 2005. (R22 (LaMont, Dep. at 80)).
465. LaMont does not know what dosage of feverfew was used in the study from the British Journal of Pharmacology in 2002. (R22 (LaMont, Dep. at 81)).

BioMixx

James Duke, Ph.D.

466. Duke does not know how much of the elements that are in BioMixx are actually in the product sold by DCO. (R18 (Duke, Dep. at 78); Duke, Tr. 534).

Sally B. LaMont, N.D.

467. LaMont recognizes that BioMixx “certainly has not gone through those kind of clinical trials that would prove that it’s going to cure cancer.” (R22 (LaMont, Dep. at 172)).
468. LaMont “do[es]n’t think as a stand-alone [product] BioMixx is going to cure their cancer or probably even effectively treat it.” (R22 (LaMont, Dep. at 176)).
469. LaMont did not write that BioMixx is effective in the treatment of cancer in her report. (R22 (LaMont, Dep. at 210)).
470. LaMont is not concluding that BioMixx is effective in the treatment of cancer. (R22 (LaMont, Dep. at 211)).
471. LaMont is not concluding that BioMixx completely heals the destructive effects of radiation and chemotherapy. (R22 (LaMont, Dep. at 211)).

472. LaMont does not know whether BioMixx is effective in the prevention, treatment, or cure of cancer. (LaMont, Tr. 580-81).

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. *Automotive 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”).

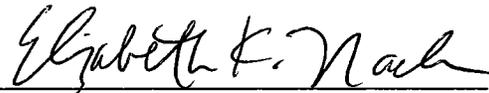
21. Respondents use testimonials to make representations to consumers, but courts consistently have found such anecdotal testimonial evidence inadequate to support such claims. *See, e.g., Direct Marketing Concepts*, 569 F. Supp. 2d at 304 (entering summary judgment for FTC where it was undisputed that 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 undisputed 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").

Respectfully submitted,



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

Dated: May 28, 2009

TAB 2

**UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION**

In the Matter of)

DANIEL CHAPTER ONE,)
a corporation,)

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

Docket No. 9329

PUBLIC DOCUMENT

**COMPLAINT COUNSEL'S
POST TRIAL BRIEF**

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**UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION**

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

COMPLAINT COUNSEL’S POST-TRIAL BRIEF

I. INTRODUCTION

The evidence at trial demonstrated 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 disseminated on the Internet that the DCO Products were effective in preventing, treating, or curing cancer or tumors. 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.” Indeed, Respondents admit that they made the following health and disease claims about the DCO Products:

- a. Bio*Shark inhibits tumor growth;
- b. Bio*Shark is effective in the treatment of cancer;
- c. 7 Herb Formula is effective in the treatment or cure of cancer;

- d. 7 Herb Formula inhibits tumor formation;
- e. GDU eliminates tumors;
- f. GDU is effective in the treatment of cancer;
- g. BioMixx is effective in the treatment of cancer; and
- h. Bio Mixx heals the destructive effects of radiation and chemotherapy.

CCPF ¶ 135.¹

Respondents also admit that they represented that they possessed and relied upon a reasonable basis that substantiated the claims that they made. CCPF ¶ 186. Because the Respondents made health and disease claims, the law requires that they possess competent and reliable scientific evidence to substantiate such claims. The evidence at trial demonstrated that Respondents lack any such evidence. Respondents' purported substantiation amounted to a collection of literature scattered about their office, which was not admitted into evidence for the truth of the matters asserted therein. Respondents' experts could not testify that there was competent and reliable scientific evidence to substantiate the claims that Respondents made.

Respondents' rhetoric about religion, paradigm fights, and the First Amendment cannot obscure the truth: Respondents made health and disease claims without substantiation, and by doing so violated the FTC Act.

II. STATEMENT OF FACTS

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 ¶ 6. From 1990 to 1997, DCO was a for-profit Rhode Island corporation that was organized “[t]o engage in the sale, retail, wholesale and distribution of health products, including but not limited to health foods and supplements, namely those with special nutritive qualities and values.”

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

CCPF ¶ 16-18. In 2002, James Feijo organized DCO as a corporation sole under Washington state laws. CCPF ¶ 1. James Feijo serves as DCO's Overseer, trustee for all DCO assets, and custodian of DCO's financial records. CCPF ¶¶ 4, 99, 105, 107. Patricia Feijo is DCO's Secretary. CCPF ¶ 5. Neither James nor Patricia Feijo is a doctor or research scientist. CCPF ¶¶ 147-49.

Respondents' principal office and place of business is located in Portsmouth, Rhode Island, where the Feijos live. CCPF ¶ 3. DCO's two Rhode Island buildings contain an Order Center and a warehouse for the products that DCO offers to the public. CCPF ¶ 9. James Feijo established another Washington corporation sole -- Messiah Y'Shua Shalom -- which he uses to own the Rhode Island property. CCPF ¶¶ 10-11.

B. Respondents are Responsible for the Development and Sale of the DCO Products

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

As the Overseer for DCO, James Feijo has responsibility for and control of its operations. CCPF ¶¶ 4, 95. James Feijo developed, created, and produced the DCO Products. CCPF ¶ 96. He established the DCO Products' price. CCPF ¶ 96. He and Patricia Feijo have been solely responsible for creating, drafting, and approving the DCO Products' directions and recommended usages. CCPF ¶ 97. They also developed the suggested dosages. CCPF ¶¶ 98. The identity and amount of each ingredient is contained on the product labels. CCPF ¶ 74. DCO contracts with Universal Nutrition to manufacture approximately 35-40 products, including Bio*Shark, GDU, and BioMixx. CCPF ¶ 81.

James Feijo and his wife, Patricia Feijo, are responsible for the information contained in DCO's advertising materials, including the BioGuide, the Cancer Newsletter, and the Web sites

www.danielchapterone.com, www.7herbformula.com, www.gdu2000.com. CCPF ¶ 180. James and Patricia Feijo also co-host the radio program, “Daniel Chapter One Health Watch,” on which they have counseled cancer patients who have called into the Daniel Chapter One radio program about taking the DCO Products. CCPF ¶¶ 183-84.

2. Respondents Sell Products to Consumers

DCO currently offers consumers 150 to 200 products. CCPF ¶ 8. DCO advertises those products on the Internet. CCPF ¶¶ 28, 134. Over one thousand consumers have purchased DCO’s products. CCPF ¶ 37. DCO has generated approximately \$2 million in annual sales for 2006, 2007, and 2008. CCPF ¶ 38. DCO offers consumers coupons for their next online store order. CCPF ¶ 52. Respondents run promotions from time to time to “give [consumers] more of an opportunity to . . . get things at a lower rate.” CCPF ¶ 53. For example, consumers can buy multiple bottles and get a bottle free. CCPF ¶ 54. Consumers can also join DCO’s Bucket-A-Month Club to obtain volume discounts on DCO’s products. CCPF ¶ 55.

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, including DCO’s shipping and handling fee of \$20.95. CCPF ¶ 50-51. Consumers have expressed concerns about Respondents’ high prices, as evidenced, for example, by a comment on Respondents’ Web site that, “I think [7 Herb Formula] costs too much.” CCPF ¶ 86.

3. The DCO Products

a. Bio*Shark

Bio*Shark contains, among other ingredients, Shark Cartilage. CCPF ¶ 75. 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 ¶ 75. Respondents invented

the term “BioMolecular Nutrition” to describe “the spiritual and physical” aspects of their products. CCPF ¶¶ 12-13. Respondents offer one bottle of Bio*Shark for \$30.95 (100 capsules) and \$65.95 (300 capsules). CCPF ¶ 76.

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 ¶ 83. 7 Herb Formula is essentially what is known as “essiac” plus watercress, Cat’s Claw, and Siberian Ginseng. 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 ¶ 83. The label further directs users to take 7 Herb Formula twice daily or as directed by a BioMolecular Nutrition health care professional. CCPF ¶ 83. Respondents offer one 32-ounce bottle of 7 Herb Formula for \$70.95. CCPF ¶ 85.

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 ¶ 87. Respondents offer GDU for \$29.95 (120 capsules) and \$45.95 (300 capsules). CCPF ¶ 88.

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 ¶ 91. Respondents offer BioMixx for \$22.95 (1 lb. powder) and \$40.95 (3 lb. powder). CCPF ¶ 92.

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

Respondents advertise their products on the Internet and disseminate information about the DCO Products through the Web sites www.danielchapterone.com, www.7herbformula.com, www.gdu2000.com, www.dc1pages.com, and www.dc1store.com. CCPF ¶¶ 134, 174, 176.

Consumers can locate the Web site www.danielchapterone.com by entering the term “cancer” in a Google search. CCPF ¶ 181. Respondents also disseminate information about the DCO Products through printed materials, including the BioGuide, the Cancer Newsletter, and “The Most Simple Guide to the Most Difficult Diseases: The Doctors’ How-to Quick Reference Guide.” CCPF ¶¶ 28, 176. These printed materials are available on the Internet. CCPF ¶¶ 178-79.

The Feijos are responsible for the information disseminated about the DCO Products. CCPF ¶¶ 141-42, 146, 180. James and Patricia Feijo also co-host DCO’s radio program, “Daniel Chapter One Health Watch,” for two hours a day, Monday through Friday. CCPF ¶ 183. They have counseled cancer patients who have called into the radio program about taking the DCO Products. CCPF ¶ 184. Respondents purposefully use the DCO radio program and the DCO Web sites to reach out to consumers. CCPF ¶ 185.

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 ¶¶ 136-40, 152-55, 157-73.

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 ¶¶ 153, 157, 166, and 171 (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 ¶ 138. Respondents reinforce this claim by listing at least ten different types of cancer with consumer “testimonials.” CCPF ¶ 139.

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 ¶ 143. 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 ¶¶ 153, 157, 166, 171.

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 ¶ 158 (*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 ¶ 160.

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 ¶ 151 (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 ¶¶ 152, 154, 157, 159, 165, 167. 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 ¶ 161 (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 ¶¶ 157, 159. 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 ¶ 167 (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 ¶¶ 154-55. 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 ¶ 140.

III. 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.

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.

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

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. *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

Respondents admit that they made the following claims:

- a. Bio*Shark inhibits tumor growth;
- b. Bio*Shark is effective in the treatment of cancer;
- c. 7 Herb Formula is effective in the treatment or cure of cancer;
- d. 7 Herb Formula inhibits tumor formation;
- e. GDU eliminates tumors;
- f. GDU is effective in the treatment of cancer;

- g. BioMixx is effective in the treatment of cancer; and
- h. Bio Mixx heals the destructive effects of radiation and chemotherapy.

CCPF ¶ 135.

In addition to Respondents' admissions, a facial analysis of the challenged DCO Products' advertisements and promotional materials establishes that the Respondents made the alleged misrepresentations. Respondents' Internet advertisements and promotional materials on the Internet for the DCO Products 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. *See* Complaint Counsel's Trial Exhibit (hereinafter referred to as CX ___) 12-12A. In the Web page's center, in bold type, appears the headline "**Bio*Shark: Tumors & Cysts.**" CX 12-12A; CCPF ¶ 152. 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" CX 12-12A; CCPF ¶ 152 (emphasis added). The claim is restated even more succinctly in an underlined link near the bottom of the Web page: "**Stop Tumor Growth & Cysts.**" CX 12-12A. Another link on the same page reinforces this claim, inviting consumers to "Read our clients [*sic*] testimonials on Bio Shark & Tumors." CX 12-12A. The link appears directly below the "BUY NOW" link through which consumers may purchase the product. CX

12-12A; CCPF ¶ 35.

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 ¶ 136.

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 ¶ 153 (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," very strongly implying, if not expressly stating, that Bio*Shark is effective in treating cancer. CCPF ¶ 163. Similarly, Respondents represented that Bio*Shark, with BioMixx and 7 Herb Formula, cured three inoperable tumors, resulting in the patient's "complete remission." CCPF ¶ 158. 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 ¶ 169.

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!,”** thus strongly implying, if not explicitly stating, that 7 Herb Formula is effective in the treatment or cure of cancer. CCPF ¶¶ 136, 157 (emphasis added).

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. CCPF ¶¶ 158, 160, 163.

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 ¶ 161 (emphasis added). In their product catalog and on their Web site under the heading “Cancer News,” Respondents claim that the 7 Herb Formula will “fight . . . tumor formation,” thus strongly implying, if not explicitly stating, that 7 Herb Formula inhibits tumor formation and prevents cancer or the recurrence of cancer. CCPF ¶¶ 157, 159.

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 ¶ 140.

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 ¶ 165 (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 ¶ 165. 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 14-14A.

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!”** thus strongly implying, if not explicitly stating, that GDU effectively treats cancer. CCPF ¶¶ 136, 166 (emphasis added),

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!," thus strongly implying, if not explicitly stating, that BioMixx effectively treats cancer. CCPF ¶¶ 136, 171 (emphasis added). DCO's "Cancer Newsletter" contains both express claims and claims so strongly implied as to be virtually express. CCPF ¶¶ 143-45. The cover displays the following:

**how to
fight
cancer is
your
choice!!!**

CX 15, 23-24; CCPF ¶ 143. 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 ¶ 173 (emphasis added).

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 ¶ 140 (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, and thus Respondents are not required to have competent and reliable scientific evidence to support those representations. *See Respondents' Opening Statement*, Tr. 241, 261. 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).

a. The Advertisements in Question Make Disease Claims, Not Structure-Function Claims

In making their structure-function assertion, Respondents ignore the applicable FDA law. In a case that the FDA brought against a maker of cancer cures, the court explained the proper legal framework under DSHEA:

In sum, if this Court finds Defendants, in the process of marketing BeneFin, MGN-3 and SkinAnswer, limited their claims to permissible structure-function claims, and those claims are truthful and not misleading, this Court may consider Defendants' arguments that the Products are supplements pursuant to § 343(r)(6)(A) of DSHEA. If, however, this Court finds Defendants made claims that the Products diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases, the Products must be considered drugs under the FDCA. This distinction is important because drugs are subject to much stricter FDA compliance standards than are dietary supplements.

United States v. Lane Labs–USA, Inc., 324 F. Supp. 2d 547, 566 (D.N.J. 2004). Here, Respondents' claims are not limited to structure-function claims. Rather, Respondents represent that the DCO Products mitigate, treat, cure, or prevent cancer or tumors, and, as a result, Respondents' DSHEA argument fails.

Respondents' argument that their advertisements contain merely “structure-function”

claims, and not health claims, simply ignores the advertisements themselves. 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"** are disease and health claims. CCPF ¶¶ 155, 158, 166, 170.

If there is any doubt that Respondents are addressing serious diseases and health conditions in their advertising, one need only refer to Respondents' publication 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. CX 20; CCPF ¶ 138.

Moreover, had Respondents 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).

DSHEA in no way altered the FTC's approach to truth in advertising, and, in fact, is fully

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

As detailed above, Respondents make 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 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>.

b. Respondents' Misrepresentations Are Not Cured By Disclaimers

Respondents' reliance on disclaimers also is unavailing. One only needs to review

Respondents' Internet advertisements (CX 12-15) 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”).

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. CCPF ¶ 186. 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.

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 ¶¶ 187-90, 198, 203, 206-09, 211. Furthermore, 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 ¶ 191. Respondents did present a series of articles that they purportedly relied upon as substantiation for their claims. However, during her testimony at trial, Patricia Feijo was unable to identify with specificity which articles she relied upon as substantiation for the specific claims that brought about the charges in this case. CCPF ¶ 197. Moreover, these articles were not admitted by the Court for the truth of the statements contained therein. *See* R9a - R9at; Tr. 601-610.

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

At trial, Complaint Counsel submitted the Expert Report and testimony of Denis R. Miller, M.D., a board-certified pediatric hematologist/oncologist, which confirmed that no

competent and reliable scientific evidence substantiates Respondents' claims concerning cancer. CCPF ¶¶ 212, 222. 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 ¶ 213. Dr. Miller has supervised numerous clinical studies of cancer treatments and authored hundreds of book chapters and peer reviewed articles on cancer. CCPF ¶¶ 215-17.

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 ¶ 218. 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 ¶ 219. 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 ¶¶ 220-21.

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 ¶ 222. 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 ¶ 223. 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 ¶ 224. 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 ¶ 225.³

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 ¶ 226. He 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. CCFS ¶ 227. 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

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).

humans with cancer. CCPF ¶ 228.

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 ¶ 229. He found no randomized, controlled clinical trials of any of the individual components of GDU or of GDU itself in patients with cancer. CCPF ¶ 230.

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 ¶ 231. Animal studies have suggested that curcumin may have activity as a cancer preventive and therapeutic agent. CCPF ¶ 232. 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 ¶ 233. Thus, Dr. Miller advised that further research on curcumin was necessary. CCPF ¶ 234.

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 ¶ 235. According to Dr. Miller, there are no reported studies of goldenseal in cancer patients. CCPF ¶ 236. 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 ¶ 236.

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 ¶ 237.

c. Respondents’ Purported Experts Did Not Possess Any Information Substantiating Respondents’ Claims and Reinforced Dr. Miller’s Conclusion that No Competent and Reliable Scientific Evidence Exists to Support Respondents’ Claims

Respondents submitted four purported experts to support their case: James Duke, Ph.D. (“Duke”), Jim Dews (“Dews”), Sally LaMont (“LaMont”), and Rustum Roy, Ph.D. (“Roy”). Respondents’ purported experts, none of whom is a medical doctor or cancer specialist, failed to provide any evidence to controvert Dr. Miller’s conclusions. CCPF ¶¶ 239-43, 296, 314, 324, 329-31. Respondents’ experts did not provide any evidence controverting Dr. Miller’s conclusion that Respondents do not possess any competent and reliable scientific evidence to substantiate the representations at issue in the Complaint.

In fact, Respondents’ experts reports, deposition testimony, and trial testimony reinforce Dr. Miller’s conclusions regarding what constitutes competent and reliable scientific evidence as well as the absence of any competent and reliable scientific evidence to support Respondents’ representations. For example, consistent with Dr. Miller’s view on the need for controlled clinical studies, Duke stated that “as a matter of science,” he did not believe that the herbal extract working in vitro proves that it would work in a human, as Duke recognizes the difference between something being efficacious in an in vitro study and something being efficacious in humans. CCPF ¶¶ 271-72. Duke also testified that anecdotal reports were “even below . . . [his]

lines of evidence.” CCPF ¶ 280. LaMont testified that until there are clinical trials, “we don’t know” whether DCO’s products would be effective in battling cancer, and that traditional use evidence does not replace human clinical trials. CCPF ¶¶ 366, 369. Similarly, Dews, offered as an expert in “[h]erbal formulations, specifically 7 Herb Formula,” stated that animal studies could not be extrapolated to humans. CCPF ¶¶ 295, 301.

Moreover, two of Respondents’ four purported experts -- Dews and Roy -- had not directly studied the DCO Products and were unfamiliar with the cancer claims that Respondents have made about them. Dews testified that he was not prepared to talk about how the herbs in 7 Herb Formula may or may not benefit a person with cancer. CCPF ¶ 408. He also stated that he did not know of any studies regarding the effectiveness of 7 Herb Formula in treating, curing, or preventing cancer, or inhibiting tumor formation. CCPF ¶¶ 409-11, 413. Furthermore, he was not familiar with any studies finding anticancer activity in any of the components of 7 Herb Formula. CCPF ¶¶ 412, 414-20.

Respondents offered Roy as “an expert in the conduct of scientific research and with the focus on health and materials.” CCPF ¶ 302. Roy and his laboratory do “zero clinical trials” and “have nothing to do with causing healing or not in a human being.” CCPF ¶¶ 308-09. Roy has never done any experiments to measure the efficacy of any medical treatments “at the human level,” and has not measured the efficacy of the DCO Products. CCPF ¶¶ 310-11. He testified that he “had no idea” what the DCO Products contain, and had not done any literature searches or research concerning any of the ingredients in the DCO Products. CCPF ¶¶ 312-13.

Respondents’ two remaining experts, Duke and LaMont, who did indeed review the DCO Products’ ingredients, echoed Dr. Miller’s conclusions. Duke, who stated that he made no effort to see whether there were any studies of any sort regarding the DCO Products, testified that he

would not recommend that people self-medicate with herbal remedies in treating cancer, and that he was sure there was a risk some people will pursue herbal medications instead of effective pharmaceutical medications and thereby die. CCPF ¶¶ 244-45, 292. Duke reviewed the literature and information regarding Respondents' products and found no evidence that those products, or their ingredients, had been shown in clinical trials to be effective in the treatment of cancer. CCPF ¶¶ 381-82, 396-402, 436-42. Indeed, to the contrary, Duke stated that the studies he had reviewed on the principal ingredients in two of Respondents' products – shark cartilage (Bio*Shark) and essaic tea (7 Herb Formula) – questioned their efficacy in treating cancer. CCPF ¶¶ 381-82, 402. At trial, Duke also testified that he was “quite surprised” that most of the chemicals in the plants used in the DCO Products “are not biblical.” CCPF ¶ 256.

LaMont testified that “cancer must be treated with conventional therapies.” CCPF ¶ 333. LaMont stated that if in the course of doing a work-up on a patient, she found “a diagnosis that looks like it could be cancer,” she absolutely would refer the patient to a traditional physician and would co-manage that patient's care with the physician. CCPF ¶ 328. She thinks that it is “best that people follow the recommendations of their oncologist and utilize protocols that are proven to be most effective for their cancer and that they should be well-informed of the potential value of the array of other therapies.” CCPF ¶ 355. She added that “[t]he awareness of the powerful chemoprotective effects of plant foods and medicines should not influence patients with cancer and other serious disease to abandon using the most effective methods that modern medicine has to offer.” CCPF ¶ 357.

LaMont also testified that there have been no clinical studies performed on the DCO Products, and stated that these products “are not silver bullets.” CCPF ¶¶ 352-53. LaMont acknowledged that since the DCO products have not been tested, we do not know the

effectiveness of GDU, BioMixx, Bio*Shark, and 7 Herb Formula in the prevention, treatment, or cure of cancer. CCPF ¶ 351. LaMont, “[do[es]n’t think that 7 Herb Formula is going to cure cancer.” CCPF ¶ 422. She also testified that “[i]t would be a stretch to suggest that [the 7 Herb Formula] is on its own going to be effective in treating cancer” and that “[i]t would be a stretch for [her] that [7 Herb Formula] is a solution to cancer.” CCPF ¶¶ 426, 428. She would have a concern if 7 Herb Formula was advertised as a cancer solution. CCPF ¶ 430.

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.

IV. 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)).*

At trial, Respondents failed to adduce any facts to dispute that their representations constitute commercial speech. The evidence at trial clearly demonstrated that the challenged

advertisements and promotional materials, which are broadly disseminated on the Internet to draw customers, contain little or no political or religious commentary. *See* CX 12-15. Thus, Respondents have engaged in commercial speech in advertising and selling the DCO Products, and their commercial speech is deceptive.

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 have asserted that their sale of the DCO Products and any attendant advertising claims are a part of their religious ministry, this purported link does not change the commercial nature of the speech at issue. In *Bolger v. Youngs Drug Products Corporation*, the Supreme Court concluded that advertisements were commercial speech, “notwithstanding the fact that they contain discussions of important public issues.” 463 U.S. 60, 67-68 (1983). Indeed, to find otherwise would allow advertisers to “immunize false or misleading product information from government regulation simply by including references to public issues.” *Id.* at 68. 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.

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

Respondents have asserted that this administrative proceeding imposes a prior restraint in violation of their First Amendment rights. 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 brought 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.

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.

V. COMPLAINT COUNSEL IS ENTITLED TO THE PROPOSED ORDER AGAINST RESPONDENTS

A. James Feijo is Individually Liable and Thus An Order is Appropriate Against Him

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 ¶¶ 4, 180. Respondents admit that Respondent Feijo is responsible for the activities of Respondent DCO as its Overseer. CCPF ¶ 4, 95. 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

dosages of the DCO Products. CCPF ¶¶ 24, 96-98. 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 ¶ 180. 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 ¶¶ 183-84. Finally, Respondent Feijo is the trustee for all DCO assets, including all funds which are held in trust. CCPF ¶ 99.

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.

B. 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).

Therefore, Complaint Counsel respectfully request that the Court enter the proposed order accompanying the Complaint. The undisputed 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"). The proposed order would prohibit 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 proposed order also contains standard provisions regarding record-keeping, dissemination of the order to officers and employees, prior notification of corporate changes, filing compliance reports, and sunseting of the order.

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VI. CONCLUSION

The evidence at trial demonstrated 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 the proposed order attached to the Complaint in this case.

Respectfully submitted,



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Alexander Hamilton U.S. Custom House
One Bowling Green, Suite 318
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Dated: May 28, 2009

TAB 3

CX 4	CD Containing Daniel Chapter One - July 8, 2008 Radio Show [Part 2] [FTC-DCO 0004]	
CX 5	July 8, 2008 DCO Radio Show Transcript [FTC-DCO 0499 - 0607]	
CX 6	CD containing Daniel Chapter One - July 14, 2008 Radio Show [Part 1] [FTC-DCO 0005]	
CX 7	CD containing Daniel Chapter One - July 14, 2008 Radio Show [Part 2] [FTC-DCO 0006]	
CX 8	July 14, 2008 DCO Radio Show Transcript [FTC-DCO 0608 - 0710]	
CX 9	CD containing testimonial of Jim Gives on DCO Website [FTC-DCO 008]	
CX 10	CD containing purchase of DCO products by FTC investigator Michael Marino [FTC-DCO 0009]	HOJ Tr. 62-67 ⁴
CX 11	Printed pages from DCO Website capturing purchase of 4 DCO Products [REDACTED] [FTC-DCO 0711-0722] (marked as Exhibit 5 at James D. Feijo's January 13, 2009 deposition)	HOJ Tr. 66-67
CX 12	Attachment A to Administrative Complaint - filed September 18, 2008 - Bio*Shark [FTC-DCO 0011 - 0012] (marked as Exhibit 4 at James D. Feijo's January 13, 2009 deposition)	Tr. 11-12 ⁵
CX 12 A	Teleport Pro view of portions of CX 12 [FTC-DCO 2826A, 2827A]	Tr. 11-12
CX 13	Attachment B to Administrative Complaint - filed September 18, 2008 - 7 Herb Formula [FTC-DCO 0013 - 0027] (marked as Exhibit 4 at James D. Feijo's January 13, 2009 deposition)	Tr. 11-12
CX 13 A	Teleport Pro view of portions of CX 13 [FTC-DCO 2828A, 2828B, 2829A, 2840A, 2840B, 2842A]	Tr. 11-12

⁴ "HOJ Tr." refers to the transcript from the April 21, 2009, hearing on jurisdiction.

⁵ "Tr." refers to the transcript for the hearing on April 23-24, and April 27, 2009.

CX 14	Attachment C to Administrative Complaint - filed September 18, 2008 - GDU [FTC-DCO 0028 - 0030] (marked as Exhibit 4 at James D. Feijo's January 13, 2009 deposition)	Tr. 11, 15-16
CX 14 A	Teleport Pro view of portions of CX 14 [FTC-DCO 2844A]	Tr. 12, 15-16
CX 15	Attachment D to Administrative Complaint - filed September 18, 2008 - BioMixx [FTC-DCO 0031 - 0032] (marked as Exhibit 4 at James D. Feijo's January 13, 2009 deposition)	
CX 16	Late January/Early February 2008 Letter and Attachments from James Feijo to FTC [FTC-DCO 0037 - 0043]	
CX 17	March 31, 2008 Letter and Attachments from James Turner to FTC [FTC-DCO 0058 - 0119] - including DCO's BioMolecular Nutrition Product Catalog (marked as Exhibit 6 at Respondent James D. Feijo's January 13, 2009 deposition); DCO Product labels (marked as Exhibits 14-16 at Patricia Feijo's January 14, 2009 deposition); and pages from DCO's Web site, dated March 31, 2008.	HOJ Tr. 61-62, 139-40
CX 18	April 4, 2008 Letter and Attachments from James Turner to FTC [FTC-DCO 0120 - 0291 and FTC-DCO 2030 - 2041] - including "Daniel Chapter One Product Labels (For Products for which Representations have been made regarding Cancer or Tumors)" (marked as Exhibits 14-18 at Patricia Feijo's January 14, 2009 deposition); "www.7HerbFormula.com;" "Web Pages from prior Daniel Chapter One Web sites."	
CX 19	June 2, 2008 Letter and Attachments from James Turner to FTC [FTC-DCO 0292 - 0305] (marked as Exhibit 8 at Respondent James D. Feijo's January 13, 2009 deposition)	
CX 20	Daniel Chapter One, <u>The Most Simple Guide to the Most Difficult Diseases: The Doctors' How-To Quick Reference Guide</u> [FTC-DCO 2714 - 2825]	Tr. 15-16

CX 21	BioGuide: The BioMolecular Nutrition Guide to Natural Health 3 [FTC-DCO 0306 - 0381] (marked as Exhibit 12 at Respondent James D. Feijo's January 13, 2009 deposition)	HOJ Tr. 60-61 Tr. 16
CX 22	DCO "The Truth Will Set You Free!" Brochure [FTC-DCO 0382 - 0385]	HOJ Tr. 135-37, 325
CX 23	"How to Fight Cancer is Your Choice!!!" - Cancer Newsletter, Millenium [sic] Edition, 2002 [FTC-DCO 0390 - 0405]	Tr. 16, 19, 398-404
CX 24	"How to Fight Cancer is Your Choice!!!" - Cancer Newsletter, 2004 [FTC-DCO 0406 - 0421]	Tr. 16, 19
CX 25	7 Herb Formula Brochure (3 panels) [FTC-DCO 0422 - 0423]	
CX 26	7 Herb Formula Brochure (1 page - double sided) [FTC-DCO 0424 - 0425]	
CX 27	GDU Caps Brochure (3 panels) [FTC-DCO 0426 - 0427]	
CX 28	GDU Caps Brochure (1 page - double sided) [FTC-DCO 0428 - 0429]	
CX 29	Printed Web pages from Daniel Chapter One Web sites [FTC-DCO 0430 - 0492] - including "7 Herb Formula: Detoxify, Acid Reflux & Cancer Help" and "DC1 Affiliate Program."	HOJ Tr. 113-15, 140-45
CX 30	Printed Web pages from Daniel Chapter One Website [FTC-DCO 0493 - 0496] - including "I want the Original Essiac formula, not some knock off brand" and "I think it costs too much."	HOJ Tr. 145-49 Tr. 14-15
CX 31	State of Washington Secretary of State Attaching Articles of Incorporation of Daniel Chapter One [FTC-DCO 0735 - 0741]	HOJ Tr. 87, 90-98, 341-42
CX 32	Printed Web pages from Accent Radio Network Web site [FTC-DCO 2950 - 2962]	HOJ Tr. 110-12

CX 33	Emails from DCO relating to FTC Investigator purchase of DCO products [REDACTED] [FTC-DCO 0723 - 0729] (marked as Exhibit 5 at Respondent James D. Feijo's January 13, 2009 deposition)	HOJ Tr. 56-59, 149-50
CX 34	DCO's purchase order form and invoice sent with shipment of DCO products for FTC Investigator purchase [FTC-DCO 2942 - 2943]	HOJ Tr. 59-60, 73, 83
CX 35	State of Washington Secretary of State Attaching Articles of Incorporation of Messiah Y'Shua Shalom [FTC-DCO 2944 - 2949]	
CX 36	Letter from Canadian Competition Bureau to James Feijo [FTC-DCO 0767 - 0772]	
CX 37	Food and Drug Administration Warning Letter to James Feijo [FTC-DCO 0773 - 0776]	
CX 38	Respondents' Responses to Complaint Counsel's First Request for Production of Documentary Materials and Tangible Things	
CX 39	Respondents' Responses to Complaint Counsel's First Set of Interrogatories and Exhibits (marked as Exhibit 7 at Respondent James D. Feijo's January 13, 2009 deposition)	
CX 40	First Supplement to Respondents' Responses to Complaint Counsel's First Set of Interrogatories (marked as Exhibit 11 at Respondent James D. Feijo's January 13, 2009 deposition)	
CX 41	Respondents' Objections to Complaint Counsel's Second Set of Interrogatories	
CX 42	Respondents' Objections to Complaint Counsel's Second Request for Production of Documentary Materials and Tangible Things	
CX 43	Respondents' Responses and Objections to Complaint Counsel's Request for Admissions	

CX 44	Daniel Chapter One Monthly Gross Sales (marked as Exhibit 9 at Respondent James D. Feijo's January 13, 2009 deposition)	
CX 45	Email and Attachments from Jay Harrison to Patricia Feijo (marked as Exhibit 10 at Respondent James D. Feijo's January 13, 2009 deposition)	
CX 46	Universal Nutrition invoices (marked as Exhibit 20 at Claudia Petra Bauhoffer-Kinney's January 15, 2009 deposition)	HOJ Tr. 239, 259
CX 47	Letter from Claudia Petra Bauhoffer-Kinney to Respondent James D. Feijo (marked as Exhibit 21 at Claudia Petra Bauhoffer-Kinney's January 15, 2009 deposition)	
CX 48	Respondents' American Express Gold Card Records [FTC-DCO 2963 - 3338]	HOJ Tr. 151-60
CX 49	Respondents' Citizens Bank Records [FTC-DCO 3339 - 3839]	HOJ Tr. 161-68, 228-32
CX 50	Respondents' Corporate Records from the Rhode Island Office of the Secretary of State [FTC-DCO 3840 - 3872]	HOJ Tr. 101-09, 118, 120-21, 123-24, 173-79, 194-97
CX 51	Copy of the Declaration of Independence	HOJ Tr. 98-99
CX 52	Expert Witness Report of Denis R. Miller, M.D.	

COMPLAINT COUNSEL'S WITNESS INDEX

Complaint Counsel called the following witnesses in this proceeding:

1. **Michael Marino**
Investigator, Federal Trade Commission
One Bowling Green, Suite 318
New York, NY 10004

Transcript pages at which the witness's testimony appears: HOJ Tr. 51-68.

2. **James Feijo**
Owner and President, Daniel Chapter One
1028 East Main Road
Portsmouth, RI 02871-0223

Transcript pages at which the witness's testimony appears: HOJ Tr. 69-239; Tr. 415-64.

3. **Denis R. Miller, M.D.**
36 East Lake Road
Tuxedo Park, NY 10987

Transcript pages at which the witness's testimony appears: Tr. 28-229.

Respectfully submitted,



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Dated: May 28, 2009

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on May 28, 2009, I have filed and served the attached **COMPLAINT COUNSEL'S POST TRIAL BRIEF** as set forth below:

The original, one paper copy, 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

Four bound copies and one electronic copy via email to:

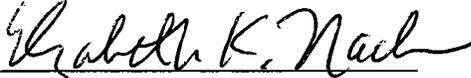
The Honorable D. Michael Chappell
Administrative Law Judge
600 Pennsylvania Ave., N.W., Room H-528
Washington, DC 20580

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

James S. Turner, Esq.
Betsy Lehrfeld, Esq.
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