Complaint

IN THE MATTER OF

DANIEL CHAPTER ONE
AND
JAMES FEIJO

COMPLAINT IN REGARD TO ALLEGED VIOLATION OF SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT; INITIAL DECISION; AND OPINION OF THE COMMISSION AND ORDER AFFIRMING THE INITIAL DECISION.

Docket No. 9329; File No. 082 3085
Complaint, September 16, 2008 - Initial Decision, August 5, 2009
Opinion and Order, December 18, 2009

The Commission issued an administrative complaint, alleging that Daniel Chapter One violated Sections 5, 12 and 15 of the Federal Trade Commission Act in connection with the advertising, promotion, offering for sale, sale, and distribution of products to the public, including Bio*Shark, 7 Herb Formula, GDU, and BioMixx, which purport to prevent, treat, or cure cancer or tumors, and other serious medical illnesses. In his Initial Decision, Chief Administrative Law Judge D. Michael Chappell remedy issued an order requiring Respondents to cease and desist from making the types of misrepresentations challenged in the Complaint after determining that Respondents lacked a reasonable basis for their claims, and that Complaint Counsel demonstrated that Respondents' statements are deceptive or misleading. Respondent appealed the Initial Decision. On appeal, the Commission unanimously affirmed the Initial Decision of the Administrative Law Judge both as a matter of fact and as a matter of law. The Commission found the order entered to be proper, but modified the language in Attachment A of the Order, the prescribed notice that the Respondents are required to send to consumers who purchased the products at issue.

Participants

For the *Commission: David W. Dulabon, William H. Efron, Leonard L. Gordon, Elizabeth K. Nach, Carole A. Paynter,* and *Theodore Zang, Jr.*

For the *Respondents: Betsy E. Lehrfeld, Christopher B. Turner,* and *James S. Turner, Swankin & Turner,* and *Michael McCormack, Solo Practitioner.*

COMPLAINT

The Federal Trade Commission ("FTC"), having reason to believe that Daniel Chapter One, a corporation, and James Feijo, individually, and as an officer of Daniel Chapter One, (collectively, "Respondents") have violated the FTC Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Daniel Chapter One ("DCO") is a Washington corporation with its principal office or place of business at 1028 East Main Road, Portsmouth, Rhode Island 02871.

2. Respondent James Feijo ("Feijo") owns DCO and does business as the President of DCO. His principal office or place of business is the same as that of DCO. He is responsible for managing the marketing and intellectual property of the DCO Products. At all times relevant to this complaint, acting alone or in concert with others, Feijo has formulated, directed, controlled, or participated in the various acts and practices set forth herein.

3. Respondents have advertised, promoted, offered for sale, sold, and distributed products to the public, including Bio*Shark, 7 Herb Formula, GDU, and BioMixx (collectively, the "DCO Products"). The DCO Products are "foods" or "drugs" within the meaning of Sections 12 and 15 of the FTC Act.

4. The acts and practices of Respondents, as alleged herein, have been in or affecting commerce, as "commerce" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

5. Since 2005, Respondents have engaged in deceptive acts or practices in connection with the advertising, promotion, offering for sale, sale, and distribution of the DCO Products which purport to prevent, treat, or cure cancer or tumors, and other serious medical illnesses. Respondents operate linked web pages on the website, www.danielchapterone.com, through which they advertise and sell the products at issue in this complaint.

Bio*Shark

6. Respondents describe Bio*Shark as a dietary supplement that contains, among other ingredients, Shark Cartilage. 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). Each 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.

Respondents' Advertisements for Bio*Shark

7. To induce consumers to purchase Bio*Shark, Respondents have created, prepared, disseminated, or caused to be disseminated advertisements, promotional web sites (including www.danielchapterone.com), and catalogues. Exhibit A hereto is a printout of portions of Respondents' web site, which contains representations concerning Bio*Shark including:

> 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.
> . .

7 Herb Formula

8. Respondents describe 7 Herb Formula as a liquid tea concentrate dietary supplement that contains, among other ingredients, distilled water, Cat's Claw, Burdock Root, Siberian Ginseng, Sheep Sorrel, Slippery Elm, Watercress, and Turkey Rhubarb Root. Respondents offer one 32-ounce bottle of 7 Herb Formula for $70.95. 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.

Complaint

Respondents' Advertisements for 7 Herb Formula

9. To induce consumers to purchase 7 Herb Formula, Respondents have created, prepared, disseminated, or caused to be disseminated advertisements, promotional web sites (including www.danielchapterone.com), and catalogues. Exhibit B hereto is a printout of a portion of Respondents' web site, which contains representations concerning 7 Herb Formula including:

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

. . .

If you suffer from any type of cancer, Daniel Chapter One suggests taking this products [sic], to fight it:
7*Herb Formula TM. . . Bio*Shark TM. . .
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!. . .

B. **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. . .'

GDU

10. Respondents describe GDU as a dietary supplement that contains, among other ingredients, Bromelain, Turmeric, Quercetin, Feverfew, and Boron. Respondents offer GDU for $45.95 (300 capsules) and $29.95 (120 capsules). Respondents' product labels direct 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.

Respondents' Advertisements for GDU

11. To induce consumers to purchase GDU, Respondents have created, prepared, disseminated, or caused to be disseminated advertisements, promotional web sites (including www.danielchapterone.com), and catalogues. Exhibit C hereto is a printout of a portion of Respondents' web site, which contains representations concerning GDU including:

> 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.

BioMixx

12. Respondents describe BioMixx as a dietary supplement that contains, among other ingredients, Goldenseal, Echinacea, and Ginseng. Respondents offer BioMixx for $40.95 (3 lb. powder) and $22.95 (1 lb. powder). Respondents' product label directs users to take five scoops daily.

Complaint

Respondents' Advertisements for BioMixx

13. To induce consumers to purchase BioMixx, Respondents created, prepared, disseminated, or caused to be disseminated advertisements, promotional web sites (including www.danielchapterone.com), and catalogues. Exhibit D hereto is a printout of a portion of Respondents' web site, which contains representations concerning BioMixx including:

> 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.

Respondents' Unsubstantiated Representations

14. Through the means described in Paragraphs 6 through 13, including, but not limited to, the statements contained in the advertisements attached as Exhibits A through D, Respondents have represented, expressly or by implication, that:

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. BioMixx heals the destructive effects of radiation and chemotherapy.

15. Through the means described in Paragraphs 6 through 13, Respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 14, at the time the representations were made.

16. In truth and in fact, Respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 14, at the time the representations were made. Therefore, the representation set forth in Paragraph 15 was, and is, unsubstantiated.

17. The acts and practices of Respondents as alleged in this complaint constitute unfair or deceptive acts or practices, in or affecting commerce in violation of Sections 5(a) and 12 of the FTC Act.

NOTICE

Proceedings on the charges asserted against the respondents named in this complaint will be held before an Administrative Law Judge (ALJ) of the Federal Trade Commission, under Part 3 of the Commission's Rules of Practice, 16 C.F.R. Part 3. A copy of Part 3 of the Rules is enclosed with this complaint.

You are notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the twentieth (20th) day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted.

If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material allegations to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint, and together with the complaint will provide a record basis on which the ALJ shall file an initial decision containing

appropriate findings and conclusions and an appropriate order disposing of the proceeding. In such answer you may, however, reserve the right to submit proposed findings and conclusions and the right to appeal the initial decision to the Commission under Section 3.52 of the Commission's Rules of Practice for Adjudicative Proceedings.

Failure to answer within the time above provided shall be deemed to constitute a waiver of your right to appear and contest the allegations of the complaint and shall authorize the ALJ, without further notice to you, to find the facts to be as alleged in the complaint and to enter an initial decision containing such findings, appropriate conclusions and order.

The ALJ will schedule an initial prehearing scheduling conference to be held not later than 7 days after the last answer is filed by any party named as a respondent in the complaint. Unless otherwise directed by the ALJ, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the prehearing scheduling conference, and Rule 3.31(b) obligates counsel for each party, within 5 days of receiving a respondent's answer, to make certain initial disclosures without awaiting a formal discovery request.

Notice is hereby given to each of the respondents named in this complaint that a hearing before the ALJ on the charges set forth in this complaint will begin on December 16, 2008, at 10:00 a.m., in Room 532, Federal Trade Commission Building, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580, or such other place as determined by the ALJ. At the hearing, you will have the right under the Federal Trade Commission Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in the complaint.

The following is the form of order which the Commission has reason to believe should issue if the facts are found to be as alleged in the complaint. If, however, the Commission should conclude from record facts developed in any adjudicative

proceedings in this matter that the proposed provisions might be inadequate to fully protect the consuming public, the Commission may order such other relief as it finds necessary or appropriate.

Moreover, the Commission has reason to believe that, if the facts are found as alleged in the complaint, it may be necessary and appropriate for the Commission to seek relief to redress injury to consumers, or other persons, partnerships or corporations, in the form of restitution for past, present, and future consumers and such other types of relief as are set forth in Section 19(b) of the Federal Trade Commission Act. The Commission will determine whether to apply to a court for such relief on the basis of the adjudicative proceedings in this matter and such other factors as are relevant to consider the necessity and appropriateness of such action.

ORDER

For purposes of this order the following definitions apply:

A. "Competent and reliable scientific evidence" shall mean 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.

B. "Covered Product or Service" shall mean any dietary supplement, food, drug, or other health-related product, service, or program, including, but not limited to, Bio*Shark, 7 Herb Formula, GDU, and BioMixx.

C. "Food" and "drug" shall mean "food" and "drug" as defined in Section 15 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 55.

D. "Advertisement" means any written or verbal statement, illustration, or depiction that is designed to effect a sale or to create interest in the purchasing of goods or services, whether it appears in a book,

brochure, newspaper, magazine, pamphlet, leaflet, circular, mailer, book insert, letter, catalogue, poster, chart, billboard, public transit card, point of purchase display, packaging, package insert, label, film, slide, radio, television or cable television, video news release, audio program transmitted over a telephone system, infomercial, the Internet, e-mail, or in any other medium.

E. Unless otherwise specified, "Respondents" shall mean Daniel Chapter One and its successors and assigns, affiliates, or subsidiaries, and its officer, James Feijo, individually and as an officer of the corporation; and each of the above's agents, representatives, and employees.

F. "Commerce" shall mean as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

G. "Endorsement" shall mean "endorsement" as defined in 16 C.F.R. § 255.0(b).

I.

IT IS HEREBY ORDERED that Respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of BioShark, 7 Herb Formula, GDU, and BioMixx, or any substantially similar health-related program, service, or product, or any other Covered Product or Service, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of product or program names or endorsements, that such health-related program, service, product, or Covered Product or Service prevents, treats, or cures or assists in the prevention, treatment, or cure of any type of tumor or cancer, including but not limited to representations that:

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; or

H. BioMixx heals the destructive effects of radiation or chemotherapy;

unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that Respondents, directly or through any person, corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product or Service, in or affecting commerce, shall not make any representation, in any manner, directly or by implication, including through the use of a product name, endorsement, depiction, or illustration, about the efficacy, performance, or health-related benefits of any Covered Product or Service unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

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III.

IT IS FURTHER ORDERED that:

A. Nothing in this order shall prohibit Respondents from making any representation for any drug that is permitted in labeling for such drug under any tentative or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and

B. Nothing in this order shall prohibit Respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

IV.

IT IS FURTHER ORDERED that:

A. Respondents shall, within seven (7) days after the date of service of this order, deliver to the Commission a list, in the form of a sworn affidavit, of all consumers who purchased Bio*Shark, 7 Herb Formula, GDU, and/or BioMixx, on or after January 1, 2005 through the date of service of this order. Such list shall include each consumer's name and address, the product(s) purchased, and, if available, the consumer's telephone number and email address;

B. Within forty-five (45) days after the date of service of this order, respondents shall send by first class mail, postage prepaid, an exact copy of the notice attached as Attachment A to all persons identified in Part IV.A. The face of the envelope containing the notice shall be an exact copy of Attachment B. The mailing shall not include any other documents; and

C. Except as provided in this order, respondents, and their officers, agents, servants, employees, attorneys, and representatives shall not sell, rent, lease, transfer, or otherwise disclose the name, address, telephone number, credit card number, bank account number, e-mail address, or other identifying information of any person who paid any money to any respondent, at any time prior to the issuance of this order, in connection with the purchase of Bio*Shark, 7 Herb Formula, GDU, and/or BioMixx. *Provided, however*, that respondents may disclose such identifying information to the FTC pursuant to Part IV.A., above, or any law enforcement agency, or as required by any law, regulation, or court order.

V.

IT IS FURTHER ORDERED that for a period of five (5) years after the last date of dissemination of any representation covered by this order, Respondents shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:

A. All advertisements and promotional materials containing the representation;

B. All materials that were relied upon in disseminating the representation; and

C. All tests, reports, studies, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question such representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

VI.

IT IS FURTHER ORDERED that Respondents shall deliver a copy of this order to all current and future principals, officers,

directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty days after the person assumes such position or responsibilities.

VII.

IT IS FURTHER ORDERED that Respondent Feijo, for a period of ten (10) years after the date of issuance of this order, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment. The notice shall include the Respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Paragraph shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

VIII.

IT IS FURTHER ORDERED that Respondent DCO and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation(s) that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. *Provided, however*, that, with respect to any proposed change in the corporation about which Respondent learns less than thirty (30) days prior to the date such action is to take place, Respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Paragraph shall be sent by certified mail to the Associate Director,

Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

IX.

IT IS FURTHER ORDERED that Respondents shall, within sixty (60) days after the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

X.

IT IS FURTHER ORDERED that this order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

A. Any paragraph in this order that terminates in less than twenty (20) years;

B. This order's application to any Respondent that is not named as a Respondent in such complaint; and

C. This order if such complaint is filed after the order has terminated pursuant to this paragraph.

Provided further, that if such complaint is dismissed or a federal court rules that the Respondents did not violate any provision of this order, and the dismissal is either not appealed or upheld on appeal, then the order will terminate according to this paragraph as though the complaint was never filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

THEREFORE, the Federal Trade Commission this sixteenth day of September, 2008, has issued this complaint against Respondents.

By the Commission.

ATTACHMENT A

LETTER TO BE SENT BY FIRST CLASS MAIL

[To be printed on letterhead of Daniel Chapter One]

[Name and address of recipient] [Date]
Dear [Recipient]:

Our records show that you bought **[name of products]** from our website **[name of website]**. We are writing to tell you that the Federal Trade Commission ("FTC") has found that our advertising claims for these products were false or unsubstantiated**,** and has issued an Order prohibiting us from making those claims in the future. The Order entered against us also requires that we send you the following information about the scientific evidence on these products.

Very little scientific research has been done concerning Shark Cartilage, Cat's Claw, Burdock Root, Siberian Ginseng, Sheep Sorrel, Slippery Elm, Watercress, Turkey Rhubarb Root, Bromelain, Turmeric, Quercetin, Feverfew, Boron, Goldenseal, Echinacea, and Ginseng as a means of prevention, treatment, or cure for cancer in humans. The scientific studies that have been done do not demonstrate that any of these ingredients, which are included in Bio*Shark, 7 Herb Formula, GDU, and BioMixx, are effective when used for prevention or treatment for cancer in humans.

It is very important that you talk to your doctor or health care provider before using **any** alternative or herbal product, including Shark Cartilage, Cat's Claw, Burdock Root, Siberian Ginseng, Sheep Sorrel, Slippery Elm, Watercress, Turkey Rhubarb Root, Bromelain, Turmeric,

Quercetin, Feverfew, Boron, Goldenseal, Echinacea, and Ginseng. Speaking with your doctor is important to make sure that all aspects of your medical treatment work together. Things that seem safe, such as certain foods, herbs, or pills, may interfere or affect your cancer or other medical treatment, or other medicines you might be taking. Some herbs or other complementary or alternative treatments may keep your medicines from doing what they are supposed to do, or could be

harmful when taken with other medicines or in high doses. It also is very important that you talk to your doctor or health care provider before you decide to take any alternative or herbal product, including Shark Cartilage, Cat's Claw, Burdock Root, Siberian Ginseng, Sheep Sorrel, Slippery Elm, Watercress, Turkey Rhubarb Root, Bromelain, Turmeric, Quercetin, Feverfew, Boron, Goldenseal, Echinacea, and Ginseng, instead of taking conventional cancer treatments that have been scientifically proven to be safe and effective in humans.

If you would like further information about complementary and alternative treatments for cancer, the following Internet web sites may be helpful:

1. The National Cancer Institute: www.cancer.gov/cancer topics/pdq; or

2. The National Center for Complementary and Alternative Medicines: www.nccam.nih.gov.

You may also contact the National Cancer Institute's Cancer Information Service at 1-800-4- CANCER or 1-800-422-6237.

Sincerely,

ATTACHMENT B

Daniel Chapter One 1028 East Main Road
Portsmouth, Rhode Island, 02871

[name and address of purchaser]

GOVERNMENT ORDERED NOTICE

Complaint

Exhibit A

ors cysts cancer help cancerous tumor research bio-shark tissue file:///E:/danielchapterone%20Telepori%20Pro%20Project/products_..

danielchapterone

ABOUT US | PRODUCTS | INFO CENTER | ON LINE STORE | TALK RADIO | LIN

- Herbs
- Immune Boosters
- 7 Herb Formula
- Bio*Shark
- BioMixx
- GDU
- Biozymes
- Body Care
- Vitamins
- Biomolecular Nutrientss
- Electrolytes
- Ergo & Thermogenics
- Minerals & Amino Acids
- Specialty & Essential Fats
- Aminoglycans
- CoEnzymes
- Homeopathy/Biotropins
- Hormonal & Fiber
- Muscle Mass/Performance

Immune Boosters

shark cartilage Supplemental Facts

BUY I

Read our clients tesi
Bio Shark & Tumors

Cancerous Tur

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. Should not be used by pregnant women, or immediately after heart surgery. Shark cartilage may also reduce the pain, inflammation, and joint stiffness of arthritis, alleviate inflammatory bowel disease, and reverse psoriasis. Shark cartilage is an excellent source of Calcium, Phosphorus, amino acids, and a family of carbohydrates called mucopolysaccharides (sulfated Oligosaccharides and Chondroitin Sulfates A and C).

In summary, Bio*Shark works to reduce inflammation and swelling, affects the formation of new blood vessels and provides essential nutrients for healing.

Warning: If you are pregnant, nursing a baby, recovering from recent surgery, or have a heart or circulatory condition, consult a health professional before using shark cartilage !

Stop Tumor Gowth & Cysts Top

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Complaint

Exhibit B

nielChapterOne - Cancer News file:///E:/danielchapterone%20Teleport%20Pro%20Project/info_cente..

danielchapterone

ABOUT US | PRODUCTS | INFO CENTER | ON-LINE STORE | TALK RADIO | LIN

FAQ - Health Questions
Articles / publications
Testimonials
Biomolecular Nutrition
Cancer Newsletter
Crohn's disease
Colitis
Arthritis
RICH Homeopathy
Diabetes - your choice
Ezekiel Oil Rinse
Genesis 1:29
Events

Cancer News.

7 Herb Formula

- purifies the blood
- promotes cell repair
- **fights tumor formation**
- fights pathogenic bacteria

to learn more click here
to buy click here

If you suffer from any type of cancer, Daniel Chapter One suggests taking this products, to fight it:

7*Herb Formula™ 2 ounces in juice or water (minimum intake) 2 times daily
Bio*Shark™ (***DO NOT TAKE IF PREGNANT,OR IMMEDIATELY AFTER HEARTSURGERY)
(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; 1/2 hr. BEFORE meals

The above information is taken from **The Most Simple Guide to the most difficult diseases , the doctors' how-to quick reference quide.**
For more information call Jim and Trish during the Radio Show

Cancer Newsletter exe. form
Cancer Newslette
Read about 7 He Formula in exe form
Page shortcuts to t about cancer
Lump is gone withou surgery!
7 Herb Formula battl cancer.
7 Herb eliminates pr growth
Pre Post™
Ancient cancer remed improved upon
Victory over Gulf Wa
Doctors gave up on
Pre-Cancerous Growt & Acid and Heartburn
Bio Shark™
Breast Mass
Listen to our testimonials about
- Fred - Breast ca
- Marie-Dad's thro

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Daniel Chapter One's Cancer solutions

To Buy the products click here

How to fight cancer is your choice!

"No type of cancer is to be taken lightly. If it is not treated properly and completely removed, it will continue to spread and eventually prove fatal. The first step is to cleanse the bloodstream by thoroughly relieving constipation and making all the organs of elimination active ... I have been asked many times what my cure for cancer is. Here it is in a nutshell: correct food, herbs, water, fresh air, massage, sunshine, and exercise, rest. If cancer is suspected, clean out the system, and get a new supply of pure blood. There are nonpoisonous herbs that will purify the blood and kill malignant growths internally or externally, leaving no bad after-effects. Cancer will not live in a system when the bloodstream is pure."

Jethro Kloss, "Back to Eden"

Lump is gone without dangerous surgery!

Joe Rocha, a custodian at Roger Williams University in Rhode Island, was outside washing windows a few years ago when a stiff breeze blew in from Mount Hope Bay. Shortly after, the career Navy veteran complained of severe pain on the right side of his face. He suspected neuralgia and then thought the pain was from a tooth. He went to his dentist and the problem was not his tooth. It was serious. Joe Rocha then went to a family friend, a physician, who thought the problem was something worse than neuralgia and he was right. There was a swelling of the neck and a lump was detected. He underwent a series of tests and a tumor was found. The prognosis sent fear through the Rocha family. Because of the location of the tumor, Joe Rocha was told that surgery could result in serious consequences. Joe's wife, Maria, said she was terrified of the prospects of the operation. Her husband's doctor was preparing his team of surgeons and nurses to perform the tricky operation in a Fall River, MA, hospital. There was little comfort from the doctor who admitted to the Rochas that the tumor was in such a difficult place the operation itself could result in a heart attack, a stroke and possible paralysis on one side. Mrs. Rocha insisted her husband see their former neighbors and longtime friends, Jim and Tricia Feijo before undergoing surgery. It was the second time

cured-7Herb and m
• Maria - Dad's thr
cured-7Herb and m
• Maureen - Cance
Arm -7HERB
• Mel - Breast Ma
and GDU
• Nancy - Cured E
Cancer in 3months-
GDU
• Robert-Prostate
cured from DC1 Pro
• Sharon-Mom's E
Healed
• Sylvia - Questior
Sugar and Cancer

Complaint

the Rochas turned to the Feijos for lifesaving advice. "Jim and Tricia saved my life when doctors said I would die from candidiasis. Thanks to the Feijos I'm here and well. I thought they could help Joe." Joe began taking herbs and shark cartilage. Mrs. Rocha, a lay minister, put her faith in God. The Rochas and their two daughters prayed that the operation could be avoided. Mrs. Rocha thought she detected the tumor getting smaller over a six-week period. It was just a few days before Joe was about to undergo surgery that the couple met with the physician at a clinic in Fall River, MA. The doctor examined his patient and Maria couldn't restrain herself. "Don't you think the lump is shrinking?" she asked the doctor.The physician said the type of tumor Joe had only grows bigger and never shrinks. Joe's wife insisted that it was her opinion that the tumor was smaller. The doctor wasn't convinced and set into motion all of the details for the surgery to take place in four days. A couple of days later, the phone rang at the Rocha home in Portsmouth, RI. It was the doctor and he asked that the Rochas meet with him in his office the day before the scheduled surgery.

"We were amazed," Mrs. Rocha said. According to Maria, "He (the doctor) told us that my words kept ringing in his ears and that a closer examination revealed the tumor had shrunk, something he had not seen before."

The family went to a restaurant to celebrate and while they were driving home Mrs. Rocha said she broke down and cried, overcome by the joy that her husband of many years had been spared. Joe faithfully took his herbs and shark cartilage and the prayers of the Rocha family were answered.

The Rocha story hit home for Tricia Feijo.

She watched as her own mother had a similar growth years ago.

Tricia's mother opted to go the route prescribed by her physician and underwent surgery, radiation then chemotherapy. Initially, immediately after the diagnosis, she started on some herbs that Tricia recommended. The tumor stopped growing but the doctor insisted that Tricia's mom was wasting time and talked her into undergoing surgery.

"I'll never forget it." Tricia said. "My mother told me that when the doctor came in to her room after the operation, he sort of smiled and said the tumor he removed was shriveled and he never saw anything like it." Tricia believes it was the herbs that had stopped the growth of the tumor. She still wished the doctor had not talked her mom into accepting surgery.

Tricia says she also wishes 7 Herb Formula was available at the time her mother was diagnosed with cancer.

After a lengthy, painful ordeal of radiation ~ to kill "stray cancer cells" ~

and chemotherapy after the cancer returned, Tricia's mom ended up on oxygen.

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. The allopathic methods of dealing with the advanced cancer would be more chemotherapy.

She had gone the chemo and radiation route just months before and knew her weakened body could not endure another round of chemo. The doctor tried to pressure Tracey into taking chemo and she refused, angering the doctor. Her rejection of his chemo protocol led to a heated argument in his office and Tracey decided to take control of her own recovery. A women that Tracey had befriended while in the hospital accepted the chemo treatment and the unfortunate result was that her friend died. 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. 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%. My weight, which dropped to 103 pounds, is on an uphill. There are other alternatives besides chemo and radiation!" Tracey's father recently called the radio show. He said Tracey had a problem. Tricia Feijo said her heart skipped a beat when she heart Tracey's father. That concern soon evaporated. "Yeah, Tracey can't keep her feet on the ground these days," he said, then revealed that the young woman's new doctor had declared her free of cancer. Below you will find the reports of Tracey's progress and what she did as an alternative to the chemotherapy.

Complaint

The Medical Report Cancer Count:

July 8	700
July 15	1100 +
Aug. 11	1040
Aug. 20	950
Sept. 2	790
Sept. 20	642 ~ free of leukemia
June 1998	Free of all cancer

Tumors

July	Significant tumor	Size of quarter	5x7 cm
Sept.	Smaller lump	Size of dime	2x2 cm
Oct.	Gone	50% smaller	smaller
June 98	Gone	Gone	Gone
June 98	On Brain	Behind Heart	On Liver
	Gone	Gone	Gone

Weight and Energy

July 8	103 lbs, no energy, feels bad, starts on natural products
Sept. 2	118 lbs, more energy, rode a bike
Sept. 20	121 lbs, rides bike, swims
Sept. 26	Also taking GDU 4000 ~ "feels terrific"
June 1998	125 lbs and continues to be free of cancer

7 Herb eliminates pre-cancerous growth

Kathy Carlton tells her story of how 7 Herb Formula helped her.

I'm 42 and I lived in Florida most of my life ... So, I've lived in the sun all my life. I had a pre-cancerous "wart" on the back of my leg and drinking 7 Herb Formula made it go away. I get these pre-cancerous things; the doctor checks me every several months. He says they are pre-cancerous. I had one on my hand once that was turning into a melanoma. The doctor burned it off. He usually burns them off. When they're small, he waits until they get bigger, then he burns them off. He gave me a cream when they were small but that irritated my skin. Anyway, I had one on the back of my leg that was getting big but the 7 Herb Formula made it go away. Maybe it took four or five weeks, but it just fell off: it got looser and looser and then it just fell off. I have the scar to prove it. I was taking the 7 Herb Formula and at first noticed no difference. But I took it about twice a day for five weeks. After five weeks I noticed better energy levels. I started taking it in August (1997) ~ so in the past four months I've gone through four bottles ~ because back in June I started getting stomach pains. In the morning I was waking up with bad pains. In June I went to the doctor because I was afraid I was having a heart attack or something. I was given an appointment for September to be tested. The doctor thought it was my

esophagus ~ a lot of acid and heartburn. So I went to the GI specialist in September and had an upper GI, but by then the pain had gone away. The 7 Herb Formula had cured it! It got rid of the acid problem but I keep taking it (7 Herb Formula). I would take a shot glass full in the mornings ~ usually straight ~ and then drink a lot of water afterward. Then I would take a shot before bed. Now I only take it once a day or, some days, not at all. If I feel I'm getting a cold or something, I take extra. I haven't gotten sick once since I've taken it ~ not the flu or anything. And usually I would have (become sick) by now. And I used to feel tired around 2:00 p.m. but not anymore. The 7 Herb really gives me energy and it keeps me from getting hungry. I do use Lean Body sometimes instead of skipping meals but I do not do Lean Body all the time. The 7 Herb helps me maintain my weight. I don't lose but I don't gain. At first I lost 10 pounds. Maybe because I have more energy, I do more. I used to get low blood sugar a lot and now I'm okay. And I don't have high blood pressure anymore (I also take dandelion root for a diuretic). I think 7 Herb Formula balances out the immune system. My sister has lupus ~ I wish she would try it out ~ I want to send her a bottle to Virginia. Mentally, I even feel better. I recently ran out before leaving for Las Vegas. We were there for seven days and I felt so tired without the 7 Herb. It makes a big difference. And the most amazing thing was when I had the upper GI in September, and the x-ray showed nothing there. Before, I had bad pain constantly ~ by then, nothing. It's so amazing. It would ease the pain ~ right away ~ in a few minutes. Before that, I tried Tagamet and it would do nothing. It actually made my stomach hurt worse. Really, it's amazing!

Pre Post™

Daniel Chapter One has been using its PrePost formula, a BioMolecular athletic food source for almost 15 years. PrePost is the world's first Soy based multi-nutritional high calorie sports supplement. Athletes and cancer patients all over the world have used PrePost for over a decade. By increasing an individual's caloric intake and adding Soy to their diet Daniel Chapter One has been able to see astounding results. Years of study and research helped Jim Feijo discover the benefits of using Soy as a protein base for overall better health. Recent studies have shown the importance of Soy protein in everyone's diet. Since Jim developed PrePost, many other Daniel Chapter One products have been developed with a Soy protein base. These products are now starting to get the recognition they have deserved. Attached below is an article from Vitamin Retailer

Magazine1. This article explains the benefits of the Soy isoflavones, genistein and daidzein, found in Daniel Chapter One's BioMolecular formulas. "Soy isoflavones (genistein and daidzein) confer protection against the so-called hormone-dependent cancers, such as breast cancer, and prostate cancer. For instance, when breast cancer cells are grown in the laboratory, genistein arrests their growth.2 Isoflavones are hypothesized to protect against cancer through at least four mechanisms. First, the weak estrogen activity of isoflavones reduces the risk of hormonedependent cancers. Second, the antioxidant effects of isoflavones protect against cancer causing free radicals. Third, isoflavones beneficially affect enzymes. Finally, isoflavones inhibit angiogenisis, a process which would otherwise nourish growing cancer cells. A growing problem faced by cancer therapy is the occurrence of very hardy tumors. A so-called "multidrug resistance gene" acts as a pump within some cancer cells, actually expelling anti-cancer drugs before they can eradicate the cancer. In effect, the isoflavones, in some difficult to treat cancer cases, may be one of the few treatments that the tumor is not able to resist."3 (Footnotes) 1 Dolby, V., Nutritional Weapons are Powerful in the War Against Cancer. Vitamin Retailer. 1997;4(8):42-46. 2 Wei H., et al. Antioxidant and antipromotional effects of the soybean isoflavone genistein. Proc. Soc. Exp. Bio. Med. 1995;208:124-129 3 Peterson G. and Barnes S. Genistein inhibition of the growth of human breast cancer cells: Independence from estrogen receptors and the multidrug resistance gene. Biochem. Biph. Res. 1991;179(1):661-667

Ancient cancer remedy is improved upon

Herbal formula taken to maximum potency by Daniel Chapter One

Jim and Tricia Feijo are the founders of Daniel Chapter One and co-hosts of a nationally syndicated talk show. Jim is the founder of BioMolecular nutrition. He holds bachelor and master degrees from Springfield College in Massachusetts. He has trained athletes ranging from Pop Warner Football to professional. Tricia is a classical homeopath who graduated from the New England School of Homeopathy. She is also a trained writer whose column appeared in publications in New England. She has studied nutrition and whole food science for nearly two decades. Jim Feijo is the ever-active researcher who looks to God-given nutrients to deal with health issues. Over the years, he has developed a number of high quality products. His unique ability to develop all-natural nutritional products that could build body mass in athletes caught the attention of Chinese doctors and

scientists. Several years ago, He was invited to lead research at the Beijing Research Institute of Sports Science working with world-class Chinese athletes. He directed the athletes on the use of Daniel Chapter One products and monitored them through his unique computer program. The results were so impressive it caught the attention of Russian scientists and he was invited to Moscow to conduct similar studies. Besides helping world-class athletes, his computer program and products were found to be effective in helping people with chronic illness. In addition to his sports nutrition line, Jim has developed a line of health supplements and natural remedies. One of the products Jim Feijo is especially proud of is his 7 Herb Formula. The reason he is so delighted with 7 Herb is the effects he has seen on those who have used the product and the results that have been documented. The testimonials keep on coming in to Daniel Chapter One. Jim improved upon the ancient Ojibway Indian Tribe remedy known as Essiac and used by the late Dr. Charles Brusch ~ personal physician to President John F. Kennedy ~ to enhance the healing properties. Dr. Brusch said of the Essiac herbal formula: "It will greatly improve any condition afflicting the body!" As a result of his research, Jim found that by adding Siberian Gineseng and Cat's Claw to the Essiac formula, he could attain remarkable healing results. The two herbs were added to Burdock Root, Turkey Rhubarb, Slippery Elm, Sheep Sorrel and Watercress. It was determined that in order to achieve maximum effectiveness of this formula, the individual herbs must be cooked to a precise temperature for that specific herb and thus ensure 100% maximum phytochemical potencies. In similar products all of the herbs are cooked together, diminishing the potency and effectiveness of the herbs. So 7 Herb was formulated to the specific requirements of Daniel Chapter One. The rigid, precise individual preparation of the ingredients was a vast improvement over the original formula. It has been called "revolutionary." "We feel blessed that God has revealed this formula to us and that we have been able to provide those in need of help an alternative to chemotherapy and radiation," Jim Feijo said. Daniel Chapter One HealthWatch, which airs coast-to-coast five days a week, continues to hear the testimony of people who are using 7 Herb Formula. Among those who spoke of dramatic results using 7 Herb Formula ~ during the live talk show ~ are Joe and Maria Rocha and Jim Givens. Their stories are contained in this newsletter. Jim Feijo concluded: "There was a time in the not-so-distant past that we were voices in the wilderness, but today the American public is crying out for alternatives to harmful drugs. Our message has a vast audience today."

Victory over Gulf War Syndrome

Complaint

The following is a letter Wayne L. Harms sent to the Gulf War Veterans Association, reprinted with his permission. Wayne went to the Persian Gulf in 1994 to lend his services as a minister for our troops overseas. He tells us how he victoriously overcame his personal war on cancer and Gulf War Syndrome with the help of Daniel Chapter One.

In January 1998, after years of declining health, my wife and I both tested positive for Mycoplasma Fermentans Incognitus (MFI), better known as Gulf War Illness. In October 1998, we both tested negative. In June 1998, a skin cancer clinic identified seven spots of Squamous Cell Carcinoma Cancer on my arms and legs. The largest spot was about the size of a quarter and the smallest was about the size of a pencil eraser. In October 1998, there is no trace of the cancer with the exception of a very small spot of light colored scar tissue where the largest spot had been. The standard treatment for MFI is 2 or more years of antibiotics in cycles of 6 weeks with a 6-week rest period in between each cycle of medication. We veered from the standard treatment for reasons I will explain below. Immediately prior to deployment to the Gulf and while in the Gulf, I was given shots which were never entered into my shot records. They were entered into medical records, but those pages conveniently disappeared when I returned to the states. Without knowing it, I passed the MFI on to my wife. The following are problems (see My Symptoms below) which I did not have before Desert Storm but developed after returning home. We were unable to find a doctor to treat us or even talk about GWI until April 1998. At that time we both began a six-week cycle of Doxycycline. The symptoms became worse for about two weeks, then seemed to clear up very well. About 3 weeks after the end of the first cycle, the symptoms returned but not as severe as they had been before treatment began. It was at this time the cancer was discovered. I had been directly exposed to insecticides in the Gulf and it lay wet on my bare skin for up to an hour before I could get to a place to wash it off. The doctor believes this may have been the cause of the cancer and that it lay dormant until I began the antibiotic treatment. She said that one of the side effects of antibiotics is a suppression of the natural immune system, which would allow the cancer to grow more rapidly. I decided to stop the antibiotic treatment and try a natural herbal and vitamin remedy I had been told about. Within about 4 weeks, all my symptoms had cleared up and have never returned. I continued on the natural remedy until today, October 19, 1998, when I was notified my tests showed I was completely cured of MFI. My wife decided to continue on the antibiotic six-week cycles, but on the six weeks in between, she also used the natural remedies. None of her symptoms

came back after beginning the natural remedy. She also was notified today that she is completely cured of MFI. The natural remedy was obtained through an organization called Daniel Chapter One. They are on the Internet at www.danielchapterone.com. They also can be heard on the radio on Accent Radio Network. I don't know how this stuff works, but it worked wonders for me and my wife. The insurance agent just laughed when I suggested a partial reimbursement of some of the expenses so, in addition to my full-time job I took 4 part-time jobs to pay for it. It paid off for us and I hope the information may help a few of you. I know there are many forms of GWI caused by things other than MFI and I don't know which of the products will help the other forms. The main thing is NEVER GIVE UP. KEEP FIGHTING. This is easy to say now, but I was at a point where death looked like the only way out. Support and encouragement from friends helped carry me through and it can do the same for you. 6

My symptoms were: 1.Very bad night vision 2.Strong sensitivity to sunlight and bright lights 3. Pain in back of eyes 4.Eyes blur, then clear up on a frequent basis while driving, cars and highway would become like a smear of finger paint blending in together, then clear up 5.Frequent severe headaches and chest pain (hospitalized for heart attack but the doctors could not find anything wrong) 6.Constant muscle pain in left arm and leg 7 Severe loss of strength in left arm and leg 7.Frequent uncontrollable shaking of both arms and hands
My wife's symptoms were: 1.Frequent coughing, Difficulty inbreathing, Short-term memory loss, Pain in back of eyes, Dizzy spells, Balance problems, Periodic nausea, Aching joints and muscles, Loss of concentration, Fatigue, Nervousness/Anxiety, & Depression Of special interest is that our complete healing with natural products took place in less than 1/4 of the time as the average cure with antibiotics and without the side effects.

Doctors gave upon Michigan man

When Jim Feijo greeted Richard Nelson, a talk show caller from East Grand Rapids, Mi, with "How are you doing Richard," he received this short reply: "Lots better now." There was more. The caller went on to explain his situation. He is living proof that doctors may be wrong in surrendering to defeat in life and death situations. Richard went into the hospital for treatment of a hernia and doctors broke the shocking news to him ~ melanoma. The outcome prediction was grim. It was in August of 1997 when Richard's cancer was discovered and he was soon undergoing chemotherapy. Even with treatment, he was told he would only have nine months to live. An angel he says, in the form of his brother-in-law, told him he had heard Daniel Chapter One HealthWatch and listened to Jim and Tricia Feijo talk about the success of 7 Herb Formula in helping people with cancer. "My brother-in-law asked me if he bought me the 7 Herb, would I take it and I assured him I would," Richard said on the coast-to-coast broadcast that was originating from Las Vegas, NV. Richard reveals: "I had lost my faith. After my fourth treatment with chemo, the cancer

Complaint

masses slayed constant. I started taking the 7 Herb and that tumor was shrinking. At the last treatment, I was told the tumors had liquid centers and were on the verge of drying up. Then I had a CAT scan and it was found that there has been massive tumor shrinkage." Jim Feijo called the Richard Nelson story a great example of how people can come to the rescue of others.

Pre-Cancerous Growths & Acid and Heartburn

"And the most amazing thing was when I had my upper G.I. in September, and the X-ray showed nothing there. Before, I had bad pain constantly...by then, nothing." ~Kathy Colton After using 7 HERB and other DC1 products for precancerous growths and for acid & heartburn.

Bio Shark™

In 1983, two researchers at the Massachusetts Institute of Technology published a study showing that shark cartilage contains a substance that significantly inhibits the development of blood vessels that nourish solid tumors, thereby limiting tumor growth. This effect is called anti-angiogenesis. Scientists recognize the benefits of starving a tumor to limit its growth. They have been looking for a drug to patent that can do the same thing as shark cartilage. They say the answer to curing cancer lies in preventing angiogenesis ~ the formation of blood vessels which feed the tumor. These scientists are trying to replicate what God has already presented to us so that they can claim rights to it, patent it and make a lot of money. But man can never lab synthesize a product and make it exactly the same ~ and all drugs have harmful side effects. Researchers have also demonstrated that shark cartilage can reduce the inflammation and pain associated with arthritis, alleviate psoriasis and have a positive effect on other degenerative diseases.

Breast Mass
Deloris Winter
Age 52, Lakeland, FL.

"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 doctors for the breast examination, and he found nothing on either breast.

Around that time I got another bottle of GDU and the Superior Herbal Fat Burners, which I took twice a day. In April I had my 6-month examination and the letter read: 'We are pleased to inform you that the results of your recent breast evaluation are normal.'

Praise GOD!"

Deloris Winter
Age 52, Lakeland, FL.

Complaint

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- Herbs
- 7 Herb Formula
- Astragalus
- Bilberry Complex
- Black Cohosh
- Cascara Sagrada
- Cats Claw
- Cayenne
- Cranberry Concentrate
- Dandelion Root
- Digest 400
- Dong Quai
- Echina Plus
- Echinacea Root Tincture
- Echinacea Goldenseal Tincture
- Ezekiel First Aid Oil
- Fenugreek Plus
- FGC
- Feverfew
- Garlic Pur
- Genesis First Aid Oil
- Ginger Root
- Ginkgo Pur
- Goldenseal
- Gotu Kola
- Hawthorn Plus C
- Herbaretic Diuretic
- HPLC (Hi Potency Liver Complex)
- Juniper Berries
- Kava Kava
- Licorice Root

Herbs

Supplemental Facts

7 Herb Formula: Detoxify, Acid Reflux & Cancer Help

7 Herb Formula with Cat's Claw & Siberian Ginseng: Herbs to purify the blood and promote cell repair. The ingredients in this tea concentrate work to clear skin, cleanse the liver, decrease cell mutation, and fight pathogenic bacteria and tumor formation. Also helps regulate blood sugar, heal ulcers, and stop indigestion and heartburn.

The herbs in 7 Herb Formula allow the body to heal by nourishing and cleansing the blood organs. In addition, the formula detoxifies blood and lymph, a key to vibrant health and fighting illness. Below is a list of these 7 herbal ingredients, which have been scrupulously and separately prepared, then combined to form a tea concentrate, and poured, boiling, into quart-size amber glass bottles to ensure freshness and potency. Many pounds of herbs go into the making of one 32 ounce bottle of 7 Herb Formula, making it 3 times the potency of any other product of its kind!

1. Burdock Root, used in Ayurvedic and Chinese medicine to treat cancer. It is a potent blood purifier, and is known to decrease cell mutation and inhibit tumors. It restores liver and gallbladder function. Burdock contains the nutrients zinc, iron, manganese, and vitamins B1, B6, B12. It also provides vitamin E and selenium, which combat free radicals. Burdock Root contains natural inulin, which is beneficial

- Nettles
- Pau D'Arco
- Ruscus
- Saw Palmetto
- Slippery Elm Bark
- St. John's Wort
- Total Prostate Complex
- Valerian Root
- Yucca Leaves

- Immune Boosters
- Body Care
- Vitamins
- Biomolecular Nutrientss
- Electrolytes
- Ergo & Thermogenics
- Minerals & Amino Acids
- Specialty & Essential Fats
- Aminoglycans
- CoEnzymes
- Homeopathy/Biotropins
- Hormonal & Fiber
- Muscle Mass/Performance

in diabetes as the body can use this to produce natural insulin.

2. Sheep Sorrel, also rich in vitamins, minerals and trace elements, high in life-giving properties. It nourishes the glandular system, and is known to relieve internal ulcers. Sheep Sorrel is a traditional folk remedy for cancer.

3. Siberian Ginseng, an herbal "tonic" which has restorative power due to its glycoside content. Glycosides are natural phytochemicals that initiate the body's stress response: so while this ingredient tones the body it also supports the immune system, while working in synergy with the other 6 ingredients to allow for an inflamed stomach to be healed. Siberian Ginseng also produces saponins, steroids found in plants, which have tumor inhibiting effects.

4. Cat's Claw, an herb from Peruvian rain forest. The inner bark, which is what is in 7 Herb Formula, is one of the most powerful cleansers of the intestinal tract. It also is an anti-oxidant and anti-inflammatory in action. Cat's Claw stimulates the immune system, enhancing white blood cells, which fight infection. Cat's Claw is used by native Peruvians to treat many diseases, including cancer.

5. Slippery Elm, according to herbalist Jethro Kloss, should be used in all stomach troubles because of its ability to heal, strengthen, and nourish the stomach. He states that it can stay in an ulcerated or even cancerous stomach when nothing else will. It nourishes the organs and tissues due to its nutrient content: bioflavanoids, calcium, phosphorous, polysaccharides, and vitamins A, B, C, and K. Slippery Elm also helps to neutralize acids from indigestion.

6. Watercress, the same plant used for salad greens and garnishes, is an excellent cleanser in the body, and it can heal mucus membranes including the stomach lining. Protects kidneys and joints from oxalic acid buildup.

7. Turkey Rhubarb Root purges the body of wastes and toxic matter. Also called Indian Rhubarb, this herb counteracts acids due to indigestion and acts as a gentle laxative. The malic acid inherent in this herb carries oxygen to all parts of the body. A substance called rhein in the herb fights both bacteria and fungus. Studies done in the 1980s show Turkey Rhubarb has anti-tumor properties. It also reduces inflammation.

BUY N

Read more about
7 Herb Formula - click

Read our clients' tes
on using this produc

- Special Forces Overcomes Pr
- Doctor Alexan
- Cancer
- HIV / AIDS
- Tumor Free!
- Prednisone Wo Masked My Kid
- Lump is Gone Dangerous Su
- Energy Boost
- 7 Herb Formul cancer
- Not Too Late!
- RENAL CELL C
- Prostate Cancı

Complaint

Exhibit C

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- Herbs
- Immune Boosters
- 7 Herb Formula
- Bio*Shark
- BioMixx
- GDU
- Biozymes
- Body Care
- Vitamins
- Biomolecular Nutrientss
- Electrolytes
- Ergo & Thermogenics
- Minerals & Amino Acids
- Specialty & Essential Fats
- Aminoglycans
- CoEnzymes
- Homeopathy/Biotropins
- Hormonal & Fiber
- Muscle Mass/Performance

Immune Boosters

Supplemental Facts

GDU - Arthirits Pain Anti inflammatory

Contains natural proteolytic enzymes (from pineapple source bromelain) to help digest protein - even that of unwanted tumors and cysts. This formula also helps to relieve pain and heal inflammation.

GDU caps also contain 300 mg Turmeric that protects the liver against toxins, 100 mg Quercetin, a natural bioflavonoid, which enhances the absorption of bromelain (the key ingredient) and relieves pain, bumps, and bruises, and 100 mg Feverfew, a natural pain killer. GDU caps with bromelain is a well-known herbal for digestive problems, helping users to digest proteins and aiding in pancreatic insufficiency.

GDU is also used for acute postoperative swelling, to heal surgical inflammation and bruises, to heal injuries, as a smooth muscle relaxant, for respiratory congestion and infections, sinusitis, pneumonia, bronchitis, angina, as a natural antibiotic, for painful menstruation, arthritis, thrombophlebitis, varicose veins, and as an adjunct to cancer therapy.

GDU caps possess a wide range of actions including anti-inflammatory and antispasmodic activity that make it suited to a wide range of uses. Safety: Even at very high dosages no toxic reactions have been found. Care should be taken when using GDU if on any medication that thins the blood. The nutrients in GDU: Bromelain, Turmeric, Quercetin, Feverfew, Boron

Complaint

TURMERIC (CURCUMIN)

Turmeric: a spice and a potent anti-inflammatory. Herbalists have recommended turmeric for the pain and swelling of arthritis for many years. It also has a beneficial effect on the liver and gallbladder.

1. Curcuma longa, turmeric, with its active ingredient curcumin, is a potent anti-inflammatory. Jean Carper reports in Food - Your Miracle Medicine (HarperCollins, 1993)

2. Curcumin, "is an anti-inflammatory agent on a par with cortisone"

3. Has reduced inflammation in animals.

4. Reduced symptoms of rheumatoid arthritis in humans.

5. A rigorous double-blind, placebo-controlled study was conducted at the Seth 1G.S. Medical College in Bombay, India, to determine the herb's anti-inflammatory effect compared to that of powerful drugs, such as phenylbutazone, for post-surgical patients. The researchers concluded that curcumin was shown to possess significant anti-inflammatory activity following surgery.

Bromelain: Natural proteolytic enzymes, which can break down proteins that are involved in the inflammatory process. They also enhance the breakdown and removal of damaged tissue and aid the lymph to cleanse and drain the inflamed area of fluid and debris. Studies have shown that the potency of the enzymes used is critical in relation to their effectiveness.

Quercetin: A bioflavonoid, a compound widely distributed in plants. Bioflavonoids like quercetin are used in the treatment of athletic injuries because they relieve pain, bumps, and bruises. They also reduce pain located in the legs or across the back. Bromelain and quercetin are synergists, and should be taken together to enhance absorption.

Feverfew: Legend has it that this herb saved the life of someone who once fell off the Parthenon, the famous temple in ancient Greece! In 1985, the British medical journal Lancet reported that feverfew inhibited the release of two different inflammatory substances- one from platelets, the other from white blood cells – thought to contribute to the onset of migraine attacks and that may play a role in rheumatoid arthritis.

Boron: Essential nutrient included in GDU because of its many functions. Regulating appropriate body levels of hormones needed for bone health and maintaining minerals needed for healthy bones are two major functions of boron in GDU.

This product is availal
GDU, 120 Caps (buy r
GDU, 300 Caps (buy r

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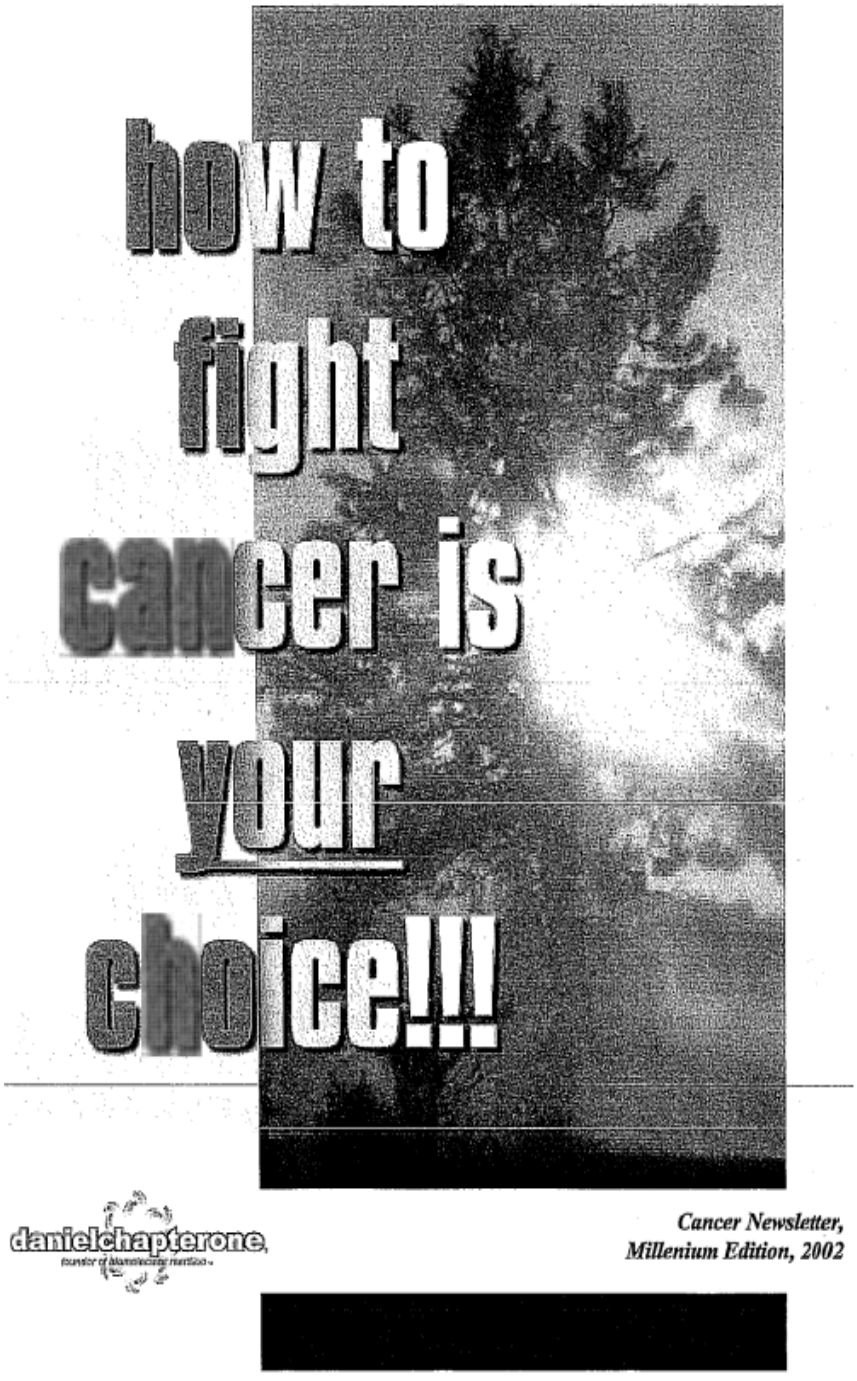
on using this anti in

- Juvenile Arthri
- Arthritis
- Professeball In
- Spinal Stenosi
- Breast Mass
- Arthritis Relief
- Prostate Cancı

Arthritis Pain Relief & Anti Inflammatory Top

Complaint

Exhibit D



Texas businessman has true friends for life

Florida family shares its discovery of Daniel Chapter One success

What are friends for?

The answer to that question is personified in the Dellinger family of Milton, FL. Drew, 37, and his parents, Dean and Dorothy, have been using Daniel Chapter One products for about a year and are enthusiastic about the results. The Dellingers heard Jim and Tricia's Daniel Chapter One HealthWatch radio show in Milton and ordered products that they say had remarkable results.

The Dellingers wanted to share their discovery with family friend, Dick N. of Garland, Texas, who has been suffering from emphysema, 18% capacity in one lung and 27% in another, and bladder cancer.

They employed the persuasive powers of a mutual friend, Ed Kulikowski, whose daughter Tracey (See related story on opposite page) is cancer-free as a result of using the Daniel Chapter One products.

Mr. Kulikowski contacted the Texas Oil company executive and said that the Dellingers were willing to provide him with Daniel Chapter One products for his breathing problems and problems associated with his cancer.

Drew Dellinger said the family friend received the package of products and hesitated to use them.

The package included 7 Herb Formula, AM*PM, Herbal Blast, Bio Shark and Bio*Mixx.

The Texas oil executive reportedly downed six ounces of 7 Herb Formula right away and as soon as he did, Drew said, Dick N. felt as though an "electrical wave" went through his system. Drew said his friend told him that he began shaking.

Dick didn't know what was going on, Drew Dellinger said. He reportedly asked his wife, Carmen, "You reckon this stuff will kill me?"

Every 15 minutes, she would bring AM*PM, 7 Herb, or Herbal Blast for Dick to drink, Drew reported.

What were the results for a man with partial use of his lungs and someone who had undergone several operations for cancer? He quickly began breathing better and is now off oxygen during the day but stays on it while sleeping. The excruciating pain that accompanied urination is gone.

According to Drew, the Texas businessman is back to work and telling people he never felt better.

He said that Dick told him the employees think he has been drinking because he seems like his jovial, energetic self.

The Dellingers are pleased they could come to the rescue of their friend. They said they have so much faith in Daniel Chapter One that it simply seemed the right thing to do to help their friend in a struggle to regain his health.

Bio Mixx-

How does Bio*Mixx work?
Boosts the immune system, cleanses the blood and feeds the endocrine system

Bio*Mixx is a combination of numerous herbs, vitamins, minerals, enzymes, amino acids and essential biomolecular nutrients. The purpose of this formula is to provide man natural immune-boosting properties in one tasty product. These include IGF-One, a natural gamma globulin complex essential for overall immunity with natural anti-fungal, antibacterial and anti-viral properties. Bio*Mixx is a foundational nutritional product.

Some other important herbs in Bio*Mixx include: Goldenseal, an antibacterial, Echinacea, an anti-viral, and Ginseng, an adaptogen that brings all body properties in to balance for overall wellness. 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.

Visit www.danielchapterone.com TODAY for access to your health questions!

We have compiled a large database of product information and testimonies that may help you in your search for the Truth!

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I. INTRODUCTION

A. Summary of Complaint and Answer

The Federal Trade Commission ("FTC") issued the Complaint in this matter on September 16, 2008 against Daniel Chapter One ("DCO") and James Feijo ("Respondents"). The Complaint alleges that Respondents have engaged in deceptive acts or practices in connection with the advertising, promotion, offering for sale, sale, and distribution of four products: BioShark, 7 Herb Formula, GDU, and BioMixx (collectively, the "Challenged Products"). Complaint ¶ 3. The Complaint also alleges that Respondents operate linked web pages on the website, www.danielchapterone.com, through which they advertise and sell the Challenged Products. Complaint ¶ 5.

The Complaint alleges that the Challenged Products are advertised to prevent, treat, or cure cancer or tumors, Complaint ¶ 5, and specifically charges that the advertisements represent, expressly or impliedly, that:

> 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
> BioMixx heals the destructive effects of radiation and chemotherapy.

Complaint ¶ 14. The Complaint further alleges that Respondents represented, either expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the claims made, but that Respondents did not, in fact, possess and rely upon such reasonable basis. Complaint ¶¶ 15, 16. The Complaint charges Respondents with unfair or deceptive acts or practices, in or affecting commerce, in violation of Sections 5(a) and 12 of the Federal Trade Commission Act ("FTC Act"). Complaint ¶ 17.

In their Answer, filed on October 11, 2008, Respondents admit that they operate a website that provides information on the Challenged Products in a religious and educational context, but otherwise deny allegations that they engaged in deceptive acts or practices in connection with the advertising or sale of the Challenged Products. Answer ¶ 5. Respondents averred that they did possess and rely upon a reasonable basis that substantiated the representations made about the Challenged Products at the time the representations were made. Answer ¶ 16.

Respondents' Answer also asserted six affirmative defenses. By stipulation of the parties, in an Order entered by the Administrative Law Judge ("ALJ") on January 8, 2009, the six affirmative defenses raised by Respondents in their Answer were stricken. On February 11, 2009, Respondents filed a motion to amend the Answer through which they sought to amend paragraphs 3, 5, and 14 of their Answer. The motion was opposed by Complaint Counsel. By Order dated March 4, 2009, Respondents' motion to amend was denied on the grounds that the proposed amendments would not facilitate a determination of a controversy, were not necessary to avoid prejudicing Respondents, did not conform to the evidence, and, coming after the close of discovery and approximately two months before trial, would have been unduly prejudicial to Complaint Counsel.

On February 25, 2009, Respondents filed a second motion to amend their answer, this time to add an affirmative defense that the Commission, in filing the Complaint and seeking the Cease and Desist Order included with the Complaint, was substantially burdening Respondents' free exercise of religion in violation of the Religious Freedom Restoration Act, 42 U.S.C. § 2000bb-1(a) and (c). Complaint Counsel opposed the motion. By Order dated March 9, 2009, Respondents' motion to amend was denied on the grounds that the proposed amendment would not facilitate a determination of a controversy, and, coming after the close of discovery and approximately two months before trial, would have been unduly prejudicial to Complaint Counsel.

B. Procedural History

Respondents filed their first motion to dismiss on January 13, 2009, in which they contended, among other things, that the FTC has no jurisdiction over Respondents because DCO is a nonprofit religious ministry, not a commercial enterprise. Complaint Counsel opposed the motion. By Order dated February 2, 2009, the first motion to dismiss was denied on the grounds that Respondents had made a facial attack on the Complaint and that an evaluation of the allegations of the Complaint, which must be and were taken as true on such a motion to dismiss, sufficiently provided a basis for jurisdiction.

On February 13, 2009, Respondents filed a motion to reconsider the Order Denying Respondents' Motion to Dismiss Complaint. The motion was opposed by Complaint Counsel. By Order dated February 23, 2009, Respondents' motion was denied on the ground that Respondents failed to meet their burden for reconsideration.

Respondents filed a second motion to dismiss on February 25, 2009, in which Respondents again challenged the FTC's jurisdiction, arguing, among other things, that DCO is a nonprofit religious ministry. The second motion to dismiss referenced evidence outside the Complaint and thus was not a facial attack that could be decided only on the allegations of the Complaint. Complaint Counsel opposed the motion. On February 25, 2009, Respondents also filed a motion for summary decision. Complaint Counsel, too, filed a motion for summary decision on February 25, 2009. Both motions were opposed. By Order dated March 20, 2009, it was held that Respondents' second motion to dismiss and both parties' motions for summary decision could not properly be resolved prior to a determination of whether the FTC has jurisdiction over Respondents. Accordingly, those motions were held in abeyance until after the conclusion of a hearing on jurisdiction.

On March 20, 2009, an order was issued setting an evidentiary hearing and oral argument to determine jurisdiction under Sections 4 and 5 of the FTC Act. 15 U.S.C. §§ 44, 45. The FTC Act gives the Commission authority over "persons, partnerships,

or corporations," 15 U.S.C. § 45(a)(2), and defines "corporation" to include "any company . . . or association, incorporated or unincorporated, without shares of capital or capital stock or certificates of interest, except partnerships, which is organized to carry on business for its own profit or that of its members." 15 U.S.C. § 44.

The hearing on jurisdiction was held on April 21, 2009. Following the conclusion of that hearing, a ruling was issued from the bench that Complaint Counsel had demonstrated, by a preponderance of the evidence, that jurisdiction does exist in this case. Respondents' second motion to dismiss and both parties' motions for summary decision were denied, as stated on the record in open court. Transcript of April 22, 2009 Final Pre-Hearing Conference, 4-6.

Respondents, on April 23, 2009, filed a motion for a Rule 3.23(b) determination authorizing Respondents to immediately appeal the denial of Respondents' motion to dismiss for lack of jurisdiction. Complaint Counsel opposed this motion. By Order dated May 5, 2009, that motion was denied on the ground that Respondents failed to satisfy any of the three prongs of the stringent three-prong test for interlocutory appeal.

Following the hearing on jurisdiction, the final pre-hearing conference was held on April 22, 2009, with trial commencing immediately thereafter. Over seventy exhibits were admitted and eleven witnesses testified at the hearing on jurisdiction and at trial. The testimonial portion of the trial concluded on April 27, 2009. On May 28, 2009, the parties filed concurrent post-trial briefs, proposed findings of fact, and proposed conclusions of law. The parties filed concurrent replies to each other's briefs and proposed findings on June 11, 2009. Closing arguments were heard on July 9, 2009.

The hearing record was closed, pursuant to Commission Rule 3.44(c), by Order dated May 7, 2009. Rule 3.51(a) of the Commission's Rules of Practice states that an Initial Decision shall be filed "within ninety (90) days after closing the hearing record pursuant to § 3.44(c) . . . or within such further time as the Commission may by order allow upon written request from the

Administrative Law Judge." 16 C.F.R. § 3.51(a). Ninety days from the close of the record is August 5, 2009.

Commission Rule 3.51(a) also states that an Initial Decision shall be filed within one year "after the issuance of the administrative complaint, except that the Administrative Law Judge may, upon a finding of extraordinary circumstances, extend the one-year deadline for a period of up to sixty (60) days." 16 C.F.R. § 3.51(a). The Complaint in this matter was issued on September 16, 2008. One year from the issuance of the Complaint is September 16, 2009.

C. Evidence

This Initial Decision is based on the exhibits properly admitted into evidence, the transcripts of testimony at the hearing on jurisdiction and at trial, and the briefs and proposed findings of fact and conclusions of law, and the replies thereto, submitted by the parties. Citations to specific numbered findings of fact in this Initial Decision are designated by "F."[1]

Under Commission Rule 3.51(c)(1), "[a]n initial decision shall be based on a consideration of the whole record relevant to the issues decided, and shall be supported by reliable and probative

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[1] References to the record are abbreviated as follows:

CX – Complaint Counsel's Exhibit
R – Respondents' Exhibit
JX – Joint Exhibit
HOJ Tr. – Transcript of Testimony from the Hearing on Jurisdiction
Tr. – Transcript of Testimony before the ALJ
Dep. – Transcript of Deposition
CC Juris. Br. – Complaint Counsel's Pre-Hearing Brief on Jurisdiction, April 13, 2009
R Juris. Br. – Respondents' Pre-Hearing Memorandum on Jurisdiction, attached to Respondents' April 14, 2009 Errata
CCB – Complaint Counsel's Post-Hearing Brief
RB – Respondents' Post-Hearing Brief
RCOL – Respondents' Conclusions of Law
RFF – Respondents' Proposed Findings of Fact
RRFF – Respondents' Response to Complaint Counsel's Proposed Findings of Fact

All testimony and exhibits from the hearing on jurisdiction are part of the record for the hearing on the merits. HOJ Tr. 13.

evidence." 16 C.F.R. § 3.51(c)(1); *see In re Chicago Bridge & Iron Co.*, No. 9300, 138 F.T.C. 1024, 1027 n.4, 2005 FTC LEXIS 215, at *3 n.4 (Jan. 6, 2005). Under the Administrative Procedure Act ("APA"), an ALJ may not issue an order "except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence." APA, 5 U.S.C. § 556(d). All findings of fact in this Initial Decision are supported by reliable, probative, and substantial evidence.

This Initial Decision is based on a consideration of the whole record relevant to the issues and addresses the material issues of fact and law. Ruling upon a decision of another Commission, and interpreting almost identical language to that in Commission Rule 3.51(c)(1) in the APA, the U.S. Supreme Court held that "[b]y the express terms of [that Act], the Commission is not required to make subordinate findings on every collateral contention advanced, but only upon those issues of fact, law, or discretion which are material." *Minneapolis & St. Louis Ry. Co. v. United States*, 361 U.S. 173, 193-94 (1959). *Accord Stauffer Labs., Inc. v. FTC*, 343 F.2d 75, 89 (9th Cir. 1965). *See also Borek Motor Sales, Inc. v. National Labor Relations Bd.*, 425 F.2d 677, 681 (7th Cir. 1970) (holding that it is adequate for the Board to indicate that it had considered each of the company's exceptions, even if only some of the exceptions were discussed, and stating that "[m]ore than that is not demanded by the [APA] and would place a severe burden upon the agency"); *In re Amrep Corp.*, No. 9018, 102 F.T.C. 1362, 1670, 1983 FTC LEXIS 17, *566-67 (Nov. 2, 1983) (the Administrative Law Judge is not required to discuss the testimony of each witness or each exhibit presented during the administrative adjudication).

Accordingly, proposed findings of fact that are not included in this Initial Decision were rejected, either because they were not supported by the evidence, or because they were not dispositive or material to the determination of the allegations of the Complaint or the defenses thereto. Similarly, legal contentions and arguments not addressed in this Initial Decision were rejected, because they lacked support in fact or law, were not material, or were otherwise lacking in merit. All contentions and arguments

in the parties' post trial-briefs and reply briefs were reviewed and considered.

D. Summary of the Initial Decision

As set forth in this Initial Decision, the record indicates that DCO, described by Respondents as a house ministry, led by Respondent James Feijo, with his wife Patricia Feijo, engaged in business for profit for itself or for its member, James Feijo. DCO's activities include spiritual and nutritional counseling to individuals, and advertising and selling dietary supplements to the public. Respondents sell four products at issue in the Complaint: BioShark, 7 Herb Formula, GDU, and BioMixx.

The evidence shows that Respondents disseminated advertisements for the purpose of inducing, and which did induce, the purchase of a food or drug, in or having an effect on commerce, and that these advertisements claim that the Challenged Products, individually or collectively, prevent, treat, or cure cancer, inhibit tumors, or ameliorate the adverse effects of radiation and chemotherapy. The evidence further shows that Respondents did not have a reasonable basis to substantiate these claims and that the claims made are material to consumers.

Complaint Counsel has carried its burden of proving that Respondents are liable under Sections 5(a) and 12 of the FTC Act. The defenses raised by Respondents have been considered and are determined to be without merit. The remedy imposed is an appropriate cease and desist Order.

II. FINDINGS OF FACT

A. Respondents

1. Daniel Chapter One and James Feijo

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 Complaint, Oct. 14, 2008 (hereinafter referred to as Answer) ¶ 1; Complaint Counsel's Trial Exhibit

(hereinafter referred to as CX __) 31; J. Feijo, Hearing on Jurisdiction Transcript, Apr. 21, 2009, (hereinafter referred to as HOJ Tr. __) 84).

2. DCO's Articles of Incorporation list the registered agent and incorporator for DCO as Rita Johnson and list her mailing location as P.O. Box 110788, Tacoma, Washington, 98411, non-domestic. (CX 31).

3. DCO's Articles of Incorporation list DCO's mailing address and principal location as James Jesse Feijo, c/o 21916 Southeast 392nd Street, Enumclaw, Washington, 98022, non-domestic. Neither Respondent DCO nor Respondent James Feijo maintains a building at that address. (CX 31; J. Feijo, HOJ Tr. 93-95).

4. DCO's principal office and place of business are located at 1028 East Main Road, Portsmouth, Rhode Island 02871. (Answer ¶ 1; Deposition of James Feijo, Jan. 13, 2009 (hereinafter referred to as R 15 (J. Feijo, Dep. at __)) at 99).

5. Respondent James Feijo is the overseer of DCO and, in this capacity, is responsible for all of the activities of Respondent DCO. (Answer ¶ 2; R 15 (J. Feijo, Dep. at 9-10, 17); J. Feijo, HOJ Tr. 70, 217; J. Feijo, Trial Transcript (hereinafter referred to as Tr. __) at 416).

6. James Feijo is the trustee for DCO's assets and for all of the funds held by DCO. He is responsible for paying all of DCO's bills and directing DCO's funds. (J. Feijo, HOJ Tr. 72-73; R 15 (J. Feijo, Dep. at 9-10, 193, 198)).

7. Patricia Feijo is Respondent James Feijo's wife and is the secretary for DCO. James and Patricia Feijo are the only officers of DCO. (Answer ¶ 2; CX 39 (Respondents' Answer to Interrogatory No. 1); J. Feijo, HOJ Tr. 209; P. Feijo, HOJ Tr. 259, 276).

2. Overview of Respondents' activities

8. Respondents currently sell 150 to 200 products ("DCO products"), including the four products challenged in the Complaint: BioShark, 7 Herb Formula, GDU, and BioMixx (collectively, the "Challenged Products"). (R 15 (J. Feijo, Dep. at 37); P. Feijo, Tr. 392; Marino, HOJ Tr. 53-54; J. Feijo, HOJ Tr. 314-15).

9. Respondents have generated approximately $2 million in annual gross sales for the years 2006, 2007, and 2008 for all of DCO's nearly 200 products. (CX 44; R 15 (J. Feijo, Dep. at 206-07, 212); J. Feijo, HOJ Tr. 109, 223-24).

10. At present, 100% of DCO's product sales or distribution is dietary supplements. (J. Feijo, Tr. 419-20).

11. In 1983, DCO began as what James Feijo described as a house church – a church operating not in the typical sense that people think of, with a building, sign, and established doctrines, but as a church that meets in houses to worship and break bread, with no set times for religious meetings. (J. Feijo, HOJ Tr. 180-82, 263-64).

12. In 1986, DCO opened a health food store and began selling food sources. DCO began selling dietary supplements within the first year. (J. Feijo, Tr. 417-19).

13. In the mid-1990s, DCO began to develop its own dietary supplements and created BioMixx, before creating BioShark, 7 Herb Formula, and GDU, which Respondents created after 1993. (J. Feijo, Tr. 421, 423-24).

14. In 1998, Respondents created the website "danielchapterone.com" (hereinafter the "DCO Website"). (R 15 (J. Feijo, Dep. at 202)).

15. Around 1999, Respondents created the "BioGuide" and the "Cancer Newsletter" (*see infra* F. 86, 94). (R 15 (J. Feijo, Dep. at 200)).

16. According to James and Patricia Feijo, DCO was created for the purpose of healing based on the scripture of Daniel Chapter One and other biblical verses including Genesis 1:29, where, according to James and Patricia Feijo, God said he created food for healing. (J. Feijo, Tr. 417-23; Deposition of Patricia Feijo, Jan. 14, 2009 (hereinafter referred to as R 16 (P. Feijo, Dep. at __)) at 39-40).

17. According to Patricia Feijo, the name Daniel Chapter One comes from the Book of Daniel in the Old Testament of the Bible, in which, Daniel and his men were in captivity and were expected to eat the king's very rich diet of meats and wine, but instead ate and drank only pulse and water; after 10 days, their eyes were said to be brighter and they were said to be stronger than the king's men. (R 16 (P. Feijo, Dep. at 40-41)).

18. According to James and Patricia Feijo, DCO's ministry activities include helping house churches in other countries, holding religious meetings, performing baptisms, delivering babies, performing marriage ceremonies, performing healings, and reaching out to interested persons to inform them about Respondents' perspectives on the integration of spiritual and physical well-being. (R 16 (P. Feijo, Dep. at 204-05); J. Feijo, HOJ Tr. 99, 180-83, 236-37; R 15 (J. Feijo, Dep. at 73); P. Feijo, Tr. 325-26).

19. Respondent James Feijo has provided nutritional counseling to some individuals and has let people in need stay in the house with the Feijos. (P. Feijo, HOJ Tr. 268-71).

20. Respondents have provided support to a junior men's fast-pitch softball team. (P. Feijo, HOJ Tr. 263).

21. In some instances, Respondents have given away, or have provided at a reduced price, DCO products. (R 15 (J. Feijo, Dep. at 209-11); R 16 (P. Feijo, Dep. at 69); J. Feijo, HOJ Tr. 137, 184-88; P. Feijo, HOJ Tr. 263, 268, 274; Mink, HOJ Tr. 293-94; Hicks, HOJ Tr. 306-07).

3. Incorporation of Daniel Chapter One

22. Respondent DCO was previously incorporated as "Daniel Chapter One, Inc.," a Rhode Island for-profit corporation, on October 10, 1990. (CX 50; J. Feijo, HOJ Tr. 101).

23. Respondent DCO's Articles of Incorporation from 1990 state that the purposes for which Daniel Chapter One, Inc. was organized were: "[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." (CX 50; J. Feijo, HOJ Tr. 101-02).

24. 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).

25. Each of these for-profit corporation annual reports of DCO bears the signature of Respondent James Feijo. (J. Feijo, HOJ Tr. 102-08).

26. From 1991 to 1997, DCO's corporate status was repeatedly revoked. (J. Feijo, HOJ Tr. 175-77, 194-97; CX 50).

27. Respondent James Feijo sold the Challenged Products while DCO was registered as a for-profit corporation. (J. Feijo, Tr. 417-18; R 15 (J. Feijo, Dep. at 224)).

28. In 2002, Respondent Daniel Chapter One was organized as a corporation sole under the laws of the State of Washington. (Answer ¶ 1; CX 31; J. Feijo, HOJ Tr. at 84).

29. DCO's Articles of Incorporation as a corporation sole describe its purposes as follows:

> [T]o do whatever will promote the Kingdom Of God, All Righteousness, and the principals [sic] of Liberty and Justice to provide for the comfort, happiness and improvement of an indefinite number of natural men and women, with special forerunner emphases upon the firm practice and lawful operation of the law, providing lawful advice, educating people in the fundamental principles of liberty and the common law, researching, developing and implementing remedies at law for any problem while holding accountable those individuals responsible for the breach of, or wrongful interference with contractual obligations, whether written, verbal, or implied; as well as other worthwhile projects for the common good of Daniel Chapter One and its close associates, along with other acts and programs beneficial to Daniel Chapter One at large.

(CX 31).

30. DCO's Articles of Incorporation do not specifically declare that DCO was organized exclusively for charitable or other clearly nonprofit purposes. DCO's Articles of Incorporation do not provide for distribution of its assets upon dissolution solely to other nonprofit entities or prohibit distribution of its earnings to the benefit of any individual or for-profit corporation. (CX 31).

31. DCO is not registered with the Internal Revenue Service as a charity. (R 15 (J. Feijo, Dep. at 45); J. Feijo, HOJ Tr. 209).

32. DCO's advertising and promotional materials (*see infra* Section II D, E) do not specifically refer to DCO as a nonprofit entity. For example, the "About Us" section on the DCO Website, www.danielchapterone.com, describes DCO as a "health food store" or "health food supplement store." (CX 1).

33. DCO uses, but does not own, two buildings in Rhode Island – one is the telephone order center (*see infra* F. 99) and the other is the warehouse. (J. Feijo, HOJ Tr. 110; R 15 (J. Feijo, Dep. 72-73)).

34. Messiah Y'Shua Shalom, a State of Washington corporation sole, owns one of the two buildings that Respondents use in Rhode Island. (R 15 (J. Feijo, Dep. at 72-73); CX 35). The other building is rented from an owner unrelated to Respondents. (R 15 (J. Feijo, Dep. at 174)).

35. Respondent James Feijo is also the overseer for Messiah Y'Shua Shalom. (R 15 (J. Feijo, Dep. at 72-73); CX 35).

36. Respondents founded Accent Radio Network in 2000. (CX 32 at FTC-DCO 2954; J. Feijo, HOJ Tr. 110-12).

B. Respondents' Finances

1. Control by James Feijo

37. Respondent James Feijo is responsible for the development, creation, production, and pricing of the Challenged Products. (CX 39 (Respondents' Answer to Interrogatory No. 2); R 15 (J. Feijo, Dep. at 116); R 16 (P. Feijo, Dep. at 77)).

38. Respondent James Feijo and his wife, Patricia Feijo, have been solely responsible for creating, drafting, and approving the directions for usage of the Challenged Products. (CX 39 (Respondents' Answer to Interrogatory No. 16)).

39. Respondent James Feijo and Patricia Feijo developed the recommended dosages of the Challenged Products. (R 16 (P. Feijo, Dep. at, 166-67, 175, 192); CX 39 (Respondents' Answer to Interrogatory No. 16).

40. Respondent James Feijo is the trustee for all of DCO's assets, including all funds, which are to be held in trust. (CX 39 (Respondents' Answer to Interrogatory Nos. 3, 9); J. Feijo, HOJ Tr. 73).

41. Respondent James Feijo is ultimately in charge of DCO. (J. Feijo, HOJ Tr. 112).

2. Bank accounts

42. Respondent DCO has bank accounts with Citizens Bank, including: Daniel Chapter One Business Partners Checking, Daniel Chapter One Business Partners Money Market Fund, Daniel Chapter One DBA Creation Science Funding, and Daniel Chapter One DBA Radio Leasing International. Revenue earned by Respondent DCO is deposited into the Daniel Chapter One Business Partners Checking account and from there is distributed, at Respondent James Feijo's discretion, to the other DCO bank accounts. (CX 49; J. Feijo, HOJ Tr. 206-08, 227, 230).

43. Records of the Daniel Chapter One Business Partners Checking account show frequent ATM cash withdrawals in the amount of $803, including multiple such withdrawals in the same month. (CX 49, *see, e.g.*, FTC-DCO 3661, 3666, 3671, 3677, 3683, 3689).

44. The Daniel Chapter One Business Partners Money Market Fund held unused funds that Respondents put aside. (J. Feijo, HOJ Tr. 230).

45. Records from the Daniel Chapter One Business Partners Money Market Fund show that from December 19, 2006 until February 20, 2008, the money market fund had a balance in excess of $1,000,000, and grew to as high as $1,303,283. On February 21, 2008, a debit was posted in the amount of $802,000. (CX 49 at FTC-DCO 3624-97).

46. According to James Feijo, DCO does not keep a ledger of the amounts it pays out. (J. Feijo, HOJ Tr. 166).

47. According to James Feijo, the trustee of DCO's funds, Feijo does not keep track of the money DCO distributes; Feijo is not aware of what bank accounts DCO has; and Feijo has no idea how much DCO pays out on a monthly basis for its credit cards. (J. Feijo, HOJ Tr. 165, 168-69, 227-28).

48. Patricia Feijo is a signatory to DCO's bank accounts and writes checks from the DCO accounts. (R 16 (P. Feijo, Dep. at 54); P. Feijo, HOJ Tr. 276).

49. Jill Feijo, James Feijo's daughter, pays DCO's bills. (J. Feijo, HOJ Tr. 204).

3. Records

50. DCO has a policy of not maintaining records. (J. Feijo, HOJ Tr. 73, 83).

51. 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). 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).

52. Respondent James Feijo had the authority to change DCO's document retention policies after receiving the orders in this proceeding to produce responsive documents to Complaint Counsel. (J. Feijo, HOJ Tr. 83).

53. DCO continued to discard documents, including Marino's purchase order form (*see infra* F. 154-55), even after receiving orders in this proceeding to produce certain documents to Complaint Counsel. (J. Feijo, HOJ Tr. 83).

54. DCO has no records indicating how much of its products it has given away or how much financial support DCO has dedicated to charitable activities. (P. Feijo, HOJ Tr. 274-75).

4. Distribution of funds

55. James and Patricia Feijo live at the Portsmouth, Rhode Island property, owned by Messiah Y'Shua Shalom, as well as in a three-bedroom house owned by DCO, with a pool on country club land, in Deerfield Beach, Florida. (R 15 (J. Feijo, Dep. at 70-71, 78-79); J. Feijo, HOJ Tr. 160, 204).

56. Respondent DCO owns two cars, a 2003 Cadillac and a 2004 Cadillac. DCO purchased one Cadillac new and the other Cadillac used. (R 15 (J. Feijo, Dep. at 71); J. Feijo, HOJ Tr. 160).

57. Respondent James Feijo uses the two Cadillacs owned by DCO. (R 15 (J. Feijo, Dep. at 96-97); J. Feijo, HOJ Tr. 160).

58. Respondent DCO pays for all of the Feijos' living expenses. (CX 39 (Respondents' Answer to Interrogatory No. 3); J. Feijo, HOJ Tr. 206; P. Feijo, HOJ Tr. 276).

59. Respondents do not maintain any records of how much DCO money is spent on the Feijos' living expenses. (P. Feijo, HOJ Tr. 277).

60. The Feijos do not file tax returns with regard to the money they receive from Respondent DCO. (P. Feijo, HOJ Tr. 278).

61. Respondent DCO pays for pool and gardening services rendered on the "Feijo house" in Florida. (CX 49 at FTC-DCO 3443, 3457).

62. Respondent DCO pays for Patricia Feijo's tennis club membership. (P. Feijo, HOJ Tr. 278).

63. Respondent DCO pays for Respondent James Feijo's membership at the Green Valley Country Club in Rhode Island. (J. Feijo, HOJ Tr. 154-55).

64. Respondent DCO pays for Respondent James Feijo to play golf at the Deer Creek Golf Course located behind the Deerfield Beach, Florida home. (CX 49; J. Feijo, HOJ Tr. 155).

65. Respondent DCO has an American Express Business Gold Card, in the names of Daniel Chapter One and of Patricia Feijo, to which Respondent James Feijo is also a signatory. (CX 48; P. Feijo, HOJ Tr. 276).

66. Respondent James Feijo has frequently used the American Express Business Gold Card to eat at restaurants, play golf, and buy cigars and other retail items. Patricia Feijo also frequently used the card at grocery stores, drug stores, book stores, gas stations, clothing and shoe stores, and home furnishing stores, such as Bed, Bath & Beyond, and Linens & Things. (CX 48; J. Feijo, HOJ Tr. 151-60; P. Feijo, HOJ Tr. 276).

67. Approximately $9,936 was charged for golf expenses on DCO's American Express Business Gold Card

during the period from December 2005 through 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).

68. Approximately $14,024 was charged for restaurant expenses on DCO's American Express Business Gold Card during the period from December 2005 through 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).

69. Approximately $28,582 was charged for automobile expenses on DCO's American Express Business Gold Card during the period from December 2005 through 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).

70. Approximately $1,077 was charged for cigar expenses on DCO's American Express Business Gold Card during the period from December 2005 through March 2009. (CX 48 at FTC-DCO 3113, 3121, 3181, 3197, 3208M, 3245, 3264, 3273).

71. Respondent DCO also has credit cards with Bank of America and Chase Bank. (J. Feijo, HOJ Tr. 161).

72. Approximately $51,087 was electronically transferred from Citizens Bank checking accounts of DCO and related entities to Bank of America during the period from February 2007 through March 2009. (CX 49 at

FTC-DCO 3352, 3359, 3363, 3367, 3674, 3680, 3685, 3701, 3706, 3726, 3733, 3741, 3750).

73. Approximately $30,277 was paid by check from DCO's Creation Science Funding account with Citizens Bank to Bank of America during the period from January 2007 through April 2007. (CX 49 at FTC-DCO 3448, 3456, 3470, 3472, 3498).

74. Approximately $25,837 was paid by check from DCO's Creation Science Funding account with Citizens Bank to Chase Card Services during the period from January 2007 through April 2007. (CX 49 at FTC-DCO 3441, 3464, 3470, 3493, 3497).

75. Respondent James Feijo does not retain receipts for his credit card purchases and credit card payments are automatically debited. (J. Feijo, HOJ Tr. 163-64).

76. Respondent James Feijo does not have his own individual bank account. (J. Feijo, HOJ Tr. 208).

77. Respondent James Feijo pays his daughter Jill Feijo $700 per week for her work at DCO. (J. Feijo, HOJ Tr. 204-05).

78. Although he paid individual income taxes prior to DCO's incorporation as a corporation sole, Respondent James Feijo has since stopped paying individual income taxes. (J. Feijo, HOJ Tr. 86).

79. DCO does not pay any state sales tax based on the sale of DCO products through the DCO Website. (J. Feijo, HOJ Tr. 210).

C. Respondents' Sales in Commerce

1. Respondents' sales of the Challenged Products

80. Respondents' sales of the Challenged Products constitute 20 or 30 percent of the approximately $2

million in annual sales of DCO products for the years 2006, 2007, and 2008. (CX 44; R 15 (J. Feijo, Dep. at 206-07, 212); J. Feijo, HOJ Tr. 109, 223-24, 315).

81. Over a thousand people have purchased the Challenged Products. (R 16 (P. Feijo, Dep. at 57)).

82. Anyone can buy and use the Challenged Products, including people who do not belong to the DCO religious community and people who do not believe in God. (Marino, HOJ Tr. 55; P. Feijo, Tr. 410-11).

83. Respondents' acquisition costs for the products they sell is 30 percent of the price Respondents charge for products such as 7 Herb Formula. (R 15 (J. Feijo, Dep. at 232); F. 127-29, 140-42, 144-46).

84. Respondents sell the Challenged Products through publications, a call center, over the Internet, and through stores and distributors. (F. 86, 89-92, 94, 97, 99, 104, 116-17, 163, 174).

a. DCO's publications

85. James and Patricia Feijo claim to have created a combined spiritual and scientific approach that maintains the balance of bodily systems which James Feijo named BioMolecular Nutrition. (CX 21).

86. Respondents created a publication entitled "BioGuide: The BioMolecular Nutrition Guide to Natural Health 3" ("BioGuide" or "BioGuide 3"). BioGuide 3 is the third printing and the current version that DCO uses. (CX 21; R 16 (P. Feijo, Dep. at 117); R 15 (J. Feijo, Dep. at 243); J. Feijo, Tr. 452-53; P. Feijo, Tr. 388).

87. According to the BioGuide, "[t]here are two aspects of BioMolecular Nutrition, the spiritual and the physical." (CX 21 at FTC-DCO 0307). "The principles of BioMolecular Nutrition were those missing principles needed to bind together those of the

nutritionists and the biochemists." (CX 21 at FTC-DCO 0309).

88. The BioGuide states that "[b]ecause of BioMolecular nutritional products developed . . . [the Feijos have] 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 at FTC-DCO 0308).

89. The BioGuide contains descriptions of DCO products, testimonies from people who have used DCO products and doctors who recommend the products, as well as Biblical passages. (CX 21; R 16 (P. Feijo, Dep. at 117); J. Feijo, Tr. 452-53).

90. The BioGuide prominently displays the toll-free number for DCO's call center and the danielchapterone.com web address. (CX 21).

91. Respondents also created the BioMolecular Nutrition Product Catalog, which lists and describes DCO products and states, "Call Toll FREE 1-800-504-5511 or shop online at www.danielchapterone.com." (CX 17).

92. There is no indication in the BioMolecular Nutrition Product Catalog that the price listed beside the products displayed is for a donation. (R 15 (J. Feijo, Dep. at 158); R 16 (P. Feijo, Dep. at 76-77); J. Feijo, HOJ Tr. 140).

93. There is no mention of a DCO ministry in the BioMolecular Nutrition Product Catalog. (R 15 (J. Feijo, Dep. at 161)).

94. Respondents produced a newsletter, "How to Fight Cancer is Your Choice!!!" (hereinafter "Cancer Newsletter"). In the Cancer Newsletter, Respondents

instruct consumers to call their toll-free number to order their products. (CX 23; CX 24).

95. The Cancer Newsletter, a one-time brochure reprinted once with minor updates, provides testimonials from users of DCO products. (J. Feijo, Tr. 452).

96. The Cancer Newsletter is available online on DCO's Website. (CX 13 at FTC-DCO 0013; CX 13A at FTC-DCO 2828A).

97. Respondents produced a publication, "The Most Simple Guide to the Most Difficult Diseases: The Doctors' How-To Quick Reference Guide" (hereinafter "The Most Simple Guide"). (CX 20).

98. "The Most Simple Guide" can be accessed by anyone, not only doctors, on DCO's Website. (P. Feijo, Tr. 395; J. Feijo, Tr. 453-55).

b. Call center sales

99. Respondent DCO has a toll-free number and a call center for consumers to purchase DCO products. (R 16 (P. Feijo, Dep. at 67); J. Feijo, HOJ Tr. 212; P. Feijo, HOJ Tr. 273-74; J. Feijo, HOJ Tr. 168, 204, 211-12).

100. Respondent James Feijo created, managed, and maintained the toll-free telephone number, designed so that consumers can order DCO products and discuss their physical and spiritual well-being. (CX 39 (Respondents' Answer to Interrogatory No. 33); P. Feijo, Tr. 357-58).

101. 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 (Respondents' Answer to Interrogatory No. 33); J. Feijo, HOJ Tr. 204).

102. Consumers learn of DCO's toll-free number from the BioGuide, DCO Website, and Respondents' radio program, "Daniel Chapter One HealthWatch." (P. Feijo, HOJ Tr. 273-74; CX 21; CX 29 at FTC-DCO 0451).

c. Internet sales

103. Respondents operate the DCO Website (www.danielchapterone.com). (Answer ¶ 5; R 15 (J. Feijo, Dep. at 62)). DCO also operates the websites www.dc1pages.com, www.dc1store.com, www.7herb formula.com, and www.gdu2000.com (collectively, the "Websites"). (CX 39 (Respondents' Answer to Interrogatory No. 11); R 15 (J. Feijo, Dep. at 62, 232-33); J. Feijo, Tr. 459).

104. DCO accepts consumers' orders over the Internet through the Websites. (P. Feijo, Tr. 397; Marino, HOJ Tr. 54).

105. DCO's Website contains a tab inviting consumers to shop at DCO's "On-Line Store." (CX 12-14).

106. DCO's Website contains an icon inviting consumers to "Buy Now." (CX 12-14; J. Feijo, HOJ Tr. 144).

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

d. Radio broadcasts

108. The "Daniel Chapter One HealthWatch" radio program is broadcast on the "Accent Radio Network" and is carried by what was characterized as an eclectic group of AM radio stations. (CX 32; R 15 (J. Feijo, Dep. at 235); Harrison, Tr. 309-10).

109. 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 (Respondents' Answer to Interrogatory No. 5); R 15 (J. Feijo, Dep. at 16-17); Harrison, Tr. 303; P. Feijo, Tr. 324; J. Feijo, Tr. 450-51).

110. James and Patricia Feijo have counseled individuals who have called into the Daniel Chapter One radio program and who have identified themselves as cancer patients about taking the Challenged Products. (R 16 (P. Feijo, Dep. at 92-97); P. Feijo, Tr. 360-64).

111. On their radio show, Respondents provide listeners with the toll-free number that people can call to purchase the Challenged Products. (P. Feijo, HOJ Tr. 272-74).

e. Fees and promotions

112. DCO's shipping and handling fees for its products are $20.95. (R 15 (J. Feijo, Dep. at 152-53)).

113. DCO offers coupons to consumers for their next online store order. (R 15 (J. Feijo, Dep. at 154); Marino, HOJ Tr. 59; J. Feijo, HOJ Tr. 149-50).

114. Respondents run sales promotions from time to time to give people an opportunity to purchase products at a lower rate. (R 15 (J. Feijo, Dep. at 154)). For example, consumers can buy multiple bottles and get a bottle free. (R 15 (J. Feijo, Dep. at 232)).

115. Consumers can join DCO's Bucket-A-Month Club to obtain volume discounts on DCO products. (CX 29 at FTC-DCO 0430; J. Feijo, HOJ Tr. 140-41).

f. Stores and distributors

116. A number of stores sell DCO products, including stores in Georgia and a store in Pennsylvania. (R 16 (P. Feijo, Dep. at 72)).

117. Respondents use distributors in various states for DCO products. (J. Feijo, HOJ Tr. 132-35). Respondents' distributors have included stores such as Nature's Pharmacy in Altoona, Florida; Herbs 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).

118. Respondents call some distributors of DCO products "silver-line carriers" or "gold-line carriers." (J. Feijo, HOJ Tr. 125). "Gold-line carriers" carry a broader range of products than "silver-line carriers." (J. Feijo, HOJ Tr. 126).

119. Respondents' distributors have also included chiropractic centers. (J. Feijo, HOJ Tr. 134-35).

120. Doctors and stores that carry DCO's product line get the products at prices below their listed prices because they are going to resell the products. (R 16 (P. Feijo, Dep. at 71)).

121. One doctor who is a distributor of DCO products places about a 40 percent markup on the DCO products he sells. (Mink, HOJ Tr. 287-88; J. Feijo, HOJ Tr. 311).

122. Respondents have created a brochure entitled "The Truth Will Set You Free!" for the stores and doctors' offices that carry 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. 136-37). 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).

123. On their webpage www.dc1store.com, Respondents promote an affiliate program, stating:

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

(CX 29 at FTC-DCO 0461-0462 (emphasis in bold in original; emphasis in italics added)).

124. An entity does not have to be a religious ministry to participate in the DC1 Affiliate Program. (J. Feijo, HOJ Tr. 114).

2. Sales information for each of the Challenged Products

125. There has been only one version of each of the Challenged Products and the information relating to the identity of each ingredient and the amount of each ingredient contained on the labels of the Challenged Products. (CX 39 Respondents' Answer to Interrogatory No. 17).

a. BioShark

126. BioShark is a product that contains, among other ingredients, shark cartilage. (Answer ¶ 6). Each BioShark product label directs users to take two to three capsules three times a day or as directed by a physician or by a BioMolecular Nutrition health care professional. (Answer ¶ 6; CX 17 at FTC-DCO 0065).

127. Respondents offer one bottle of BioShark for $30.95 (for 100 of the 800 mg capsules) and another bottle of BioShark for $65.95 (for 300 of the 800 mg capsules). (Answer ¶ 6).

128. Respondents pay Universal Nutrition $3.15 per unit for the 100 capsule bottle of BioShark and $8.75 per unit for the 300 capsule bottle of BioShark. (Deposition of Claudia Petra Bauhoffer-Kinney, Jan. 15, 2009 (hereinafter referred to as R 17 (Bauhoffer-Kinney, Dep. at 44).

129. During 2008, Respondents paid Universal Nutrition approximately $1,437 to manufacture 479 units of the 100 capsule bottle of BioShark and approximately $6,256 to manufacture 782 units of the 300 capsule bottle of BioShark. (R 17 (Bauhoffer-Kinney, Dep. at 44-45)).

130. Universal Nutrition has its own brand of products and is also a private-label manufacturer. (R 17 (Bauhoffer-Kinney, Dep. at 17)).

131. DCO falls under the private-label side of Universal Nutrition. (R 17 (Bauhoffer-Kinney, Dep. at 17)).

132. Universal Nutrition makes approximately thirty-five to forty products for DCO, including BioShark, GDU, and BioMixx. (R 17 (Bauhoffer-Kinney, Dep. at 20-21)).

133. Universal Nutrition started manufacturing BioShark for Respondents approximately eight to ten years ago. (R 17 (Bauhoffer-Kinney, Dep. at 42-43)).

b. 7 Herb Formula

134. 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. The 7 Herb Formula is an essiac formula to which Respondents added cat's claw and Siberian ginseng. (Answer ¶ 8; J. Feijo, HOJ Tr. 146-48; J. Feijo, Tr. 439).

135. Respondents' product label directs users to take one to two ounces of 7 Herb Formula with two to four ounces of hot or cold, filtered or distilled water. The label further directs users to take 7 Herb Formula twice daily or as directed by a BioMolecular Nutrition health care professional. (Answer ¶ 8; CX 17 at FTC-DCO 0064).

136. Respondents offer one thirty-two ounce bottle of 7 Herb Formula for $70.95. (Answer ¶ 8).

137. On their websites www.danielchapterone.com and www.dc1pages.com, Respondents state regarding 7 Herb Formula: "I think it costs too much: Essiac formulas normally retail for $45 to $69 per bottle. If you compare that to the cost of a hospital stay and drug treatment, this is cheap! Daniel Chapter One's 7 Herb Formula is equally priced with most other brands

but with ours you get a great deal more. Remember you are not only getting 32 ounces per bottle, when some of the other brands are only 16 ounces; you are also getting 2 more expensive herbs (Cat's Claw and Siberian Ginseng). We use 3 times the herbs and prepare each individually using a double water filtering process. If that is the case you must at least double the price they are asking to get equal price comparison." (CX 18 at FTC-DCO 0159-60).

138. On the DCO Website, Respondents state: "Daniel Chapter One is the first and only company to add Siberian Ginseng to the formula." (CX 30).

c. GDU

139. GDU is a product that contains, among other ingredients, bromelain, turmeric, quercetin, feverfew, and boron. (Answer ¶ 10). "GDU" stands for "gelatin digesting units." (J. Feijo, Tr. 442). Respondents' GDU product label directs users to take three to six capsules two to four times per day or as directed by a physician or by a BioMolecular Nutrition health care professional. (Answer ¶ 10; CX 17 at FTC-DCO 0068).

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

141. Respondents pay Universal Nutrition $3.28 per unit for the 120 tablet bottle of GDU and $7.07 per unit for the 300 tablet bottle of GDU. (R 17 (Bauhoffer-Kinney, Dep. at 34-35)).

142. During 2008, Respondents paid Universal Nutrition approximately $5,127 to manufacture 1,709 units of the 120 tablet bottle of GDU and approximately $52,661 to manufacture 7,523 units of the 300 tablet bottle of GDU. (R 17 (Bauhoffer-Kinney, Dep. at 34-35)).

d. BioMixx

143. 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 18 at FTC-DCO 0127).

144. Respondents offer BioMixx for $40.95 (for 3 pounds of powder) and $22.95 (for one pound of powder). (Answer ¶ 12).

145. Respondents pay Universal Nutrition $11.50 per unit for the three pound bottle of BioMixx. (R 17 (Bauhoffer-Kinney, Dep. at 46)).

146. During 2008, Respondents paid Universal Nutrition approximately $8,778 to manufacture 798 units of the three pound bottle of BioMixx. (R 17 (Bauhoffer-Kinney, Dep. at 46)).

3. Purchase of the Challenged Products by the FTC investigator

147. On January 3, 2008, FTC investigator Michael Marino ("Marino") purchased the Challenged Products from the DCO Website. (CX 10; Marino, HOJ Tr. 53-55, 62-67).

148. At the time of Marino's purchase, each of the Challenged Products was displayed on the DCO Website with a picture of the product, a short description of the product, and a corresponding price. (Marino, HOJ Tr. 54).

149. Nothing on the DCO Website indicated to Marino that the Challenged Products could be obtained in exchange for a donation, could be purchased at a reduced price, or could be received for free. (Marino, HOJ Tr. 54-55).

150. Nothing on the DCO Website indicated to Marino that a consumer would have to be part of any religious community in order to purchase the Challenged Products. (Marino, HOJ Tr. 55).

151. Prior to making the purchase of the Challenged Products, Marino created an undercover e-mail account to confirm and monitor the progress of the purchase. Marino received four e-mails from DCO relating to the purchase of the Challenged Products. (CX 33; Marino, HOJ Tr. 56-59).

152. One of the e-mails Marino received from DCO, which was sent the day after he purchased the Challenged Products, stated: "Thank you for your purchase on our online store. . . . We appreciate your business with us," and offered a ten percent discount on a subsequent purchase. (CX 33; Marino, HOJ Tr. 59).

153. On or about January 3, 2008, Marino purchased the Challenged Products, and received all four of the Challenged Products thereafter. (CX 33, 34; Marino, HOJ Tr. 55-60).

154. Included in the shipment of the DCO Products ordered by Marino were the following: "BioGuide 3: The BioMolecular Nutrition Guide to Natural Health 3," "BioMolecular Nutrition Product Catalog," a blank purchase-order form, and an invoice form. (CX 34; Marino, HOJ Tr. 55-56, 61).

155. According to the purchase-order form and invoice, the shipment to Marino originated from Daniel Chapter One, 1028 E. Main Road, PO Box 223, Portsmouth, RI 02871, and was sent to an FTC undercover address in a state in the United States other than Rhode Island. (CX 34; Marino, HOJ Tr. 60).

156. The shipment of the Challenged 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).

157. According to Commission records, the amount charged to the undercover credit card used for the purchase of the Challenged Products was $175.75. The Commission records indicate that this charge was made by "DANIEL CHAPTER ONE." (CX 34; Marino, HOJ Tr. 58, 60).

D. DCO's Advertisements

158. Information about the Challenged Products is disseminated to the public through a variety of media, the Internet, written publications, and a radio show. (F. 161, 163-64, 169-70, 172, 175-77).

159. DCO has spent money to have its websites and written publications created. (J. Feijo, HOJ Tr. 139).

160. DCO has spent money for cable advertising services. (CX 48 at FTC-DCO 3058).

161. The Challenged Products are advertised on the websites www.danielchapterone.com, www.dc1pages .com, www.dc1store.com, www.7herbformula.com, and www.gdu2000.com. (CX 39 (Respondents' Answer to Interrogatory No. 11); R 15 (J. Feijo, Dep. at 62, 232-33); J. Feijo, Tr. 459).

162. Any consumer can be directed to the DCO Website by entering the term "cancer" in a Google search. (R 15 (J. Feijo, Dep. at 136)).

163. The DCO publication, "The Most Simple Guide," promotes particular DCO products for particular medical conditions, and each alternating page of this publication sets forth the DCO Website and DCO's toll-free number for telephone orders. (CX 20; J. Feijo, Tr. 453-54). This guide is available to the public to order. (CX 23 at FTC-DCO 0404; CX 24 at

FTC-DCO 0420). The guide remains available on the DCO Website where anyone can download it. (CX 29 at FTC-DCO 0430; P. Feijo, Tr. 395). There has never been a charge to obtain the guide. (P. Feijo, Tr. 382-83).

164. DCO also promotes the Challenged Products through its publication BioGuide 3 ("BioGuide"). (CX 21; CX 39 (Respondents' Answer to Interrogatory No. 11); F. 86, 89- 90).

165. James Feijo was responsible for putting together the BioGuide. (R 15 (J. Feijo, Dep. at 243)).

166. Patricia Feijo wrote the content of the BioGuide. (R 16 (P. Feijo, Dep. at 20)).

167. The BioGuide frequently and prominently refers readers to the DCO Website and DCO's toll-free ordering number. (*E.g.*, CX 21 at FTC-DCO 0309-11, 0313).

168. The BioGuide is prominently promoted in the Cancer Newsletter. (CX 23 at FTC-DCO 0397; CX 24 at FTC-DCO 0413 (noting the BioGuide's "Updated Products, Prices, Testimonies! . . . Only $9.95.").

169. The BioGuide is available as a download from the DCO Website. (CX 29 at FTC-DCO 0430). There has never been a charge to obtain the BioGuide. (P. Feijo, Tr. 389).

170. DCO promotes the Challenged Products through its publication, the Cancer Newsletter. (CX 23; CX 24).

171. Although there is a price displayed for the Cancer Newsletter, the Cancer Newsletter was given away without charge. (P. Feijo, Tr. 387).

172. The Cancer Newsletter is available on-line through the DCO Website. (CX 13 at FTC-DCO 0013; CX 13A at FTC-DCO 2828A).

173. The Cancer Newsletter was written primarily by Patricia Feijo. (CX 39 (Respondents' Answer to Interrogatory No. 8); P. Feijo, Tr. 395-96).

174. In the Cancer Newsletter, the toll-free order number and the DCO Website address appear on every other page and on the final page. (CX 23 at FTC-DCO 0392, 0394, 0396, 0398, 0400, 0402, 0404, 0405; CX 24 at FTC-DCO 0407, 0409, 0411, 0413, 0415, 0417, 0419, 0421).

175. The Cancer Newsletter promotes obtaining "The Most Simple Guide" and listening to DCO's radio program. (CX 23 at FTC-DCO 0403-05; CX 24 at FTC-DCO 0419-21).

176. Information about the Challenged Products is disseminated through the radio program, "Daniel Chapter One HealthWatch." (CX 39 (Respondents' Answer to Interrogatory No. 11); P. Feijo, Tr. 325; F. 108-09, 111).

177. "The Most Simple Guide," the BioGuide, and the Cancer Newsletter all promote DCO's radio show. (CX 20 at FTC-DCO 2824; CX 21 at FTC-DCO 0379, CX 23 at FTC-DCO 0405; CX 24 at FTC-DCO 0421). The DCO Website has a link to a webpage for "Talk Radio." (CX 12; CX 13, CX 14).

178. James and Patricia Feijo are responsible for the information provided in the BioGuide, the DCO Website, the Cancer Newsletter, the "Most Simple Guide," and the radio program, "Daniel Chapter One HealthWatch." (R 15 (J. Feijo, Dep. at 62); J. Feijo, Tr. 452-53; P. Feijo, Tr. 380, 395-96; CX 39 (Respondents' Answer to Interrogatory No. 11-12).

E. DCO's Advertising Claims

1. The Challenged Products collectively

a. Website advertising

179. CX 13 is a printout from a webpage from the DCO Website, entitled "Cancer News." This printout is Exhibit B to the Complaint. CX 13A is another depiction of the same product webpage as that depicted in CX 13, but captured so as to view the entire width of the page. (CX 13; CX 13A).

180. The DCO webpage, Cancer News, contains a picture and text advertising 7 Herb Formula. Directly below the 7 Herb Formula advertisement, the webpage states the following regarding the Challenged Products as a group:

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

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

To Buy the products click here

How to fight cancer is your choice!

(CX 13 at FTC-DCO 0013-14; CX 13A) (emphasis in original).

181. Immediately beneath "How to fight cancer is your choice!" is a quote from a book entitled "Back to Eden," which includes the book author's statement that his "cure for cancer" includes herbs. (CX 13 at FTC-DCO 0014; CX 13A at FTC-DCO 2828B).

182. The "Back to Eden" quote referred to in F.181 is followed by a series of testimonials in bold headlines including: "**Lump is gone without dangerous surgery!**," "**7 Herb Formula battles cancer**," "**7 Herb eliminates pre-cancerous growth**," "**Ancient cancer remedy is improved upon**," "**Doctors gave up on Michigan man**," "**Pre-Cancerous Growths & Acid and Heartburn**," and "**Breast Mass**." (CX 13 at FTC-DCO 0014-24) (emphasis in original).

183. The testimonials on the Cancer News webpage claim that the Challenged Products, individually or in combination with each other and/or other DCO products, are effective in the prevention, treatment, or cure of cancer. (CX 13; CX 13A; F. 184-85).

184. The Cancer News webpage includes the following testimonial, accompanied by a picture of a smiling woman:

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.

. . .

> 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 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%. . . .

(CX 13 at FTC-DCO 0016) (emphasis in original).

185. Another testimonial on the Cancer News webpage states:

> **Pre-Cancerous Growths & Acid and Heartburn**
>
> And the most amazing thing was when I had my upper G.I. in September, and the X-ray showed nothing there. . . . [a]fter using 7 Herb and other DC1 products for precancerous growths and for acid & heartburn.

(CX 13 at FTC-DCO 0023) (emphasis in original).

186. The testimonials referred to in F. 184 and 185, as well as other testimonials, are hyperlinked to Cancer News webpage, below the bold-type message: "**Page shortcuts to testimonials about cancer**." (CX 13 at FTC-DCO 0013) (emphasis in original).

187. At the side of the Cancer News webpage is the bold-type message: "**Listen to our audio testimonials about cancer**," with bulleted headlines, including "Fred - Breast cancer," "Marie - Dad's throat tumor cured - 7 Herb and more," "Nancy - Cured Breast Cancer in 3 months - 7 Herb and GDU," "Robert - Prostate cured from DC1 products," and "Sharon -

Mom's breast tumor Healed." (CX 13 (emphasis in original); CX 13A).

188. On the side of the Cancer News webpage, there is a link to the Cancer Newsletter. (CX 13; CX 13A).

189. The overall net impression from the www.daniel chapterone.com website advertising described in F. 179-88 is that the Challenged Products, individually and/or collectively, prevent, treat, or cure cancer. Viewing the Cancer News webpage as a whole, and the interaction of the words, pictures, and testimonials, the claim that the Challenged Products prevent, treat, or cure cancer is so strongly implied as to be virtually express.

190. The Challenged Products are promoted as a group on the website www.dc1pages.com, where the following text appears:

> **Supporting Products**
>
> To enhance 7 Herb Formula's healing qualities Daniel Chapter One advises to get familiar with the supporting products below . . . .

Immediately below the text is a photograph of bottles of each of the Challenged Products. Adjacent to the picture, in bold print, the following text appears:

> **CANCER**
> **TREATMENT**:
>
> **7 Herb Formula**
> **Bio*Shark**
> **BioMixx**
> **GDU Caps**
>
> **also**
>
> **Ezekiel Oil**

topically

(CX 18 at FTC-DCO 0190) (emphasis in original).

191. The overall net impression from the www.dc1pages.com content described in F. 190 is that the Challenged Products, individually and/or collectively, are effective in the treatment of cancer.

b. "The Most Simple Guide to the Most Difficult Diseases"

192. The Challenged Products are promoted collectively for cancer in the DCO publication "The Most Simple Guide to the Most Difficult Diseases: The Doctors' How-To Quick Reference Guide." (CX 20). The advertisements in this publication are organized by disease types. (CX 20 at FTC-DCO 2724). On the page for cancer, the following appears:

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

Next to each product name is a "sun" symbol. The page states: "This sun [symbol] placed before a product indicates the most essential products for the above condition." The only "condition" referred to on that page is cancer. (CX 20 at FTC-DCO 2739) (emphasis in original).

193. The overall net impression from the "cancer" page in the "The Most Simple Guide" described in F. 192 is that the Challenged Products, individually and/or collectively, treat or cure cancer. Viewing the Guide as a whole, and the interaction of the words, pictures, and testimonials, the claim that the Challenged Products prevent, treat, or cure cancer is so strongly implied as to be virtually express

c. Cancer Newsletter

194. The 2002 edition of the DCO Cancer Newsletter is entitled "How to fight cancer is your choice!!!" (CX 23). A two-page excerpt from this newsletter constitutes Exhibit D to the Complaint. (CX 15). There is also a 2004 version of the Cancer Newsletter. (CX 24). Both the 2002 and the 2004 editions are referred to collectively herein as the "Cancer Newsletter." (CX 23; CX 24).

195. The Cancer Newsletter is "strictly all about the products for cancer." (R 15 (J. Feijo, Dep. at 143)). 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 BioShark, GDU, BioMixx, and 7 Herb Formula. (P. Feijo, Tr. 402-04).

196. The Cancer Newsletter opens with a quote from a book entitled "Back to Eden," which also appears at the Cancer News webpage of the DCO Website and includes the book author's statement that his "cure for cancer" includes herbs. (F. 181; CX 23 at FTC-DCO 0391; CX 24 at FTC-DCO 0407).

197. The Cancer Newsletter includes descriptions of eight DCO products, four of which are the Challenged Products, and one of which, Siberian ginseng, is an ingredient of one of the Challenged Products, 7 Herb Formula. Interspersed with the product descriptions are testimonials, including testimonials asserting the successful use of one or more of the Challenged Products, and/or other DCO products, for cancer. Other than product descriptions, this publication consists almost entirely of testimonials asserting the successful use of DCO products, including the Challenged Products, for cancer. (CX 23; CX 24).

198. Many of the testimonials in the Cancer Newsletter are the same as those appearing on the Cancer News webpage of www.danielchapterone.com, including, "Lump Is Gone Without Dangerous Surgery!," "7 Herb Formula Battles Cancer," "7 Herb Eliminates Pre-Cancerous Growth," "Ancient Cancer Remedy Is Improved Upon," "Doctors Gave Up On Michigan Man," and "Pre-Cancerous Growths & Acid and Heartburn." (CX 24 at FTC-DCO 0407; F. 182-85; *see also* CX 17 at FTC-DCO 0100-119 (testimonials).

199. The testimonials in the Cancer Newsletter include such statements as:

- "I started taking the 7 Herb and that tumor was shrinking . . . there has been massive tumor shrinkage." ("Doctors gave up on Michigan man," CX 23 at FTC-DCO 0397; CX 24 at FTC-DCO 0413);
- "Tricia convinced [them] that [the] best hope was to take natural remedies rather than go under the knife . . . . The growth is gone . . . ." ("Cancer Success a Lie!," CX 23 at FTC-DCO 0399; CX 24 at FTC-DCO 0415);
- "With stage 4 cancer and given only 6 months to live, Joe's dad was not doing well. . . . With 4 ounces of 7*Herb Formula per day, in just 2 days . . . the family watched dad's color come back . . . .

GDU to the rescue! . . . PSA 3.3, no pain, alive . . . ." ("Not too late!," CX 23 at FTC-DCO 0401; CX 24 at FTC-DCO 0417).

200. The Cancer Newsletter includes testimonials such as: "Texas businessman has true friends for life," which describes a bladder cancer sufferer who receives a package from friends that "included 7 Herb Formula, . . . BioShark and Bio*Mixx," (CX 23 at FTC-DCO 0400; CX 24 at FTC-DCO 0416); and "Tumor Free!," which describes a brain cancer sufferer who takes "7 HERB, BIO MIXX, BIO SHARK, and GDU Caps," and states, "the tumors were completely gone." (CX 23 at FTC-DCO 0404; CX 24 at FTC-DCO 0420) (emphasis in original).

201. At the bottom of one page in the Cancer Newsletter which includes a description of BioMixx and a testimonial to 7 Herb Formula, BioShark and BioMixx, is the statement, "Visit www.danielchapter one.com TODAY for access to your health questions!" (CX 23 at FTC-DCO 0400; CX 24 at FTC-DCO 0416).

202. The overall net impression from the Cancer Newsletter is that the Challenged Products, individually and/or in combination with one or more of the other Challenged Products, prevent, treat, or cure cancer. (F. 194-201; *see also* F. 182-85, 242 (testimonials)).

d. BioGuide

203. Another DCO publication is entitled "BioGuide: The BioMolecular Nutrition Guide to Natural Health 3" ("BioGuide"). Interspersed with the product descriptions in the BioGuide are testimonials, including testimonials asserting the successful use of one or more of the Challenged Products and/or other DCO products, for cancer. Other than product descriptions, this publication consists almost entirely of testimonials about DCO products. (CX 21).

204. In the BioGuide, on the page immediately following an advertisement for 7 Herb Formula, there is a picture of a smiling woman and the heading, in large, colored, and bold type, "**Cancer Brain Tumor**." Next to that entry is the colored, italicized text:

> ***The doctors had pretty much given up on Tracey. She had leukemia and tumors on the brain, behind the heart and on her liver.***

The testimonial continues in pertinent part:

> 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%. . . .

(CX 21 at FTC-DCO 0353 (emphasis in original); *see also* F. 184, 198 (same testimonial appears on DCO Website and in Cancer Newsletter)).

205. In the BioGuide, next to the testimonial entitled "Cancer Brain Tumor," is a testimonial with the heading, in large, colored, and bold type, "**Lowered PSA**," which states in part, "My GOOD NEWS is that my PSA went from 6.9 to 6.0 after I finished using my first four bottles of 7 Herb formula, in combination with your Bio C 1000, GDU and other minerals and vitamins. I believe it was your products that did the trick. . . ." (CX 21 at FTC-DCO 0353) (emphasis in original).

206. The BioGuide contains a testimonial with a heading, in large, colored, and bold type, "**Prostate Cancer**," adjacent to a picture of a smiling man, which states in pertinent part: "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 in original).

207. The BioGuide contains a testimonial with a heading, in large, colored, and bold type, "**Renal Cell Cancer**," next to a picture of a smiling man. The text states in pertinent part:

> I had Renal Cell Cancer in my left kidney, with a tumor attached that was slightly larger than a baseball. I went on 7 Herb Formula and GDU . . . . They had found 3 spots in my lungs, although very small, that are being watched. I continue to drink the 7-Herb, and take Bio-Shark, and GDU. I drink ENDO24 everyday because of the spots in my lungs and ribs. To date, my oncologist is amazed that no further activity has occurred. . . .

Then immediately underneath, the following excerpt is repeated in large, bold, green type:

> ***To date, my oncologist is amazed that no further activity has occurred.***

(CX 21 at FTC-DCO 0317) (emphasis in original).

208. The BioGuide contains a testimonial with a heading in large, colored, and bold type, "**Skin Cancer**," next to a picture of a smiling couple. The text states in pertinent part that natural products "seemed to stabilize the cancer in that it quit spreading and getting larger but none of it decreased in size. After switching to DC1 products – 7-Herb Formula, BioShark, GDU, Garlic Pur, Siberian Ginseng, Ezekiel Oil and BioMixx – it cleared up quickly." Below this text is a statement in large, bold, colored type:

> ***I had a thorough medical exam three weeks ago and was told I was completely clear of all types of cancer. The doctor didn't know how I got rid of it.***

(CX 21 at FTC-DCO 0357) (emphasis in original).

209. In the BioGuide, next to a large, bold print caption, "**DOCTORS**," Dr. Jonas and Marla Marry are quoted as stating: "My son was diagnosed with a tumor on his left temple. The tumor was extremely aggressive. . . . [A] friend suggested we speak to Jim and Trish. They suggested 7-Herb, BioShark and GDU, which we bought and started him on. . . . [I]n the time it took us to find a specialist who eventually told us he could not help either, the tumor had already begun to shrink. . . . Four months later the whole family is using the products, as well as my patients, and you would never know my son had a tumor." Next to the testimony are photographs of a happy-looking man and small children. (CX 21 at FTC-DCO 0313).

210. In the BioGuide, next to a large, bold print caption, "**NUTRITION CENTERS**," Don and Janice Feagin, described as proprietors of a Daniel Chapter One center called the "Herbal Gallery," are quoted as stating: "One lady, who had a history of cancer, used the 7 Herb Formula, GDU & BioShark and was

blessed to get rid of a large breast tumor." Next to these statements is a photograph of a smiling couple. (CX 21 at FTC-DCO 0315).

211. The overall net impression from the portions of BioGuide relating to the Challenged Products, described in F. 203-10, is that the Challenged Products, individually and/or in combination with one or more other Challenged Products, prevent, treat, or cure cancer.

e. The radio show

212. James and Patricia Feijo are not doctors. (R 16 (P. Feijo, Dep. at 114); P. Feijo, Tr. 404; J. Feijo, Tr. 416).

213. James and Patricia Feijo have given treatment advice to cancer patients who have called in to the radio program. (R 16 (P. Feijo, Dep. at 96-97); J. Feijo, HOJ Tr. 221-22; P. Feijo, Tr. 360-64). This treatment advice has involved advising individuals to obtain and take the Challenged Products. (F. 214, 216-17).

214. 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. [His] skin cleared up after a few months in the late 1980s [sic], early '99, [he] 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).

215. 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).

216. 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).

217. During the July 14, 2008 DCO HealthWatch radio program, Patricia Feijo advised an individual 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).

f. Summary

218. The DCO publications and their content referred to in F. 161, 163, 164, 168, 170, 179-88, 190, 192, 194-201, 203-10 are for the purpose of inducing, are likely to induce, and did induce, directly or indirectly, the purchase of the Challenged Products in interstate commerce. (F. 8-9, 80-81, 106, 159-78, 180, 221, 266).

219. The DCO advertising for the Challenged Products collectively, referred to in F. 179-88, 190, 192, 194-

201, and 203-10, makes claims that relate to consumer health. (F. 189, 191, 193, 202, 211).

2. BioShark

a. DCO Website

220. CX 12, a printout of the webpage for BioShark on the DCO Website, is Exhibit A to the Complaint. CX 12A is another depiction of the same product webpage as CX 12, but captured so as to show the entire width of the page. (CX 12; CX 12A).

221. The webpage content begins with a heading in bold type, "**Immune Boosters**." Underneath that heading is a picture of bottles of BioShark, and under that a phrase in small print, "shark cartilage Supplemental Facts." Immediately appearing under this small phrase is the following:

> **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. Should not be used by pregnant women, or immediately after heart surgery. Shark cartilage may also reduce the pain, inflammation, and joint stiffness of arthritis, alleviate inflammatory bowel disease, and reverse psoriasis. Shark cartilage is an excellent source of Calcium, Phosphorus, amino acids, and a family of carbohydrates called mucopholysaccharides (sulfated Oligosaccharides and Chondriotin Sulfates A and C).
>
> In summary, Bio*Shark works to reduce inflammation and swelling, affects the formation of new blood vessels and provides essential nutrients for healing.

> Warning: If you are pregnant, nursing a baby, recovering from recent surgery, or have a heart or circulatory condition, consult a health professional before using shark cartilage!

Adjacent to that text is a shopping cart icon with the instruction, "**BUY NOW!**" Immediately below that is the message: "Read our clients [sic] testimonials on BioShark & Tumors," and a link to a bulleted title "Cancerous Tumor." At the bottom of the webpage is a link to "Stop Tumor Growth & Cysts Top." (CX 12; CX 12A) (emphasis in original).

222. The words used to describe BioShark on the DCO Website product webpage, as set forth in F. 221 – "Pure skeletal tissue of sharks which provides a protein that inhibits angiogenesis - the formation of new blood vessels. This can stop tumor growth" – strongly imply that BioShark inhibits tumors.

223. An earlier version of the DCO Website stated "Bio*Shark Shark Cartilage Stops tumor growth in its tracks." (CX 18 at FTC-DCO 2032).

224. The overall net impression from the BioShark product webpage on the DCO Website is that BioShark inhibits the growth of tumors, including cancerous tumors. (F. 220-22).

225. The Cancer News webpage on the DCO Website includes the following statements under the heading, in bold type, **Bio*Shark ™**:

> In 1983, two researchers at the Massachusetts Institute of Technology published a study showing that shark cartilage contains a substance that significantly inhibits the development of blood vessels that nourish solid tumors, thereby limiting tumor growth. This effect is called anti-angiogenesis.

> Scientists recognize the benefits of starving a tumor to limit its growth. They have been looking for a drug to patent that can do the same thing as shark cartilage. They say the answer to curing cancer lies in preventing angiogenesis – the formation of blood vessels which feed the tumor. These scientists are trying to replicate what God has already presented to us so that they can claim rights to it, patent it and make a lot of money. But man can never lab synthesize a product and make it exactly the same – and all drugs have harmful side effects.
>
> Researchers have also demonstrated that shark cartilage can reduce the inflammation and pain associated with arthritis, alleviate psoriasis and have a positive effect on other degenerative diseases.

(CX 13 at FTC-DCO 0023) (emphasis in original).

226. The DCO webpage, "Cancer News," which makes representations regarding the Challenged Products as a group (F. 180-88) states: "If you suffer from any type of cancer, Daniel Chapter One suggests" taking several DCO products, including BioShark. Following the text is a prominent picture of a bottle of BioShark, adjacent to which, is a statement in bold type, "**Daniel Chapter One's Cancer solutions**." Under the picture, the text states:

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

(CX 13 at FTC-DCO 0013-0014; CX 13A) (emphasis in original).

227. The overall net impression from the information on the Cancer News webpage on the DCO Website set forth in F. 225-26 is that BioShark is effective in the

treatment or cure of cancer, including cancerous tumors. *See also* F. 189.

b. BioGuide

228. The BioGuide includes the following product description for BioShark:

> Pure skeletal tissue of sharks which provides a protein that inhibits angiogenesis – the formation of new blood vessels. This can stop tumor growth, and halt the progression of eye diseases such as diabetic retinopathy and macular degeneration. Should not be used by pregnant women, or immediately after heart surgery. Shark cartilage may also reduce the pain, inflammation, and joint stiffness of arthritis, alleviate inflammatory bowel disease, and reverse psoriasis. Shark cartilage is an excellent source of Calcium, Phosphorus, amino acids, and a family of carbohydrates called mucopholysaccharides (sulfated Oligosaccharides and Chondriotin Sulfates A and C).
>
> *In summary, Bio*Shark works to reduce inflammation and swelling, affects the formation of new blood vessels and provides essential nutrients for healing.*
>
> *Warning: If you are pregnant, nursing a baby, recovering from recent surgery, or have a heart or circulatory condition, consult a health professional before using this product.*

(CX 21 at FTC-DCO 0322) (emphasis in original).

229. The words used to describe BioShark in the BioGuide, as set forth in F. 228 – "Pure skeletal tissue of sharks which provides a protein that inhibits angiogenesis – the formation of new blood vessels. This can stop tumor growth . . ." – strongly imply that BioShark inhibits tumors.

230. The overall net impression of the portions of the BioGuide regarding BioShark is that BioShark inhibits tumor growth, and is effective in the prevention, treatment, or cure of cancer. (F. 204, 207-11. 228-29).

c. Cancer Newsletter

231. The Cancer Newsletter includes a page on BioShark. Adjacent to testimonials with headlines in large, bold, and highlighted type, "**Doctors gave up on Michigan Man**," and "**Pre-Cancerous Growths & Acid and Heartburn**," the following product information about BioShark appears:

> In 1983, two researchers at the Massachusetts Institute of Technology published a study showing that shark cartilage contains a substance that significantly inhibits the development of blood vessels that nourish solid tumors, thereby limiting tumor growth. This effect is called anti-angiogenesis.
>
> Scientists recognize the benefits of starving a tumor to limit its growth. They have been looking for a drug to patent that can do the same thing as shark cartilage. They say the answer to curing cancer lies in preventing angiogenesis – the formation of blood vessels which feed the tumor. These scientists are trying to replicate what God has already presented to us so that they can claim rights to it, patent it and make a lot of money. But man can never lab synthesize a product and make it exactly the same –and all drugs have harmful side effects.
>
> Researchers have also demonstrated that shark cartilage can reduce the inflammation and pain associated with arthritis, alleviate psoriasis and have a positive effect on other degenerative diseases.

(CX 23 at FTC-DCO 0397; CX 24 at FTC-DCO 0413) (emphasis in original).

232. The overall net impression from the Cancer Newsletter is that BioShark is effective in the treatment or cure of cancer. (F. 195, 197, 200-02, 231).

d. BioMolecular Nutrition Product Catalog

233. The BioMolecular Nutrition Product Catalog states the following regarding BioShark: "Shark Cartilage protein inhibits angiogenesis, stops tumor growth, and halts eye diseases. Reduces pain, inflammation, joint stiffness of arthritis, inflammatory bowel disease, and reverses psoriasis. Affects the formation of new blood vessels." (CX 17 at FTC-DCO 0061).

234. The phrase, "stops tumor growth," in the BioMolecular Nutrition Product Catalog description for BioShark, and set forth in F. 233, expressly claims that BioShark inhibits tumors. (F. 233).

235. The overall net impression from the portion of the BioMolecular Nutrition Product Catalog relating to BioShark, described in F. 233, is that BioShark inhibits tumor growth.

236. The DCO advertising regarding BioShark referred to in F. 221, 225-26, 228, 231, and 233 makes claims that relate to consumer health. (F. 222, 224, 227, 229-30, 232, 234-35).

3. 7 Herb Formula

a. DCO Website

237. The 7 Herb Formula webpage on the DCO Website shows a heading of "Herbs." Underneath that heading, there is a picture of 7 Herb Formula bottles and a close-up of the front of the label. Under the picture is

the small print phrase "Supplemental Facts" and a product description, which includes the following:

> **7 Herb Formula: Detoxify, Acid Reflux & Cancer Help**
>
> 7 Herb Formula with Cat's Claw & Siberian Ginseng: Herbs to purify the blood and promote cell repair. The ingredients in this tea concentrate work to clear skin, cleanse the liver, decrease cell mutation, and fight pathogenic bacteria and tumor formation. Also helps regulate blood sugar, heal ulcers, and stop indigestion and heartburn.

(CX 13 at FTC-DCO 0025; CX 13A at FTC-DCO 2840A) (emphasis in original).

238. The DCO product 7 Herb Formula is featured first on the webpage for Cancer News on the DCO Website. The webpage includes a large picture of bottles of 7 Herb Formula and the following statements:

> **7 Herb Formula**
>
> - purifies the blood
> - promotes cell repair
> - **fights tumor formation**
> - fights pathogenic bacteria
>
> to learn more click here
> to buy click here

(CX 13 at FTC-DCO 0013; CX 13A at FTC-DCO 2828A) (emphasis in original).

239. Statements in the product description for 7 Herb Formula on the DCO Website Cancer News webpage that 7 Herb Formula "fights tumor formation" and "decrease[s] cell mutation," as set forth in F. 237-38, clearly imply that 7 Herb Formula inhibits tumors and treats cancer.

240. The DCO webpage, "Cancer News," which makes representations regarding the Challenged Products as a group (F. 180-88) states: "If you suffer from any type of cancer, Daniel Chapter One suggests taking" several DCO products, including 7 Herb Formula ™. Following the text is a prominent picture of a bottle of 7 Herb Formula, adjacent to which is the statement in bold type, "**Daniel Chapter One's Cancer solutions**." Under the picture, the text states:

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

(CX 13 at FTC-DCO 0013-14; CX 13A) (emphasis in original).

241. Adjacent to the 7 Herb Formula picture and text on the Cancer News webpage on the DCO Website are links to the Cancer Newsletter and to "**Page shortcuts to testimonials about cancer**," with titles such as "7 Herb Formula battles cancer" and "7 Herb eliminates pre-cancerous growth." (CX 13 at FTC-DCO 0013; CX 13A at FTC-DCO 2828A) (emphasis in original).

242. Many of the testimonials on the Cancer News webpage are devoted to 7 Herb Formula. For example, a testimonial with the headline "**7 Herb eliminates pre-cancerous growth**" states in part, "I had a pre-cancerous 'wart' on the back of my leg and drinking 7 Herb Formula made it go away." (CX 13 at FTC-DCO 0017) (emphasis in original). The testimonial section also includes a passage entitled "**Ancient cancer remedy is improved upon**," which states in part: "In addition to his sports nutrition line, Jim has developed a line of health supplements and natural remedies. One of the products Jim Feijo is especially proud of is his 7 Herb Formula. . . . Jim improved upon the ancient Ojibway Indian Tribe remedy known as Essiac. . . . As a result of his research, Jim found that by adding Siberian Ginseng and Cat's Claw to the

Essiac formula, he could attain remarkable healing results. . . . 'We feel blessed that God has revealed this formula to us and that we have been able to provide those in need of help an alternative to chemotherapy and radiation,' Jim Feijo said." (CX 13 at FTC-DCO 0019-20 (emphasis in original); *see also* F. 184, 185, 187 (7 Herb Formula testimonials)).

243. A testimonial on the Cancer News webpage with the headline "**Doctors gave up on Michigan man**" tells the story of a caller to the Daniel Chapter One HealthWatch radio program who reportedly suffered from cancer. It describes how the man's brother-in-law heard "Jim and Tricia Feijo talk about the success of 7 Herb Formula in helping people with cancer" on the radio show. Thereafter, according to the testimonial, the man took 7 Herb Formula and experienced "massive tumor shrinkage." (CX 13 at FTC-DCO 0022-23) (emphasis in original).

244. On the DCO Website, in the question and answer section regarding 7 Herb Formula, the response to the statement, "I want the ORIGINAL ESSIAC formula, not some knock off brand," includes the statement: "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 30 at FTC-DCO 0493) (emphasis in original).

245. The overall net impression from the DCO Website advertising for 7 Herb Formula is that 7 Herb Formula inhibits tumors and is effective in the prevention, treatment, or cure of cancer. (F. 180, 182, 184-85, 187, 189, 237-38, 240-44).

b. dc1pages.com website

246. On the website www.dc1pages.com, in the question and answer section regarding 7 Herb Formula, the response to the statement, "I want the ORIGINAL ESSIAC formula, not some knock off brand," includes

the statement: "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 0140-42).

247. On the website www.dc1pages.com, in the question and answer section regarding 7 Herb Formula, the response to the statement, "I use Brand X," includes the statement: "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).

248. The overall net impression from the www.dc1pages.com content relating to 7 Herb Formula is that 7 Herb Formula inhibits tumors and is effective in treatment of cancer. (F. 190-91, 246-47).

c. BioGuide

249. Three pages in the BioGuide are specifically devoted to promoting 7 Herb Formula. (CX 21 at FTC-DCO 0352-54). Two of those pages contain the following description: "7 Herb Formula with Cat's Claw & Siberian Ginseng: Herbs to purify the blood and promote cell repair. The ingredients in this tea concentrate work to clear skin, cleanse the liver, decrease cell mutation, and fight pathogenic bacteria and tumor formation. Also helps regulate blood sugar, heal ulcers, and stop indigestion and heartburn." (CX 21 at FTC-DCO 0352, 0354). In between these two pages is a page devoted to two testimonials, "**Cancer Brain Tumor**" and "**Lowered PSA**." (CX 21 at FTC-DCO 0353).

250. The overall net impression from the portions of the BioGuide relating to 7 Herb Formula is that 7 Herb Formula inhibits tumors and is effective in the prevention, treatment, or cure of cancer. (F. 204-11, 249).

d. Cancer Newsletter

251. The Cancer Newsletter includes a page specifically devoted to advertising 7 Herb Formula. That page prominently features the 7 Herb Formula name and logo. The text includes the statements: "**How does it work?** Daniel Chapter One's 7 Herb Formula has been created to purify the blood and to promote cell repair. It fights pathogenic bacteria and tumor formation. The ingredients . . . cleanse the liver and decrease cell mutation." (CX 23 at FTC-DCO 0402; CX 24 at FTC-DCO 0418).

252. The page immediately following the 7 Herb Formula product description set forth in F. 251 displays a heading in large, highlighted and bold type:

Heartburn?
Acid Reflux?
Esophageal Cancer?

Immediately below that heading is italicized text which includes the statement: "The herbs in 7*Herb Formula . . . improve digestion, gall bladder, and bowel function, cleanse and detoxify the body, heal ulcers anywhere, and may prevent and even heal cancer. Be in control, don't be a victim!" (CX 23 at FTC-DCO 0403; CX 24 at FTC-DCO 0419) (emphasis in original).

253. The Cancer Newsletter contains testimonials specifically referring to 7 Herb Formula. The headings for these testimonials are each in highlighted, large, bold type and include the following: "**7 Herb Formula battles cancer**" (CX 23 at FTC-DCO 0393; CX 24 at FTC-DCO 0409; *see* F. 184) (emphasis in original); "**7 Herb eliminates pre-cancerous growth**" (CX 23 at FTC-DCO 0394; CX 24 at FTC-DCO 0410) (emphasis in original); and "**7 Herb Formula helps battle cancer**" (CX 23 at FTC-DCO 0398; CX 24 at FTC-DCO 0414, describing a single father diagnosed

with a prostate tumor who "began taking the 7 Herb and shark cartilage. . . . Within 60 days, . . . PSA level dropped from 256 to 5. . . . [Thereafter, n]o evidence of . . . tumor.") (emphasis in original).

254. The logo for 7 Herb Formula is the only product logo featured in the Cancer Newsletter. In addition to appearing on the 7 Herb Formula product page, the logo appears on the last page of the Cancer Newsletter, under the reminder, "REMEMBER! How to fight cancer is your choice!" (CX 23 at FTC-DCO 0405; CX 24 at FTC-DCO 0421).

255. The overall net impression from the Cancer Newsletter is that 7 Herb Formula inhibits tumors and is effective in the prevention, treatment, or cure of cancer. (F. 195, 197-202, 251-54).

e. BioMolecular Nutrition Product Catalog

256. In DCO's BioMolecular Nutrition Product Catalog, the text next to pictures of the 7 Herb Formula bottle states that the herbs in 7 Herb Formula "purify the blood and promote cell repair, clear skin, cleanse the liver, decrease cell mutation, [and] fight pathogenic bacteria and tumor formation." (CX 17 at FTC-DCO 0061).

257. The phrase, "fight . . . tumor formation," used in the product description for 7 Herb Formula in the BioMolecular Nutrition Product Catalog, as set forth in F. 256, strongly implies that the 7 Herb Formula inhibits tumor formation. Combined with the additional phrases in the description, "promote cell repair," "decrease cell mutation," and "fight pathogenic bacteria," the words of the product description as a whole imply that 7 Herb Formula is effective in treating cancer.

258. The overall net impression from the portion of the BioMolecular Nutrition Product Catalog relating to 7 Herb Formula is that 7 Herb Formula inhibits tumors

and is effective in the prevention, treatment, or cure of cancer. (F. 256-57).

259. The DCO advertising regarding 7 Herb Formula, referred to in F. 237-38, 240-44, 246-47, 249, 251-54, and 256, makes claims that relate to consumer health. (F. 239, 245, 248, 250, 255, 257-58).

f. Radio Show

260. During the July 8, 2008 DCO HealthWatch radio program, in response to a caller's concern about colon cancer and question about whether the caller should follow her doctor's recommendation of a colonoscopy, James Feijo stated, "Polyps are nothing. . . . Polyps should be left alone." In addition, in response to the caller's question about taking 7 Herb Formula, Patricia Feijo stated "It's a good idea for anyone to take a little bit every day, you know, as a preventive, sure." (CX 5 at FTC-DCO 0562-66).

261. 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).

4. GDU

a. DCO Website

262. CX 14, a printout of the webpage for GDU on the DCO Website, is Exhibit C to the Complaint. CX 14A is another depiction of the same product webpage as CX 14, but captured so as to show the entire width of the page. (CX 14; CX 14A).

263. The webpage content for GDU on the DCO Website begins with a heading, in bold type, "**Immune Boosters**." Underneath that heading is a picture of bottles of GDU, and under that, is a phrase, in small print, "Supplemental Facts." The product description that follows includes the heading in bold type, "**GDU -**

Arthritis Pain Anti Inflammatory" and opens with the following paragraph:

> 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.

(CX 14 at FTC-DCO 0028; CX 14A at FTC-DCO 2844A). James and Patricia Feijo both took credit for writing this statement. (R 15 (J. Feijo, Dep. at 138-39); R 16 (P. Feijo, Dep. at 185-86)). Following this statement are several paragraphs describing the ingredients of GDU and its "wide range of actions . . . that make it suited to a wide range of uses." Among these promoted uses is "as an adjunct to cancer therapy." (CX 14 at FTC-DCO 0028).

264. The description of GDU on the product webpage on the DCO Website, as set forth in F. 263, implies that GDU inhibits tumors and is a cancer treatment.

265. At the side of the GDU product webpage is a link to "buy now." Below that, is the instruction: "Read our clients [sic] testimonials on using this anti inflammatory," and links to subjects including arthritis, injuries, and spinal stenosis. Also included are links to "Breast Mass" and "Prostate Cancer." (CX 14A).

266. The DCO webpage "Cancer News," which makes representations regarding the Challenged Products as a group (F. 180-88), states: "If you suffer from any type of cancer, Daniel Chapter One suggests taking" several DCO products, including GDU. A prominent picture of a bottle of GDU follows, adjacent to which is the statement in bold type, "**Daniel Chapter One's Cancer solutions**." Under the picture, the text states:

To Buy the products click here

How to fight cancer is your choice!

(CX 13 at FTC-DCO 0013-14; CX 13A) (emphasis in original).

267. A testimonial entitled "Breast Mass," linked to the Cancer News webpage on the DCO Website, states:

> 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. Around that time I got another bottle of GDU and the Superior Herbal Fat Burners, which I took twice a day. In April I had my 6-month examination and the letter read: "We are pleased to inform you that the results of your recent breast evaluation are normal."

(CX 13 at FTC-DCO 0024; *see also* CX 17 at FTC-DCO 0101 (same)).

268. There are testimonials linked to the Cancer News webpage that specifically refer to GDU, including: "Nancy – Cured Breast Cancer in 3 months - 7 Herb and GDU"; and "Mel – Breast Mass [illegible] and GDU." (CX 13 at FTC-DCO 0014).

269. The overall net impression of the DCO Website content relating to GDU is that GDU inhibits tumors and is an effective treatment for cancer. (F. 180, 187, 189, 262-63, 265-68).

b. BioGuide

270. The product pages devoted to GDU in DCO's BioGuide begin with the following statement: "**GDU:** Contains natural proteolytic enzymes (from pineapple source bromelain) to help digest protein - even that of unwanted tumors and cysts." (CX 21 at FTC-DCO 0329) (emphasis in original). This same statement is repeated on the following page. (CX 21 at FTC-DCO 0330).

271. On the first page devoted to GDU in the BioGuide is a paragraph describing a variety of uses for GDU, which include "as an adjunct to cancer therapy." Immediately below this section is text in large, colored type, "**to help digest protein even that of unwanted tumors and cysts. This formula also helps to relieve pain and heal inflammation**." Immediately below this statement is a headline in large, bold, colored type, "**Prostate Cancer**," along with a picture of a smiling man. (CX 21 at FTC-DCO 0330) (emphasis in original). On the following page is a headline in large, bold, colored type, "**Breast Mass**," adjacent to a photograph of a smiling woman. (CX 21 at FTC-DCO 0331) (emphasis in original).

272. The description of GDU in the BioGuide implies that GDU inhibits tumors. (F. 270-71).

273. The testimonial in the BioGuide entitled "Breast Mass" includes the following text:

> 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. Around that time I got another bottle of GDU and the Superior Herbal Fat Burners, which I

> took twice a day. In April I had my 6-month examination and the letter read: "We are pleased to inform you that the results of your recent breast evaluation are normal."

At the conclusion of the testimonial, the following excerpt appears in large, bold, green type:

> ***'We are pleased to inform you that the results of your recent breast evaluation are normal.'***

(CX 21 at FTC-DCO 0331) (emphasis in original).

274. In DCO's BioGuide there is a testimonial under a headline in large, bold, bright green type, "**Lowered PSA**." The testimonial states in pertinent part: "My GOOD NEWS is that my PSA went from 6.9 to 6.0 after I finished using my first four bottles of 7 Herb formula, in combination with your Bio C 1000, GDU and other minerals and vitamins. I believe it was your products that did the trick. . . ." (CX 21 at FTC-DCO 0353) (emphasis in original).

275. The overall net impression from the portions of the BioGuide relating to GDU is that GDU inhibits tumors and is an effective treatment for cancer. (F. 205, 207-11, 270-74).

c. Cancer Newsletter

276. The Cancer Newsletter includes a feature on GDU, with a picture of a GDU bottle next to a headline in large, bold type, "**Enzymes attack growths**." The opening paragraph states:

> Daniel Chapter One GDU Caps contains [sic] proteolytic enzymes that metabolize protein and can aid the body in breaking down a tumor. **The importance of oral enzymes in treating cancers has been the subject of scholarly papers and**

> **books for almost a century. . . . Enzymes, according to researchers, can change leukemia cells, returning those cells to a normal state. Enzymes have been shown to induce T cells and tumor necrosis factor.** The enzymes, while helping to destroy cancer cells, are not toxic, unlike other forms of treatment currently being imposed on cancer patients. . . . Daniel Chapter One GDU Caps contains [sic] proteolytic enzymes that God created to break up an excess protein mass and can aid the body in eliminating a tumor."

(CX 23 at FTC-DCO 0399; CX 24 at FTC-DCO 0415) (emphasis in original).

Adjacent to the GDU headline, photograph, and text are two testimonials with headlines in large, highlighted and bold type, "**Lump is gone without dangerous surgery**" and "**Cancer Success a Lie!**" (CX 23 at FTC-DCO 0399; CX 24 at FTC-DCO 0415) (emphasis in original).

277. The phrases "treating cancer," returning leukemia cells "to a normal state," and "helping to destroy cancer cells," in the product description for GDU in the Cancer Newsletter, as set forth in F. 276, imply that GDU treats cancer.

278. The overall net impression from the Cancer Newsletter is that GDU inhibits tumors and is an effective treatment for cancer. (F. 195, 197, 199-200, 202).

d. BioMolecular Nutrition Product Catalog

279. DCO's BioMolecular Nutrition Product Catalog states, next to pictures of GDU bottles, 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).

280. The language of the product description for GDU in the BioMolecular Nutrition Product Catalog, as set forth in F. 279 implies, that GDU inhibits tumors and is an effective treatment for cancer.

281. The overall net impression from the portion of the BioMolecular Nutrition Product Catalog relating to GDU is that GDU inhibits tumors and is an effective treatment for cancer. (F. 279).

282. The DCO advertising regarding GDU, referred to in F. 262-63, 265-68, 270-71, 273-74, 276, and 279, makes claims that relate to consumer health. (F. 264, 269, 272, 275, 277-78, 280-81).

5. BioMixx

a. Website advertising

283. The www.danielchapterone.com webpage, "Cancer News," which makes representations regarding the Challenged Products as a group (F. 180-88) states: "If you suffer from any type of cancer, Daniel Chapter One suggests taking" several DCO products, including BioMixx ™. A prominent picture of a bottle of BioMixx follows, adjacent to which is a statement in bold type, "**Daniel Chapter One's Cancer solutions**." Under the picture, the text states:

To Buy the products click here

How to fight cancer is your choice!

(CX 13 at FTC-DCO 0013-14; CX 13A) (emphasis in original).

284. The www.danielchapterone.com Cancer News webpage includes the following testimonial, accompanied by a photograph of a smiling woman:

> *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.
> . . . .
>
> 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 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%. . . .

(CX 13 at FTC-DCO 0016) (emphasis in original).

285. BioMixx is promoted along with the other Challenged Products on the DCO website www.dc1pages.com, where the following text appears:

> **Supporting Products**
>
> To enhance 7 Herb Formula's healing quantities Daniel Chapter One advises to get familiar with the supporting products below:

Immediately below that text is a photograph of bottles of each of the Challenged Products. Adjacent to the photograph, in bold print, the following appears:

> **CANCER**
> **TREATMENT**:
>
> **7Herb Formula**
> **Bio*Shark**

BioMixx
GDU Caps

(CX 18 at FTC-DCO 0190) (emphasis in original).

286. The overall net impression from the website content for BioMixx described in F. 283-85 is that BioMixx is effective in the prevention, treatment, or cure of cancer.

b. BioGuide

287. The product description for BioMixx in DCO's BioGuide includes the statements:

> Helps detoxify the body, boosts immunity and energy. . .. 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. BioMixx . . . is the most powerful, most advanced formula ever developed for strengthening and building the immune system. . . . This scientifically designed formula provides your body with . . . nutrients . . . for cell, organ, and tissue health necessary for a healthy immune system. Whether you're losing weight battling illness, or are weakened due to intense training, BioMixx is the best.

(CX 21 at FTC-DCO 0334).

288. The language of the product description for BioMixx in DCO's BioGuide, as set forth in F. 287, clearly implies that BioMixx is an effective treatment for the adverse effects of chemotherapy and radiation.

289. DCO's BioGuide refers to BioMixx in the testimonial entitled "**Cancer Brain Tumor**." (F. 204; *see* CX 21 at FTC-DCO 0353 (emphasis in original)).

290. DCO's BioGuide refers to BioMixx in the testimonial entitled "**Prostate Cancer**." This headline, in large, bold type appears next to a picture of a smiling man. The testimonial states in pertinent part: "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!" (CX 21 at FTC-DCO 0330) (emphasis in original).

291. The overall net impression from the portions of the BioGuide relating to BioMixx is that BioMixx is effective in the treatment of cancer and that BioMixx heals the adverse effects of radiation and chemotherapy. (F. 204, 208, 211, 297-90).

c. Cancer Newsletter

292. The Cancer Newsletter refers to BioMixx in the testimonial "7 Herb Formula Battles Cancer." This testimonial states in part: "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. Then I added Garlic, Siberian Ginseng, and Bio*Shark. I am now in complete remission." (CX 23 at FTC-DCO 0393; CX 24 at FTC-DCO 0409).

293. The Cancer Newsletter includes the following statements in the product description of BioMixx: "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." (CX 23 at FTC-DCO 0400; CX 24 at FTC-DCO 0416).

294. The overall net impression from the Cancer Newsletter is that BioMixx is effective in the treatment of cancer

and that BioMixx heals the adverse effects of radiation and chemotherapy. (F. 195, 197, 200, 202, 292-93).

295. The DCO advertising regarding BioMixx, referred to in F. 283-85, 287, 289-90, and 292-93, makes claims that relate to consumer health. (F. 286, 288, 291, 294).

6. Disclaimers

296. On the DCO Website, at the very end of the content, at the bottom of the webpage, a copyright notice appears. Within the notice, after the copyright language, the following language appears:

> The information on this website is intended to provide information, record, and testimony about God and His Creation. It is not intended to diagnose a disease. The information provided on this site is designed to support, not replace, the relationship that exists between a patient/site visitor and his/her health care provider. Caution: some herbs or . . . supplements should not be mixed with certain medications.

The above quoted statement appears in type font that is significantly smaller than the type font used for other content on the DCO Website. (CX 12 at FTC-DCO 0012; CX 13 at FTC-DCO 0027; CX 14 at FTC-DCO 0030).

297. At the bottom of the "checkout" page, located at www.dc1store.com, to which individuals are directed for purchasing a DCO product, there appears a copyright notice. Within the notice, after the copyright language, the following language appears:

> The information on this website is intended to provide information, record, and testimony about God and His Creation. It is not intended to diagnose a disease. The information provided on this site is designed to support, not replace, the

> relationship that exists between a patient/site visitor and his/her health care provider. Caution: some herbs or . . . supplements should not be mixed with certain medications.

The above quoted statement appears in type font that is approximately the same size as the type font used for most of the other content on the checkout page. (CX 11 at FTC-DCO 0712-0713).

298. At the end of the BioGuide, before the index, in the lower right hand corner is a bordered text box. Inside the box, after a notice of copyright paragraph, the next paragraph states:

> This catalog is intended to provide information, record, and testimony about Y'shua and His Creation. It is not intended to diagnose or treat disease. Caution: some herbs should not be mixed with certain medications.

The above quoted statement appears in type font that is significantly smaller than the type font used for most other content in the BioGuide. (CX 21 at FTC-DCO 0377).

299. At the bottom of the last page of the Cancer Newsletter, in the lower right hand corner, there is a copyright notice paragraph, and thereafter, the following text:

> The information on this website is intended to provide information, record, and testimony about God and His Creation. It is not intended to diagnose or treat disease. Caution: some herbs or supplements should not be mixed with certain medications.

The above quoted statement appears in type font that is tiny in relation to the type font used for other content

in the Cancer Newsletter, and is nearly illegible. (CX 23 at FTC-DCO 0405; CX 24 at FTC-DCO 0421).

300. At the bottom of certain webpages from www.dc1pages.com, at the very end of the web content, a copyright notice appears. Within the notice, after the copyright language, there is the following language:

> The information on this website is intended to provide information, record, and testimony about Y'shua and His Creation. It is not intended to diagnose or treat disease. The information provided on this site is designed to support, not replace, the relationship that exists between a patient/site visitor and his/her health care provider. Caution: some herbs . . . should not be mixed with certain medications.

The above quoted statement appears in type font that is significantly smaller than the type font used for other content on www.dc1pages.com. (CX 18 at FTC-DCO 0133, 0189; *see also* CX 30 at FTC-DCO 0496).

301. Some product ordering pages on the website www.dc1store.com contain the following language in italicized type:

> **These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent disease.*

The above quoted statement appears in type font that is approximately the same size as the type font used for other content on the product pages. (CX 17 at FTC-DCO 0073, 0076, 0080, 0084, 0089, 0095, 0098).

302. "The Most Simple Guide" contains no language disclaiming any intent to diagnose or treat disease. (CX 20).

303. Where disclaimer language does appear in the websites, BioGuide, and Cancer Newsletter, it appears in a font size that is equal to or significantly smaller than that used for other written material. (F. 297-299, 301-02). In the Cancer Newsletter, "How to fight Cancer is Your Choice!!!" the quoted disclaimer language is infinitesimal in relation to the other written material. (F. 300).

304. In the pages from the website www.dc1pages.com (CX 18 at FTC-DCO 0133, 0189), the sentence purporting to disclaim any intent to "treat" disease was followed on the next page by a statement touting, in far larger type font:

> **CANCER TREATMENT**
>
> **7 Herb Formula**
> **Bio*Shark**
> **BioMixx**
> **GDU Caps**

(CX 18 at FTC-DCO 0190).

305. The purported disclaimers are ambiguous and inconspicuous in relation to other messages conveyed by the advertisements. (F. 296-301, 303-04).

306. The purported disclaimers do not alter the overall net impression from the advertisements that the Challenged Products prevent, treat, or cure cancer. (F. 296-301, 303-04).

F. Substantiation for DCO's Advertising Claims

1. Testing of the Challenged Products

307. Respondents represented that they possessed and relied upon a reasonable basis that substantiated the DCO advertising claims at the time they were made. (Answer ¶ 15).

308. Respondents did not conduct or direct others to conduct any scientific testing of the effects of the Challenged Products. Respondents are not aware of any such testing having been performed by others. (CX 39 (Respondents' Answer to Interrogatory 15); R 16 (P. Feijo, Dep. at 161); R 15 (J. Feijo, Dep. at 201-02); P. Feijo, Tr. 405).

309. Respondents conducted no scientific testing on BioShark. (P. Feijo, Tr. 405; R 16 (P. Feijo, Dep. at 161)).

310. Universal Nutrition, the manufacturer of BioShark, did not conduct any testing on BioShark. (R 17 (Bauhoffer-Kinney, Dep. at 45-46)).

311. Respondents never had an outside lab study the components of 7 Herb Formula to determine its effects. (R 16 (P. Feijo, Dep. at 132)).

312. GDU was never subjected to clinical trials and Respondents have not conducted any studies to see whether GDU would counteract with any conventional cancer medicine someone might also be taking. (R 16 (P. Feijo, Dep. at 190, 194)).

313. Respondents did not conduct any tests or clinical studies on BioMixx and did not engage anybody else to do any kind of clinical tests on BioMixx. (R 16 (P. Feijo, Dep. at 199)).

314. Universal Nutrition, the manufacturer of BioMixx, has not conducted any testing on BioMixx. (R 17 (Bauhoffer-Kinney, Dep. at 50)).

315. It was not Respondents' practice to obtain scientific studies about any of the components in their products. (R 16 (P. Feijo, Dep. at 120)).

316. Respondents' basis for making their claims about the Challenged Products includes personal observations

and customer testimonials. (R 15 (J. Feijo, Dep. at 141); R 16 (P. Feijo, Dep. at 116, 132, 186-87, 199)).

317. Respondents' substantiation for their claims regarding BioShark includes an article by I. W. Lane entitled "Sharks Don't Get Cancer." (R 16 (P. Feijo, Dep. at 161-62)).

318. Respondents relied upon a variety of materials, books, magazines, and articles, which James and Patricia Feijo had read, which provided them with an understanding of how certain substances in the Challenged Products could be utilized to help healing. (R 15 (J. Feijo, Dep. at 176-86); P. Feijo, Tr. 605-08; R 10).

319. The reference materials relied upon by Respondents do not constitute adequate substantiation for a claim that any of the Challenged Products prevent, treat, or cure cancer. (F. 326, 328, 343-49, 362, 365-67, 368-69, 372, 376, 383).

2. Summary of proffered experts' testimony on substantiation

a. Complaint Counsel's proffered expert

(1) Qualifications

320. Dr. Denis Miller ("Miller"), who was called to testify as an expert for Complaint Counsel, is a board-certified pediatric hematologist/oncologist. (Miller, Tr. 29; Expert Report of Denis R. Miller, M.D., dated Jan. 28, 2009, (hereinafter referred to as CX 52 (Miller Report) at 1).

321. For over forty years, 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 (Miller Report) at 1).

322. Miller also has served as Associate Medical Director of Cancer Treatment Centers of America ("CTCA") and as Scientific Director of CTCA's Cancer Treatment Research Foundations. (CX 52 (Miller Report) at 1).

323. As Scientific Director, 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 (Miller Report) at 1-2).

324. 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 (Miller Report) at 3).

325. 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 (Miller Report) at 2).

326. Based on his training, experience, and familiarity with this area of research, Miller is qualified to give expert opinions in the area of cancer, cancer research, and research methodology. (F. 320-25).

(2) Scope of work and materials considered

327. Miller was asked to determine whether there is competent and reliable scientific evidence to substantiate the following claims: BioShark inhibits tumor growth; BioShark 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 BioMixx heals the destructive effects of radiation and chemotherapy. (CX 52 (Miller Report) at 4).

328. To form his opinions, in addition to drawing upon his expertise in cancer care and treatment, Miller conducted literature searches, including searches in PubMed, Google, PDQ, NCI, MSKCC, MD Anderson Cancer Center, Dana Farber Cancer Institute, Search Medica, Stanford HighWire, Clinical Trials.gov, and many cancer and hematology journals such as the Journal of Clinical Oncology, Clinical Cancer Research, Blood, British Journal of Haematology, Supportive Care in Oncology, American Journal of Oncology, and the New England Journal of Medicine. Miller also reviewed materials provided by Complaint Counsel, including the Complaint and the DCO advertising attached to the Complaint as exhibits A through D, DCO advertising on www.danielchapter one.com, the BioGuide, the labels for the Challenged Products, and thirty testimonials regarding DCO products. Miller also reviewed the materials Respondents stated that they relied upon for substantiation. (CX 52 (Miller Report) at 5-7).

b. Respondents' proffered experts

(1) Qualifications

329. Respondents proffered five individuals as expert witnesses: James Duke, Ph.D.; Sally LaMont, N.D.; Rustum Roy; James Dews; and Jay Lehr, Ph.D.

330. Dr. Duke ("Duke") is a retired economic botanist. He has compiled and maintains a database, which includes the chemical composition ("phytochemicals") of approximately 3,000 species of herbs, and codes the nature and extent of published data indicating biological actions for those chemicals. The data

ranges from folklore, to animal or in vitro evidence, to approval of the chemical for those biological actions by foreign bodies referred to as Commission E or the Tramil Commission. (Duke, Tr. 476-78; R 18 (Duke, Dep. at 59, 91, 93, 118-19)).

331. Dr. LaMont ("LaMont") is a licensed naturopathic doctor and acupuncturist. Naturopathic doctors focus on primary prevention of illness and on stimulating the body's innate healing capacities to treat the underlying causes of disease. Naturopathic doctors, including LaMont, commonly use herbs in their practice. (LaMont Tr. 539, 541-42). LaMont also works with mind-body therapies and regularly suggests meditation, qigong, yoga, and other biofeedback-type of therapies that would strengthen the connection between a person's mind and immune system. (R 22 (LaMont, Dep. at 20)).

332. Rustum Roy ("Roy") is a scientist and an educator in the physical sciences and in integrative medicine. (Expert Report of Rustum Roy, dated Feb. 4, 2009 (hereinafter referred to as R 5 (Roy Report) at 2).

333. James Dews ("Dews") is a manufacturer of pharmaceuticals and "nutraceuticals," which Dews described as a merger of food supplements and pharmaceuticals. A nutraceutical can be created by extracting the chemical compounds from a food supplement. He helped create and manufacture the product that eventually became 7 Herb Formula. (R 19 (Dews, Dep. at 17-18, 34-36, 76)).

334. Jay Lehr ("Lehr") is a Ph.D. environmental scientist and has written a book on health and fitness. (R 21 (Lehr, Dep. at 9-10)). Lehr has known James Feijo for approximately ten years and takes the Daniel Chapter One products PrePost, Endeurosine, and Mito/ATP to enhance his athletic performance. He has also recently begun taking GDU for his arthritic hip. (R 21 (Lehr, Dep. at 16-18)).

335. None of Respondents' proffered experts is a medical doctor. (F. 329-34; *see also* R 18 (Duke, Dep. at 56); Duke, Tr. 521; R 20 (Roy, Dep. at 26); R 5 (Roy Report) at FTC-DCO 234-36; Expert Report of James Dews, dated Feb. 4, 2009 (hereinafter R 6 (Dews Report) at 1-3; Expert Report of Jay Lehr (undated) (hereinafter referred to as R 21 (Lehr Report) at 1-2)).

336. None of Respondents' proffered experts has specialized training or experience regarding cancer or cancer treatment. (R 18 (Duke, Dep. at 19, 56); Duke, Tr. 521; R 22 (LaMont, Dep. at 11-12); LaMont, Tr. 576-77; *see generally* R 5 (Roy Report) at FTC-DCO 0234-36; R 6 (Dews Report) at 1-3; R 21 (Lehr Report) at 1-2).

337. None of Respondents' proffered experts has conducted clinical studies regarding cancer treatments. (R 18 (Duke, Dep. at 55); R 22 (LaMont, Dep. at 184); LaMont, Tr. 577; R 20 (Roy, Dep. at 14); R 21 (Lehr, Dep. at 34); R 19 (Dews, Dep. at 61-63)).

(2) Scope of work and materials considered

338. None of Respondents' proffered experts reviewed the DCO advertising claims at issue in the case in preparing their opinions. (R 18 (Duke, Dep. at 36-37); Duke, Tr. 534; R 22 (LaMont, Dep. at 32-34, 56-58, 77-78); R 5 (Roy Report) at 1, FTC-DCO 0238-99; R 20 (Roy, Dep. at 7); R 6 (Dews Report) at 7-8; R 19 (Dews, Dep. at 36-38); R 21 (Lehr Report) at 2-4).

339. Respondents did not ask their proffered experts to render an opinion as to whether Respondents' purported substantiation materials constituted competent and reliable scientific evidence substantiating a claim that any of the Challenged Products prevent, treat, or cure cancer. (R 3 (Duke Report) at 1; R 4 (LaMont Report) at 3; R 5 (Roy Report) at 1; R 6 (Dews Report) at 2; R 21 (Lehr Report) at 2).

340. Respondents did not ask their proffered experts to render an opinion as to whether there existed any competent and reliable scientific evidence substantiating a claim that any of the Challenged Products prevent, treat, or cure cancer. (R 3 (Duke Report) at 1; R 4 (LaMont Report) at 3; R 5 (Roy Report) at 1; R 6 (Dews Report) at 2; R 21 (Lehr Report) at 2).

341. Respondents' proffered experts did not opine as to whether there is competent or reliable scientific evidence substantiating a claim that any of the Challenged Products prevent, treat, or cure cancer. (R 3 (Duke Report) at 1, 3; R 4 (LaMont Report) at 3, 40; R 5 (Roy Report) at 1; R 6 (Dews Report) at 2, 14; R 21 (Lehr Report) at 2).

342. None of Respondents' proffered experts reviewed the DCO advertising claims at issue in the case in preparing their opinions. (R 18 (Duke, Dep. at 36-37); Duke, Tr. 534; R 22 (LaMont, Dep. at 32-34, 56-58, 77-78); R 5 (Roy Report) at 1, DCO 0238-99; R 20 (Roy, Dep. at 7); R 6 (Dews Report) at 7-8; R 19 (Dews, Dep. at 36-38); R 21 (Lehr Report) at 2-4).

3. Level of substantiation required to support anti-cancer effects

343. "Competent and reliable scientific evidence" is required to conclude that a cancer treatment is effective. (Miller, Tr. 66-68).

344. Competent and reliable scientific evidence means in part that a hypothesis has been established. To constitute competent and reliable scientific evidence that a product treats, cures, or prevents cancer, the product's efficacy and safety must be demonstrated through controlled clinical studies. (CX 52 (Miller Report) at 7; *see also* LaMont, Tr. 596 (stating that the definition of competent and reliable scientific evidence includes a "spectrum" of evidence, such as studies of

animals and cell culture lines, but that investigation into a compound's safety and efficacy progresses "towards clinical outcome studies in an office-based practice or a university setting, and eventually moves towards human clinical trials")).

345. Clinical studies are studies on humans. Non-clinical studies are performed in test tubes and in animals with the aim of demonstrating potential activity and acceptable safety. Once non-clinical studies have been performed, the study proceeds into progressive phases of clinical trials in humans. (CX 52 (Miller Report) at 9).

346. Only data from well-designed, controlled, clinical trials will substantiate a claim that a new therapy is safe and effective to treat, cure, or prevent cancer. (CX 52 (Miller Report) at 30).

347. The proper format for any clinical trial protocol includes the following: Details of the rationale for the study; clear elucidation of primary and secondary objectives; clear presentation of the investigation plan, including study design, selection of subjects, study treatments, documentation of prior and concomitant illnesses and treatments, and study procedures; description of specific methods of data collection, quality assurance, and quality control; description of statistical procedures; reporting of studies of pharmacokinectics, pharmacodynamics, quality of life, and health economics; discussion of overall conclusion regarding safety and efficacy; relevant references; tables and figures; selected subject listings of demographics, disease and treatment parameters, endpoints, safety factors, and deaths; and subject narratives for serious adverse events and deaths. (CX 52 (Miller Report) at 8-9; Miller Tr. 66-68).

348. Claims that a dietary supplement prevents cancer, aids in the treatment of cancer, or can be used as a primary treatment for cancer, as opposed to claims that a

dietary supplement is good nutrition, require substantiation. (Miller, Tr. 152).

349. Anti-cancer agents may work by preventing cell proliferation (division), inducing programmed cell death (apoptosis), inhibiting growth factors or biochemical pathways that result in cell death, and inhibiting new blood vessel formation (angiogenesis). Anti-angiogenic agents have an important role in the treatment of some types of cancer. (CX 52 (Miller Report) at 10).

350. The process required to prove that a drug is safe and effective for the treatment of disease is very costly. Testing used to prove that a drug is a safe and effective treatment for disease is a particularly challenging and costly endeavor to undertake for testing herbal products, because it is difficult to extract and test a single chemical component from an herb, and because an herb may comprise thousands of chemical components. (Miller, Tr. 181; Duke, Tr. 499-502, 537-38; *see also* LaMont, Tr. 596-97).

351. Testimonials do not substitute for a well-designed clinical trial. (CX 52 (Miller Report) at 30).

352. Anecdotal reports are the weakest form of evidence to support the anti-cancer activity of a new agent. (CX 52 (Miller Report) at 11-12).

353. Testimonials have very little scientific validity. In the thirty testimonials reviewed by Miller, many of the patients were taking other modalities of anti-cancer therapy. There was insufficient documentation that the individuals had cancer. There was no valid instrument to measure their reported response to the Challenged Products. A patient's report that he or she "felt better," standing alone, does not scientifically measure the patient's response. (Miller, Tr. 141-42, 214-15).

4. Potential harm from alternative or ineffective remedies

354. The need to substantiate a claim of anti-cancer activity with competent and scientific evidence is the same whether the purported agent is an herbal medicine or a conventional pharmaceutical agent. "There [are] not . . . two kinds of medicine. There's not conventional medicine and alternative medicine. There's one medicine, medicine that works. The other medicine may or may not work, but to show that it works you have to go through the process . . . . [T]here shouldn't be a separate, different, less rigorous way of identifying the safety and the efficacy of so-called complementary medicine just because it's complementary. It has to go through the same process because we want to help cancer patients and we want to make sure that what they're getting is safe and effective." (Miller, Tr. 144).

355. Effective complementary medicine adds to the efficacy of standard anti-cancer therapy, reducing some of cancer therapy's adverse side effects (e.g., nausea and vomiting, severe neutropenia, anemia, fatigue), improving general well-being and quality of life, and permitting oncologists to administer effective doses of therapy on time. Many new targeted therapies work better when given with conventional anti-cancer therapy and rarely are as efficacious when given as single agents. Suggesting that complementary medicine can be an effective substitute for traditional medicine would be a disservice to cancer patients because delays in effective therapy may allow cancer cells to regrow, develop resistance to therapy, and metastasize. (CX 52 (Miller Report) at 11).

356. Taking the Challenged Products presents a potential harm. This is most acute if a cancer patient foregoes potentially beneficial and effective therapy and replaces that option with BioShark, 7 Herb Formula, GDU, or BioMixx, alone or in combination with other

DCO products. Diagnosing cancer early and treating it appropriately and effectively still offers the best chance of curing it. The use of complementary or alternative therapies exclusively as front-line treatment will result in disease progression. (CX 52 (Miller Report) at 12).

357. The Challenged Products are not necessarily harmless simply because they are herbs as opposed to drugs. Everything has potential side effects. One example is cat's claw, an ingredient in 7 Herb Formula. Cat's claw may have an effect on a very important enzyme system in the liver that causes either the breakdown of other drugs or may activate other drugs. As a result of this interaction, cat's claw might increase the concentrations of some drugs in the patient's system, which can lead to toxicity, or can cause an increased breakdown of those drugs, thereby lessening their efficacy. Cat's claw increases the activity of many drugs given for high blood pressure, which can result in hypotension (low blood pressure). Cat's claw can cause diarrhea, which is particularly adverse for a cancer patient who already may be nutritionally challenged. Cat's claw may also cause bleeding by affecting the blood's clotting system, thereby potentially increasing the risk of bleeding in a cancer patient. Thus, if a cancer patient is already taking a medication that lowers his or her platelet count or increases his or her risk of bleeding, this could be an extremely dangerous interaction. (Miller, Tr. 111-13).

358. Side effects are also affected by the dosing. One example of the importance of proper dosing is with Turkish rhubarb root, a component of 7 Herb Formula. Turkish rhubarb root contains tannins, which, in high doses, cause diarrhea and, in lower doses, cause constipation. (Miller, Tr. 117).

359. Another example of the importance of proper dosing comes from a study of parthenolide, the active ingredient in feverfew, a component of GDU. The

study was designed to determine through dose escalation what dose of parthenolide would show evidence of activity in cancer patients. Researchers were unable to measure any parthenolide in the bloodstream at the doses administered in the study. Even with very low doses, patients had side effects, including fever, chills, nausea, diarrhea, blurred vision, and fatigue. (Miller, Tr. 130-31).

360. An example of potentially harmful interactions was reported in a study of curcumin, the active ingredient in tumeric, a component of GDU. That study reported that curcumin can block or decrease the activity of a number of commonly used anti-cancer chemotherapy agents, including those used to treat breast cancer, colon cancer, and lymphoma. (Miller, Tr. 126).

361. Enhancing a deficient immune system is important. An over-enhanced immune system can be related to a number of autoimmune diseases, including malignancies like multiple myeloma. (Miller, Tr. 218-19).

5. No competent and reliable scientific evidence to substantiate claims about the Challenged Products, either alone or in combination with other DCO products

362. The reference materials relied upon by Respondents do not constitute competent and reliable scientific evidence that any of the Challenged Products prevent, treat, or cure cancer. (CX 52 (Miller Report) at 31; Miller Tr. 143).

363. There is no competent and reliable scientific evidence that the Challenged Products are effective, either alone or in combination with other DCO products, in the prevention, treatment, or cure of cancer, in inhibiting tumor formation, or in ameliorating the adverse effects of radiation and chemotherapy. (CX 52 (Miller Report) at 31; Miller Tr. 143).

364. Since BioShark, 7 Herb Formula, GDU, and BioMixx have not been tested, their effectiveness in the prevention, treatment, or cure of cancer is not known. (R 22 (LaMont, Dep. at 47-48); LaMont, Tr. 579-82).

365. The majority of the materials relied upon by Respondents as substantiation were not peer-reviewed papers. The materials did not include controlled clinical trials. The materials consisted of author opinions and reviews of literature on the use of herbal medicines for a number of different diseases, including cancer. (Miller, Tr. 81-82).

366. Many of the studies cited by Respondents as substantiation were non-clinical studies, i.e., in vitro or animal studies. (CX 52 (Miller Report) at 10).

367. Other studies relied upon by Respondents as substantiation evaluated isolated compounds that are present in some of the Challenged Products and showed nonspecific immunostimulatory activities or suggested cancer preventive effects. This does not substitute for an actual evaluation of each Challenged Product itself. It is not possible to extrapolate from results of a published non-clinical study of curcumin that GDU can eliminate tumors. GDU itself, or each active ingredient in GDU, must be subjected to the same experimental conditions as those to which the curcumin was subjected. (CX 52 (Miller Report) at 11).

6. No competent and reliable scientific evidence to substantiate BioShark claims

368. The reference materials relied upon by Respondents do not constitute competent and reliable scientific evidence that BioShark inhibits tumor growth in humans or that it is effective in the treatment of cancer in humans. (CX 52 (Miller Report) at 13).

369. 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 (Miller Report) at 16).

370. There have been no adequate and well-controlled studies demonstrating that BioShark is anti-angiogenic 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 (Miller Report) at 17).

371. There is no competent and reliable scientific evidence that any crude shark cartilage product is effective in treating human cancer. (CX 52 (Miller Report) at 17).

7. No competent and reliable scientific evidence to substantiate 7 Herb Formula claims

372. The reference materials relied upon by Respondents do not constitute competent and reliable scientific evidence that 7 Herb Formula is effective in the treatment or cure of cancer or that it inhibits tumor formation. (CX 52 (Miller Report) at 18).

373. There is no competent and reliable scientific evidence that 7 Herb Formula is effective in the treatment or cure of cancer or that it inhibits tumor formation. (CX 52 (Miller Report) at 18).

374. There are no clinical or non-clinical studies supporting claims that 7 Herb Formula, or any of its individual ingredients, is an effective anti-cancer agent or inhibits tumor formation. (CX 52 (Miller Report) at 19).

375. There have been animal and in vitro studies on the ingredients in 7 Herb Formula: Burdock root, cat's claw, sheep sorrel, slippery elm bark, Turkish rhubarb root, Siberian ginseng, and watercress. There have

been no controlled clinical trials on humans with cancer. (CX 52 (Miller Report) at 18-22).

8. No competent and reliable scientific evidence to substantiate GDU claims

376. The reference materials relied upon by Respondents do not constitute competent and reliable scientific evidence that GDU eliminates tumors or is effective in the treatment of cancer. (CX 52 (Miller Report) at 22).

377. There is no competent and reliable scientific evidence that GDU eliminates tumors or is effective in the treatment of cancer. (CX 52 (Miller Report) at 22).

378. There have been no randomized, controlled clinical trials of any of the individual components of GDU or of GDU itself in patients with cancer. (CX 52 (Miller Report) at 27).

379. 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 (Miller Report) at 22).

380. Some animal studies have suggested that curcumin may have activity as a cancer preventive and therapeutic agent. (CX 52 (Miller Report) at 23).

381. Some animal studies have also suggested that curcumin may actually inhibit the anti-cancer activity of some approved anti-cancer agents, as well as exacerbate iron deficiency. (CX 52 (Miller Report) at 27).

382. Further research on curcumin is necessary to determine if curcumin has cancer preventive or chemotherapeutic effects. (CX 52 (Miller Report) at 27).

9. No competent and reliable scientific evidence to substantiate BioMixx claims

383. The reference materials relied upon by Respondents do not constitute competent and reliable scientific evidence that BioMixx is effective in the treatment of cancer or heals the destructive effects of radiation and chemotherapy. (CX 52 (Miller Report) at 27).

384. There is no competent and reliable scientific evidence that BioMixx is effective in the treatment of cancer or heals the destructive effects of radiation and chemotherapy. (CX 52 (Miller Report) at 27).

385. There are no reported studies that either BioMixx, or any of its constituent ingredients, is effective in the treatment of cancer in humans. (CX 52 (Miller Report) at 27-29).

386. There are absolutely no scientific data to support a statement that BioMixx assists the body in fighting cancer or in healing the destructive effects of radiation and chemotherapy treatments. (CX 52 (Miller Report) at 29).

10. Substantiation through competent and reliable scientific evidence for Respondents' claims about the efficacy of the Challenged Products was not addressed by Respondents' proffered experts

a. Duke

387. Duke was provided statements made by Respondents to review and was asked if the data he reviewed supported the accuracy of those statements. (Duke, Tr. 519). The statements he was given mirror selected statements from the product descriptions for the Challenged Products. (F. 238, 263, 293). Duke concluded:

> There is a reasonable basis for the claims that the ingredients of 7 Herb Formula "fights [sic] tumor formation, and fights [sic] pathogenic bacteria."
>
> There is a reasonable basis for the claims that the ingredients of GDU "contains [sic] natural proteolytic enzymes (from pineapple source bromelain) to help digest protein – even that of unwanted tumors and cysts. This formula also helps to relieve pain and heal inflammation. . . . GDU is also used for . . . and as an adjunct to cancer therapy. GDU possesses a wide range of actions including anti-inflammatory and antispasmodic activity . . . ."
>
> There is a reasonable basis for the claims that the ingredients of BioMixx "boosts [sic] the immune 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."

(R 3 (Duke Report) at 3; Duke, Tr. 519-21, 536).

388. Duke's opinions do not address whether competent and reliable scientific evidence is necessary to substantiate advertising claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 3 (Duke Report)).

389. Duke's opinions do not address whether there is competent and reliable scientific evidence to support advertising claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 3 (Duke Report)).

390. Duke's opinions do not address whether Respondents possessed and relied upon adequate substantiation to support their claims that any of the Challenged

Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 3 (Duke Report)).

391. Duke does not recall seeing any articles that James or Patricia Feijo believe to have substantiated the claims that Respondents made regarding the Challenged Products. (R 18 (Duke, Dep. at 185)).

392. Duke made no effort to determine whether there were any studies of any sort regarding the Challenged Products. (R 18 (Duke, Dep. at 190-91)).

393. Duke did not analyze any of the Challenged Products themselves, but instead analyzed only constituent ingredients of the Challenged Products. (Duke Tr. 524-27).

394. Duke did not know the concentrations of the ingredients contained in the Challenged Products. (Duke Tr. 533-34).

b. LaMont

395. LaMont was provided labels from the Challenged Products, and the substantiation evidence upon which Respondents relied to support statements reflected in the then-draft complaint, including claims that BioShark inhibits tumor growth, 7 Herb Formula is effective in treating and curing cancer, GDU eliminates tumors, and BioMixx is effective in treating cancer. (R 22 (LaMont, Dep. Exs. 1, 2)).

396. LaMont was asked to evaluate the labels and the substantiation evidence upon which Respondents relied, and to write a report that would describe the mechanism of action of some of the constituents of the Challenged Products. In addition to reviewing Respondents' substantiation evidence, LaMont reviewed published medical literature in MedLine, PubMed, the Memorial Sloan-Kettering cancer

website, and the American Botanical website, among other sources. (R 4 (LaMont Report at 3); LaMont, Tr. 549-550).

397. Based on her review, LaMont concluded:

> There is a reasonable basis to claim that the ingredients of GDU contain bromelain, a source of natural proteolytic enzymes from the pineapple, which helps digest unwanted proteins. GDU also contains tumeric, feverfew and quercitin, which help to reduce inflammation and relieve pain.
>
> Next, it is reasonable to claim that these ingredients as a whole may be used as an adjunct to cancer therapy, and that the ingredients possess a wide range of actions as anti-inflammatory agents.
>
> There is a reasonable basis to claim that the ingredients of 7 Herb Formula fight tumor formation, and fight pathogenic bacteria.
>
> There is a reasonable basis to claim that the ingredients of BioMixx boost the immune system, build lean body mass and support healing. It is also reasonable to claim that these ingredients assist the body in fighting cancer, cachexia and in healing the destructive effects of radiation and chemotherapy treatments.

(R 4 (LaMont Report) at 40; LaMont, Tr. 572-74).

398. LaMont's opinions do not address whether competent and reliable scientific evidence is necessary to substantiate advertising claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 4 (LaMont Report)).

399. LaMont's opinions do not address whether there is competent and reliable scientific evidence to support advertising claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 4 (LaMont Report)).

400. LaMont's opinions do not address whether Respondents possessed and relied upon competent and reliable scientific evidence when Respondents made claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 4 (LaMont Report)).

401. LaMont did not analyze any of the Challenged Products themselves, but instead analyzed only the constituent ingredients of the Challenged Products. LaMont did not know the concentrations of the ingredients contained in any of the Challenged Products. (LaMont, Tr. 579, 582-83).

402. LaMont was unable to conclude that there was any evidence to support a claim that 7 Herb Formula is effective in treating or curing cancer. (R 22 (LaMont, Dep. at 205)).

403. LaMont was unable to conclude that BioMixx is itself effective in the treatment of cancer or that it heals the destructive effects of radiation and chemotherapy. (R 22 (LaMont, Dep. at 210-11)).

c. Roy

404. Roy was asked to provide his opinion on the scientific validity of randomly controlled trials to evaluate whole-person healing; the science of homeopathy; and the scientific validity of traditional testing of herbal medicines. (R 5 (Roy Report) at 1).

405. Roy's conclusions included: Traditional randomly controlled double blind studies are inappropriate to evaluate whole-person healing approaches; whole-person healing approaches focus on the effect on the structure and function of the whole person, as opposed to the use of a drug to cure the symptoms of a disease; and cancer is a particular instance where whole-body healing approaches make more scientific sense than pharmaceutical approaches. (R 5 (Roy Report) at 1-2).

406. The bases for Roy's conclusions in F. 405 include his opinion that homeopathy was developed empirically, from observations of the effects of various different materials on the functioning of healthy subjects, as opposed to trying a specific biochemical drug to cure a symptom. (R 5 (Roy Report) at 1-2).

407. The bases for Roy's conclusions in F. 405 include his opinion that herbal medicines have been tested epidemiologically by nature over thousands of years and hundreds of human generations, while pharmaceutical drug testing relies on statistical projections from small controlled trials. (R 5 (Roy Report) at 3-4).

408. Roy's opinions do not address whether there is competent and reliable scientific evidence to support Respondents' claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 5 (Roy Report)).

409. Roy's opinions do not address whether Respondents possessed and relied upon competent and reliable scientific evidence to support Respondents' claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 5 (Roy Report)).

410. Roy did not review the Complaint in this matter or any of the challenged advertisements. (R 20 (Roy, Dep. at 7)).

411. Roy is not an expert in homeopathy. (R 20 (Roy, Dep. at 12)).

412. Roy has no idea what ingredients the Challenged Products contain. (R 20 (Roy, Dep. at 24)).

413. Roy did not review or obtain any of the products or product labels for the Challenged Products. (R 20 (Roy, Dep. at 7-8)).

414. Roy does not have any formal training in medicine. (R 20 (Roy, Dep. at 26)).

415. Roy has never treated patients, or consulted with healers who were treating particular patients. (R 20 (Roy, Dep. at 28)).

416. Roy and his laboratory have not performed any clinical trials. (R 20 (Roy, Dep. at 13)).

417. Roy has never performed any experiments on humans to measure the efficacy of any medical treatments. (R 20 (Roy, Dep. at 14)).

d. Dews

418. Dews was asked to provide his opinion on 7 Herb Formula. He concluded that all seven herbs are listed in the Herbal Phyicians' Desk Reference, that there are many references on what these herbs are used for, and that, in manufacturing the formula, he was careful to make sure it was safe. When formulating the product that eventually became 7 Herb Formula, Dews avoided using too much rhubarb, which has a laxative action, because he did not want the product to cause diarrhea. (R 6 (Dews Report) at 1, 8-9).

419. Dews' opinions do not address whether competent and reliable scientific evidence is necessary to substantiate advertising claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 6 (Dews Report)).

420. Dews' opinions do not address whether there is competent and reliable scientific evidence to support advertising claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 6 (Dews Report)).

421. Dews' opinions do not address whether Respondents possessed and relied upon competent and reliable scientific evidence to support Respondents' claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 6 (Dews Report)).

e. Lehr

422. Lehr was asked to opine on the efficacy of DCO products. His opinions are based on his own personal experience in taking the DCO product called PrePost. It was Lehr's opinion that since he started taking the DCO product PrePost, his "life is totally different. . . . It's just incredible. . . . And it's astounding, I mean." (R 21 (Lehr Report) at 6).

423. Lehr's opinions do not address whether competent and reliable scientific evidence is necessary to substantiate advertising claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 21 (Lehr Report)).

424. Lehr's opinions do not address whether there is competent and reliable scientific evidence to support

Respondents' advertising claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 21 (Lehr Report)).

425. Lehr's opinions do not address whether Respondents possessed and relied upon competent and reliable scientific evidence to support claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 21 (Lehr Report)).

III. ANALYSIS AND CONCLUSIONS OF LAW

A. Burden of Proof

The parties' burdens of proof are governed by Federal Trade Commission Rule 3.43(a), Section 556(d) of the Administrative Procedure Act ("APA"), and case law. FTC Rules of Practice, Interim rules with request for comments, 66 Fed. Reg. 17,622, 17,626 (Apr. 3, 2001). Pursuant to Commission Rule 3.43(a), "[c]ounsel representing the Commission . . . shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto." 16 C.F.R. § 3.43(a). Under the APA, "[e]xcept as otherwise provided by statute, the proponent of a rule or order has the burden of proof." 5 U.S.C. § 556(d).

Respondents contend that, because of the constitutional issues raised by Respondents, Complaint Counsel should be required to prove the elements of the charges against Respondents by "clear, cogent and convincing evidence." RCOL 1; RB at 4 n.2 (citing *Addington v. Texas*, 441 U.S. 418 (1979)). Respondents' argument has no merit. *Addington* addressed the standard of proof required to commit an individual involuntarily to a state mental hospital – a serious deprivation of a well-recognized, constitutionally protected liberty interest. As shown in Section III E *infra*, Respondents' constitutional arguments are unsupported by fact or law. Accordingly, *Addington* does not alter the applicable standard of proof for this case.

It is well established that the preponderance of the evidence standard governs FTC enforcement actions. *In re Telebrands Corp.*, No. 9313, 140 F.T.C. 278, 426, 2004 FTC LEXIS 154, at *76 (Sept. 15, 2004), *aff'd*, 140 F.T.C. 278, 2005 FTC LEXIS 178 (Sept. 19, 2005), *aff'd*, 457 F.3d 354 (4th Cir. 2006); *In re Automotive Breakthrough Sciences, Inc.*, No. 9275, 1998 FTC LEXIS 112, at *37 n.45 (Sept. 9, 1998) (holding that each finding must be "supported by a preponderance of the evidence in the record"); *In re Adventist Health System/West*, No. 9234, 117 F.T.C. 224, 1994 FTC LEXIS 54, at *28 (Apr. 1, 1994) ("[e]ach element of the case must be established by a preponderance of the evidence"); *In re Bristol-Meyers Co.*, No. 8917, 102 F.T.C. 21, 1983 FTC LEXIS 64, at *143 (July 5, 1983) (stating that complaint counsel has "the burden of proving by a preponderance of credible evidence that the challenged advertising claims have not been established or did not have a reasonable basis"), *aff'd,* 738 F.2d 554 (2d Cir. 1984). *See also Steadman v. SEC*, 450 U.S. 91, 102 (1981) (holding that APA establishes preponderance of the evidence standard of proof for formal administrative adjudicatory proceedings).

"[T]he Commission has only such jurisdiction as Congress has conferred upon it by the Federal Trade Commission Act." *Community Blood Bank v. FTC*, 405 F.2d 1011, 1015 (8th Cir. 1969) (citations omitted). When the jurisdiction of the Commission is challenged, the Commission bears the burden of establishing its jurisdiction. *Id.* (citations omitted); *In re College Football Ass'n*, No. 9242, 1994 FTC LEXIS 350, at *7 n.3 (July 21, 1991) (citing *Oliver v. Trunkline Gas Co.*, 789 F.2d 341, 343 (5th Cir. 1986)) ("Complaint [C]ounsel bear the burden of 'affirmatively' establishing that jurisdiction exists."). Jurisdictional facts, like substantive liability, must be established by a preponderance of the evidence. *See McNutt v. General Motors Acceptance Corp.*, 298 U.S. 178, 189 (1936); *FTC v. Warner Chilcott Holdings Co. III*, No. 05-2179, 2007 U.S. Dist. LEXIS 4240, at *17 (D.D.C. Jan. 22, 2007).

The Complaint in this case alleges that Respondents did not possess and rely upon a reasonable basis that substantiated the representations Respondents made in the challenged advertisements. Complaint ¶ 16. Complaint Counsel has the

burden of proving by a preponderance of credible evidence that Respondents made the claims in the challenged advertising and did not have a reasonable basis for such claims. *In re Bristol-Myers Co.*, 1983 FTC LEXIS 64, at *143. *See FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 959 (N.D. Ill. 2006) (holding that to prevail on a reasonable basis theory, the FTC must prove that the advertiser lacked a reasonable basis for asserting the challenged claim, that the advertiser has the burden of establishing the substantiation it relied on for its claim, and that the FTC has the burden of proving that the advertiser's substantiation is inadequate), *aff'd*, 512 F.3d 858 (7th Cir. 2008).

B. Jurisdiction over Respondents

1. Positions of the parties and procedural background

Respondents assert that DCO is a not-for-profit religious organization and, as such, is not subject to the jurisdiction of the FTC. R Juris. Br. at 1-2. Specifically, Respondents assert that DCO is a religious ministry, incorporated as a corporation sole under the nonprofit corporation statutes of the State of Washington, and that James Feijo is the overseer of DCO, as defined under the corporation sole statute. R Juris. Br. at 1. Respondents further state that, as part of its missionary work, DCO addresses the health concerns of its followers, which led DCO to develop the Challenged Products. R Juris. Br. at 2. Maintaining that its religious ministry is not organized to carry on business for its own profit or that of its members, Respondents argue that DCO is not a corporation, as is required for jurisdiction under Sections 4 and 5 of the FTC Act. R Juris. Br. at 7-8.

Complaint Counsel argues that DCO is not a bona fide charitable institution, but is instead a for-profit commercial enterprise, completely controlled by James Feijo, from which he and his family derive substantial pecuniary benefits. CC Juris. Br. at 4. Complaint Counsel further contends that Feijo runs a multi-million dollar commercial operation that competes with for-profit entities in commerce. CC Juris. Br. at 5.

On April 21, 2009, a hearing was held for the limited purpose of determining whether DCO is a corporation within the meaning

of Section 4 of the FTC Act, 15 U.S.C. § 44, and applicable case law. Apr. 21, 2009 Hearing on Jurisdiction ("HOJ"). After the conclusion of that hearing, a ruling was issued from the bench that Complaint Counsel had demonstrated, by a preponderance of the evidence, that there is jurisdiction over both Respondents, DCO and James Feijo, under Sections 4 and 5 of the FTC Act, 15 U.S.C. §§ 44 and 45, and that the conduct challenged in this case is in or affecting commerce within the meaning of those Sections. HOJ Tr. 347-48. *See also* Order Memorializing Bench Rulings on Jurisdiction, Respondents' Motion to Dismiss, Motions for Summary Decision, and Respondents' Motion for Stay Pending Interlocutory Appeal, Apr. 27, 2009. The analysis in support of that ruling follows.

2. Summary of background facts

Respondents maintain that DCO is a house church. According to James Feijo, a house church is a church operating not in the typical sense, with a building, sign, and established doctrines, but instead is a church meeting in houses to worship and break bread, with no set times for religious meetings. (J. Feijo, HOJ Tr. 180-82, 263-64). James and Patricia Feijo testified that DCO was created for the purpose of healing based on the scripture of Daniel Chapter One and other Biblical verses, including Genesis 1:29 where it is written that God said he created all things for our food for healing. (J. Feijo, Tr. 417-23; R 16 (P. Feijo, Dep. at 39-40)). According to Patricia Feijo, the name Daniel Chapter One comes from the Book of Daniel in the Old Testament of the Bible, in which Daniel and his men were in captivity and were expected to eat the king's very rich diet of meats and wine, but instead ate and drank only pulse and water; after 10 days, their eyes were said to be brighter and they were said to be stronger than the king's men. (R 16 (P. Feijo, Dep. at 40-41)).

James and Patricia Feijo testified that DCO's ministry activities include helping house churches in other countries, holding religious meetings, performing baptisms, delivering babies, performing marriage ceremonies, performing healings, and reaching out to others to inform them about Respondents' perspectives on the integration of spiritual and physical well-being. (R 16 (P. Feijo, Dep. at 204-05); J. Feijo, HOJ Tr. 99, 180-

83, 236-37; R 15 (J. Feijo, Dep. at 73); P. Feijo, Tr. 325-26). Respondents claim that they have created a combined spiritual and scientific approach that maintains the balance of bodily systems. F. 85. James Feijo named this approach "BioMolecular Nutrition." F. 85.

Respondents sell the four products challenged in the Complaint over the Internet through their websites and through the BioMolecular Nutrition Product Catalog, which lists and describes products sold by DCO. F. 84, 91. The BioMolecular Nutrition Product Catalog sets forth the DCO Website address, www.danielchapterone.com, for consumers to shop online, and lists the toll-free number that consumers can use to place orders. F. 91. In addition, Respondents operate a radio program, DCO HealthWatch, to which cancer patients have called in and received counseling about taking the Challenged Products. F. 108-10. Respondents contend that because their activities in promoting and selling the DCO Products are in furtherance of the Feijos' spiritual and scientific beliefs, they are outside the FTC's jurisdiction.

3. Analytical framework

In analyzing whether the FTC has jurisdiction over Respondents, the starting point is the language of the statute itself. *United States v. Turkette*, 452 U.S. 576, 580 (1981). Section 5(a)(1)-(2) of the FTC Act grants the FTC the authority to "prevent unfair or deceptive acts or practices in or affecting commerce" by "persons, partnerships, or corporations." 15 U.S.C. § 45(a)(1)-(2). Section 4 of the FTC Act defines "corporation" in part as "any company, trust, so-called Massachusetts trust, or association, incorporated or unincorporated, . . . without shares of capital or capital stock or certificates of interest, except partnerships, which is organized to carry on business for its own profit or that of its members." 15 U.S.C. § 44.

In interpreting the language of Section 4 of the FTC Act, courts and the Commission have consistently held that an entity organized as a nonprofit is within the jurisdiction of the FTC if the entity in fact engages in business for its own profit or that of

its members. *California Dental Ass'n v. FTC*, 526 U.S. 756, 766-67 (1999); *Community Blood Bank*, 405 F.2d at 1017 (Commission's jurisdiction extends to any legal entity without shares of capital which engages in business for profit in the traditional meaning of that language). In *Community Blood Bank*, the Court of Appeals explained that "under § 4 the Commission lacks jurisdiction over nonprofit corporations without shares of capital, which are organized for and actually engaged in business for only charitable purposes, and do not derive any 'profit' for themselves or their members within the meaning of the word 'profit' as attributed to corporations having shares of capital." 405 F.2d at 1022. Commenting on *Community Blood Bank*, the Commission stated: "The court thus established a two-pronged test looking both to the source of the [entity's] income, i.e., to whether the corporation is 'organized for and actually engaged in business for only charitable purposes,' and to the destination of the income, i.e., to whether either the corporation or its members derive a profit." *In re College Football Ass'n*, 1994 FTC LEXIS 350, at *51-52.

Thus, the analysis of jurisdiction in this case begins with an evaluation of the source of DCO's income and an inquiry into whether DCO is actually engaged in business only for charitable purposes. Then, the focus turns to whether DCO in fact engages in business for its own profit or that of its members. In addition, jurisdiction over James Feijo individually is assessed. Finally, the evidence that Respondents' activities are in or affecting commerce is evaluated to establish that the FTC has jurisdiction over Respondents with respect to the acts or practices challenged in the Complaint.

4. DCO is not a business organized or engaged in only charitable purposes

a. DCO operates a commercial enterprise

Profit, the "jurisdictional touchstone" of the FTC Act, *California Dental*, 526 U.S. at 767, is determined in accordance with the "traditional and generally accepted meaning of that word." *Community Blood Bank*, 405 F.2d at 1017. "According to a generally accepted definition 'profit' means gain from business

or investment over and above expenditures, or gain made on business or investment when both receipts or payments are taken into account." *Community Blood Bank*, 405 F.2d at 1017. The dictionary definition of profit includes "a valuable return: GAIN," and "to be of service or advantage . . . to derive a benefit: GAIN," as well as the traditional concept of profit in business as "the excess of returns over expenditure in a transaction or series of transactions; esp[ecially] the excess of the selling price of goods over their cost." *Merriam-Webster's Collegiate Dictionary* (10th ed. 1993).

Respondent DCO has a toll-free phone number and a call center and operates websites through which consumers may purchase DCO products. F. 84, 99, 103-04. In addition, DCO sells its products through stores in Georgia and Pennsylvania and through various distributors, including chiropractic centers. F. 116-19. The DCO Website contains a tab inviting consumers to shop at DCO's "On-Line Store." F. 105. The "About Us" section on the DCO Website describes the company as a "health food store" or "health food supplement store." F. 32. In their websites and brochures, Respondents compare their products and their organization to "other brands" or "other companies." *E.g.*, F. 137; F. 138 (DCO Website stating: "Daniel Chapter One is the first and only company to add Siberian ginseng to the formula").

Over a thousand consumers have purchased DCO's products. F. 81. Respondents have generated approximately $2 million in annual sales for the years 2006, 2007, and 2008 for all of DCO's nearly 200 products. F. 9. Its sales of the Challenged Products constitute twenty or thirty percent of its sales. F. 80. Respondents charge consumers three to ten times what it costs Respondents to purchase the Challenged Products from manufacturers. F. 83, 127-29, 140-42, 144-46.

Significantly, DCO was incorporated as a for-profit corporation from 1991 to 1997 and sold the Challenged Products since at least 1993 and throughout the 1990s. F. 12-13, 22-23, 27. DCO's Articles of Incorporation during this period stated that the purpose for which DCO was organized as a for-profit corporation was: "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." F. 23. DCO changed its corporate form to corporation sole in 2002 and continued to sell the Challenged Products. F. 8-9, 28.

It appears that DCO's revenues exceed its expenses, since DCO was able to completely support two individuals and their homes (*see infra* Section III B 5) and to maintain surpluses in various accounts in the hundreds of thousands of dollars for extended periods of time.[2] F. 42-45. A showing that DCO was successful in running its business, however, is not required. *See California Dental*, 526 U.S. at 768 n.6 ("It should go without saying that the FTC Act does not require for Commission jurisdiction that members of an entity turn a profit on their membership, but only that the entity be organized to carry on business for members' profit."); *In re Ohio Christian College*, No. 8820, 80 F.T.C. 815, 849-50, 1972 FTC LEXIS 223, at *72 (May 19, 1972) (stating that the fact that respondents "were apparently not very successful in their enterprise" was of "little consequence").

[2] The record on DCO's revenues and expenditures is not clear. It is noted that Respondents failed to fully comply with discovery requests regarding their finances, even after being ordered to do so, but Complaint Counsel was able to obtain some limited financial records by subpoena. Complaint Counsel asked for an adverse inference that the information sought from Respondents in discovery would have defeated Respondents' nonprofit argument. CC Juris. Br. at 22. James Feijo, DCO's sole trustee, testified that he does not keep records or keep track of the money DCO distributes. F. 6, 40, 47; *see also* F. 50-54 (Respondents did not maintain documents even after being ordered to produce documents in this procceding). Although an adverse inference in this case may have been appropriate, *see Hamilton v. Accu-Tex*, 32 F. Supp. 2d 47, 68 (E.D.N.Y. 1998) (drawing adverse inference on interstate revenue in order to determine interstate commerce, an element for long-arm jurisdiction, and finding "since the necessary information is in the exclusive control of defendants, where they have failed to provide the information, this Court finds that plaintiffs have satisfied their burden, and the case should proceed"), it is not necessary here, because the facts are sufficient to demonstrate that DCO operated as a business for its own profit or that of its members.

b. DCO is not organized only for charitable purposes

Respondents' principal ground for arguing that the FTC lacks jurisdiction is that DCO is a ministry, organized as a corporation sole under the laws of the State of Washington as of October 30, 2002, and that James Feijo is the overseer of Daniel Chapter One, within the meaning of the Washington State statute authorizing the creation of a corporation sole. R Juris. Br. at 1 (citing R 1 (DCO's Articles of Incorporation) and Rev. Code Wash. (ARCW) § 24.12.030). However, courts and the Commission look to the substance, rather than the form, of incorporation in determining jurisdiction under the FTC Act. *Community Blood Bank*, 405 F.2d at 1019 ("mere form of incorporation does not put [an entity] outside the jurisdiction of the Commission"); *In re American Medical Ass'n*, No. 9064, 94 F.T.C. 701, 1979 FTC LEXIS 182, at *239 (Oct. 12, 1979), *enforced as modified*, 638 F.2d 443 (2d Cir. 1980), *aff'd by an equally divided court*, 455 U.S. 676 (1982). Regardless of DCO's form of incorporation, the evidence shows that DCO bears none of the substantive indicia of a corporation that is truly organized only for charitable purposes.

DCO is not registered with the Internal Revenue Service as a tax-exempt organization under Section 501(c)(3) or any other section of the IRS Code. F. 31. In evaluating the FTC's jurisdiction, "[t]he Commission has long recognized that while the terms employed in other statutes and the interpretation adopted by other agencies are not controlling, the treatment of exemptions for nonprofit corporations by other branches of the Federal Government is helpful." *In re College Football Ass'n*, 1994 FTC LEXIS 350, at *52 (June 16, 1994) (citing *In re Ohio Christian College*, 80 F.T.C. at 848; *In re American Medical Ass'n*, 1979 FTC LEXIS 182, at *254 (finding an entity's tax-exempt status certainly one factor to be considered and observing that a determination by another federal agency that a respondent is or is not organized and operated exclusively for eleemosynary purposes should not be disregarded)). In *Community Blood Bank*, the fact that respondents were exempt from federal income tax liability was among the factors weighed in finding that the FTC lacked jurisdiction. 405 F.2d at 1020.

Respondents contend that it is immaterial for jurisdictional purposes that DCO does not have a Section 501(c)(3) tax exemption because, according to Respondents, churches do not need to obtain such exemption, pursuant to Section 508(c)(1)(A) of the IRS Code. Contrary to Respondents' argument, Section 508(c)(1)(A) exempts churches from certain notice requirements applicable to other entities seeking to obtain a Section 501(c)(3) tax exemption, and has no bearing on the issue of FTC jurisdiction.[3]

Moreover, as summarized below, in Section III B 5, DCO distributes funds for the use of both James and Patricia Feijo, private individuals and DCO's corporate officers. The Internal Revenue Code provides an exemption from income taxation for corporations where "no part of the net earnings of which inures to the benefit of any private . . . individual." 26 U.S.C. § 501(c)(3). The Nonprofit Corporation Act of the State of Washington defines a nonprofit corporation as a corporation no part of the income of which is distributable to its members, directors, or

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[3] Section 508 provides in pertinent part:

(a) . . . Except as provided in subsection (c), an organization organized after October 9, 1969, shall not be treated as an organization described in section 501(c)(3) [26 USCS § 501(c)(3)] --
(1) unless it has given notice to the Secretary, in such manner as the Secretary may by regulations prescribe, that it is applying for recognition of such status, or
(2) for any period before the giving of such notice, if such notice is given after the time prescribed by the Secretary by regulations for giving notice under this subsection.

(b) Presumption that organizations are private foundations. Except as provided in subsection (c), any organization (including an organization in existence on October 9, 1969) which is described in section 501(c)(3) [26 USCS § 501(c)(3)] and which does not notify the Secretary, at such time and in such manner as the Secretary may by regulations prescribe, that it is not a private foundation shall be presumed to be a private foundation.

(c) Exceptions.

(1) Mandatory exceptions. Subsections (a) and (b) shall not apply to
(A) *churches*, their integrated auxiliaries, and conventions or associations of churches. . . .

(emphasis added).

officers. Rev. Code Wash. (ARCW) § 24.03.005. With the distribution of funds for use by James and Patricia Feijo, DCO would not qualify as a tax-exempt nonprofit corporation under either the Internal Revenue Code or laws of the State of Washington.

In addition, DCO's Articles of Incorporation do not declare that DCO was organized exclusively for charitable or other clearly nonprofit purposes, but instead include provisions permitting "other worthwhile projects for the common good of Daniel Chapter One and its close associates, along with other acts and programs beneficial to Daniel Chapter One at large." F. 29-30. Further, DCO's Articles of Incorporation do not provide for distribution of its assets upon dissolution solely to other nonprofit entities or prohibit distribution of its earnings to the benefit of any individual or for-profit corporation. F. 30. By contrast, in *Community Blood Bank,* in which the Court found the FTC lacked jurisdiction, the articles of incorporation of the nonprofit entities: declared that they were organized exclusively for educational and charitable purposes; declared that no part of their earnings shall inure to the benefit of any member or any other individual or corporation; and, required that the corporation's assets, upon dissolution, be disposed of in accordance with the provisions of the state's nonprofit corporation law. 405 F.2d at 1020.

c. DCO is not engaged in business only for charitable purposes

It is not disputed that DCO has engaged in some charitable activities. In some instances, Respondents gave away DCO products and provided counsel to persons in need. F. 19, 21. Respondents have at times allowed people in need to stay in their house and provided support to a junior men's fast-pitch softball team. F. 19-20. However, Respondents did not provide documents to indicate how much of DCO's products they have given away or how much financial support they have dedicated to charitable activities, and the testimony on this point was inconclusive. F. 54. Furthermore, the evidence shows, as summarized in Section III B 5 *infra*, that in addition to its charitable activities, DCO distributes funds to support all of the living expenses of both James and Patricia Feijo. This

contribution of funds to the Feijos defeats Respondents' claim that DCO is operated exclusively for charitable purposes. As noted in *Community Blood Bank*: "A religious association might sell cookies at a church bazaar, or receive income from securities it holds, but so long as its income is devoted exclusively to the purposes of the corporation, and not distributed to members or shareholders, it surely does not cease to be a nonprofit corporation merely because it has income. . . ." *Community Blood Bank*, 405 F.2d at 1019-20 (quoting with approval dissenting opinion in *In re Community Blood Bank*, 70 F.T.C. 728, 1966 FTC LEXIS 30, at *455 (Sept. 28, 1968)). In *Community Blood Bank*, the uncontradicted evidence showed that no part of any funds received by respondents had ever been distributed to or inured to the benefit of any of their members, directors, or officers. *Community Blood Bank*, 405 F.2d at 1020. But here, as summarized below, where the evidence clearly shows that DCO distributes funds to the Feijos, DCO's income is not devoted exclusively to charitable or other nonprofit purposes.

5. DCO engages in business for its own profit or that of its members

Whether Respondent DCO is a ministry is not dispositive in determining the FTC's jurisdiction over Respondents' activities. Instead, the pivotal inquiry is whether Respondent DCO engaged in business for its own profit or that of its members. *California Dental*, 526 U.S. at 766-67; *Community Blood Bank*, 405 F.2d at 1017. In *Community Blood Bank*, the individual respondents "were 'public-spirited volunteers' and derived no personal profit, benefit or advantages in their individual occupations . . . from their participation in the activities of the community-wide blood bank program." 405 F.2d at 1021. "Their activities at all times were directed toward promoting a community-sponsored program in the public interest and at no time were infected with commercial intent." *Id.* at 1021-22. The Commission, in *Ohio Christian College*, noted that the court in *Community Blood Bank* found that the challenged boycotting activities were motivated by a sincere belief that commercial trafficking in blood was immoral and not in the public interest. *In re Ohio Christian College*, 1972 FTC LEXIS 223, at *65. The Commission went on to state: "Whether one agrees with this belief or not, it is apparent the

actions of the corporate respondents in *Community Blood Bank* were well-intentioned and did not inure to the financial benefit of anyone." *Id.*

Thus, the Commission has made clear that, for finding jurisdiction, what matters is not what respondents' subjective motivations are, but whether respondents' actions inure to their own financial benefit. Applying that principle to this case, what matters, for finding jurisdiction, is not whether Respondents' commercial activities are motivated by religious beliefs, but whether Respondents' activities inured to their own financial benefit, which, as summarized below, they clearly did.

a. DCO distributes funds to the Feijos

"[T]he distribution of funds to private persons or for-profit companies as opposed to their use for 'recognized public purposes' is one basis for finding an entity to be 'organized to carry on business for . . . profit.'" *In re College Football Ass'n*, 1994 FTC LEXIS 350, at *49. *See also California Dental*, 526 U.S. at 766-67 (holding that jurisdiction arose from economic and pecuniary benefits conferred by nonprofit trade association on its for-profit members); *In re American Medical Ass'n*, 1979 FTC LEXIS 182, at *240 (stating that Section 4 does not require a transfer or delivery of monetary profits to the members of a non-stock corporation, but only pecuniary benefits to its members from the corporation's activities); *In re Ohio Christian College*, 1972 FTC LEXIS 223, at *68 ("'Profit does not necessarily mean a direct return by way of dividends, interest, capital account or salaries. A saving of expense which would otherwise necessarily be incurred is also a profit to the person benefitted.'") (citation omitted).

It is undisputed that DCO pays all of the Feijos' living expenses. F. 58. DCO or its affiliate owns two houses (one in Rhode Island and one in Florida, on country club land with a pool in the back), in which the Feijos stay without paying rent. F. 55. DCO also owns two cars (a 2003 Cadillac and a 2004 Cadillac) which the Feijos use. F. 56-57. Respondent James Feijo does not have his own individual bank account. F. 76. Both James and Patricia freely use DCO credit cards for personal expenses. F. 66.

DCO pays all of the Feijos' expenses, including pool and gardening services for the Feijo house in Florida; Patricia Feijo's tennis club membership; James Feijo's membership at the Green Valley Country Club in Rhode Island; and, during the period from December 2005 to March 2009, golf expenses of $9,936, restaurant expenses of $14,024, automobile expenses of $28,582, and cigar expenses of $1,077. F. 58, 61-70. This distribution of funds, which amounts to a saving of expense which might otherwise be incurred by the Feijos, is a profit to the Feijos and provides a basis for finding that DCO is organized to carry on business for profit.

Respondents argue that jurisdiction should not be based upon the economic benefits conferred upon the Feijos because the Feijos do not take salaries from DCO for their work and because they live modestly. R Juris. Br. at 7. Neither of these things affects jurisdiction in this case. The Feijos have no need to take salaries, since James Feijo controls all of the assets of DCO and can direct whatever funds he chooses for the support of himself and his wife. F. 6, 40. Second, it is not necessary for the Feijos to live lavishly for jurisdiction to be proper under Section 4. The Supreme Court, in *California Dental*, specifically rejected the notion that the profit received must be substantial: "There is accordingly no apparent reason to let the statute's application turn on meeting some threshold percentage of activity for this purpose [of profit], or even satisfying a softer formulation calling for a substantial part of the nonprofit entity's total activities to be aimed at its members' pecuniary benefit. To be sure, proximate relation to lucre must appear . . . ." 526 U.S. at 766. It is sufficient for the purpose of finding jurisdiction that the economic benefits conferred are more than "*de minimis*" or "merely presumed." *Id*. at 767 and 767 n.6. In this case, the complete financial support of James and Patricia Feijo, including, among other things, two homes, two cars, tennis lessons, rounds of golf, cigars, restaurant meals, and club memberships, constitutes neither simply presumed nor *de minimis* economic benefits.

The Commission found jurisdiction under Section 4 on similar facts in *Ohio Christian College*, which involved deceptive trade practices by a nonprofit religious college. The Commission stated:

> [T]he question is not whether a corporation amassed profit, but how it disposed of such profit. From the facts available to the Commission, we find the relationship between [Ohio Christian College] and the individual respondents in dealing with the dissipation of profits strikingly similar to that existing between a closely-held commercial corporation and its officer-shareholders. The cavalier treatment of the corporate assets and finances leads us to conclude that respondents considered them their own. The individual respondent . . . has complete control over the purse strings, he sets all salaries (including his own), determines all allocation and expenditures, signs all checks and exercises plenary power over the affairs of the school. The record shows the corporation was organized and controlled so that the individual respondents could take what they wanted prior to any further disposition or comingling of funds.

1972 FTC LEXIS 223, at *69-70.

In this case, as well, James Feijo treated the income and expenditures of DCO cavalierly. He claimed to keep no financial records, and to have no idea of how much money DCO had or how much money was spent on various aspects of its operations or for the support of the Feijos' living expenses. F. 47, 50, 59. Moreover, since James Feijo had no individual bank account, he used DCO's assets at will, thereby treating those assets as his own. As in *Ohio Christian College*, such circumstances support jurisdiction over DCO as an entity that is organized to carry on business for profit.

b. DCO's profit inures to its sole member, James Feijo

As a corporation sole, DCO has one member, James Feijo, the overseer of DCO. Pursuant to the State of Washington's Nonprofit Corporation Act, under which DCO is organized:

> Any person, being the . . . overseer . . . of any church or religious denomination in this state, may, in conformity with the constitution, canons, rules, regulations or discipline of such

church or denomination, become a corporation sole, in the manner prescribed in this chapter . . . ; and, thereupon, said . . . overseer . . . shall be held and deemed to be a body corporate, with all the rights and powers prescribed in the case of corporations aggregate; and with all the privileges provided by law for religious corporations.

Rev. Code Wash. (ARCW) § 24.12.010. *See also Barnett v. Hicks*, 792 P.2d 150, 155 (Wash. 1990) (Dore, J., dissenting on other grounds) (noting that under Washington law, a corporation sole vests full management power in one individual).

The evidence in this case shows that James Feijo controls the money made by DCO. F. 6, 40-41. The structure of the corporation sole enables James Feijo to set his and his wife's salaries and benefits without the check of a managing board of directors or other individuals. Further, DCO pays all of the Feijos' living expenses, including food, clothing, housing, transportation, travel, recreation, and more. F. 55-58, 61-70. These economic benefits constitute profit to James Feijo. Thus, DCO engages in business for the profit of its sole member, James Feijo.

6. James Feijo is a person over whom the FTC has jurisdiction

The FTC has jurisdiction under Section 5(a)(2) over persons, partnerships or corporations. 15 U.S.C. § 45(a)(2). If individuals direct and control the acts and practices of a corporation amenable to the FTC's jurisdiction, then they too may be made subject to the FTC's jurisdiction. *In re Ohio Christian College*, 1972 FTC LEXIS 223, at *62-63; *see FTC v. Amy Travel Serv., Inc.*, 875 F.2d 564, 573 (7th Cir. 1989) (holding that individual who either participated directly in or had the authority to control deceptive acts or practices may be held liable under the FTC Act for the violations of his corporation).

Respondent James Feijo both participated directly in and had the authority to control the acts or practices challenged in this case. Respondents admit that Respondent Feijo is responsible for the activities of Respondent DCO as its overseer. F. 5. The

activities for which he is responsible include the development, creation, production, and distribution of the Challenged Products; the creation, management, and maintenance of DCO's toll-free telephone number through which consumers may order the Challenged Products; the setting of prices for the Challenged Products; and the creation, drafting, and approval of the directions for usage and the recommended dosages of the Challenged Products. F. 37-39, 100. Respondent James 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 Most Simple Guide, and the websites www.danielchapterone.com, www.7herbformula.com, and www.gdu2000.com. F. 165-66, 173, 178. In addition, Respondent Feijo and his wife co-host the DCO radio program, Daniel Chapter One HealthWatch, for two hours daily, Monday through Friday, on which they have counseled individuals who have called into the radio program about taking DCO's products. F. 108-10, 178. Finally, Respondent Feijo is the trustee for all of DCO's assets, including all funds which are held in trust. F. 6, 40. Thus, Respondent James Feijo had the authority to direct and control, in fact did direct and control, and participated directly in the challenged acts or practices of DCO, a corporation that is subject to the FTC's jurisdiction. Accordingly, Respondent James Feijo is a person over whom the Commission has jurisdiction, and he may be held individually liable under the FTC Act for the deceptive acts and practices found below.

7. Respondents engage in interstate commerce

Section 5(a)(1) of the FTC Act declares unlawful "unfair or deceptive acts or practices in or affecting commerce." 15 U.S.C. § 45(a)(1). Section 12 of the FTC Act provides that the dissemination of any false advertisement, for the purpose of inducing the purchase in or having an effect upon commerce, of food or drugs, shall be an unfair or deceptive act or practice in or affecting commerce within the meaning of Section 5. 15 U.S.C. § 52.

In their Answer, Respondents admit that they distribute the Challenged Products in commerce. Answer ¶ 4. Respondent DCO operates a call center and websites through which

consumers may purchase the Challenged Products. F. 99, 103-04. DCO has sold its products nationally through a number of stores, distributors, and chiropractic centers, including those in Florida, Georgia, Missouri, and Pennsylvania. F. 116-17, 119. These sales are in or affecting commerce. *See United States v. Robertson*, 514 U.S. 669, 672 (1995) ("[A] corporation is generally engaged in commerce when it is itself directly engaged in the production, distribution, or acquisition of goods or services in interstate commerce.") (per curiam) (citation omitted). In addition, Respondents' advertisements of its products through the DCO websites (F. 158-61), which reach a national audience invoke the FTC's jurisdiction. *See FTC v. Simeon Management Corp.*, 391 F. Supp. 697, 703 (N.D. Cal. 1975) (holding that advertisements placed in newspapers, magazines, and on television with out-of-state circulations and broadcasting ranges, were sufficiently involved in or affecting commerce to invoke the FTC's jurisdiction).

To the extent that Respondents maintain that they do not sell the Challenged Products, but instead offer them for suggested donations, the evidence is to the contrary. For example, on their website www.dc1store.com, Respondents state: "For Information on Special offers for purchasing multiple bottles of 7-Herb call 1-800-504-5511 between 9-6 EST Mon-Fri." F. 107. In the BioMolecular Nutrition Product Catalog, which lists and describes the Challenged Products and states "Call Toll free or shop online," there is no indication that the listed prices are suggested donations. F. 91-92.

An FTC investigator purchased the Challenged Products from the DCO Website, www.danielchapterone.com, on January 3, 2008. F. 147. At the time of his purchase, each of the Challenged Products was displayed on the DCO Website with a picture of the product, a short description of the product, and a corresponding price. F. 148. The shipment to the investigator of the Challenged Products did not contain any documents indicating that the purchase was a donation or thanking the purchaser for making a donation to DCO. F. 156. An e-mail the FTC investigator received after his purchase of the Challenged Products stated: "Thank you for your purchase on our online store. . . . We

appreciate your business with us," and offered a ten percent discount on a subsequent purchase. F. 152.

The evidence clearly demonstrates that Respondents advertise and sell products, including the Challenged Products, throughout the United States, and that their sales are in or affecting commerce. Thus, the Commission has jurisdiction over Respondents, and the conduct challenged in the Complaint, pursuant to Sections 4 and 5 of the FTC Act, 15 U.S.C. §§ 44, 45.

8. Summary of jurisdiction

The FTC has jurisdiction over DCO as a corporation, within the meaning of Section 4 of the FTC Act. Jurisdiction is also proper as to James Feijo, as a person directly participating in and controlling all activity of DCO, under Section 5 of the FTC Act. The conduct of Respondents is in or affecting commerce, pursuant to Sections 5 and 12 of the FTC Act. Accordingly, the FTC has jurisdiction in this matter.

C. Respondents' Dissemination of Advertisements to Induce Purchases of Food or Drugs

Section 12 of the FTC Act makes it unlawful "for any person, partnership, or corporation to disseminate, or cause to be disseminated, any false advertisement . . . [b]y any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase in or having an effect upon commerce of food, drugs, devices, services, or cosmetics." 15 U.S.C. § 52. Prior to addressing whether the DCO materials are false, within the meaning of Section 12, it must be determined preliminarily whether the materials constitute: (1) the dissemination of advertisements; (2) for the purpose of inducing, or which are likely to induce, purchases in or affecting commerce; (3) of "food" or "drugs."

1. Materials disseminated about the Challenged Products constitute advertisements

"Advertisement" is not defined in the FTC Act. The ordinary meaning of the word is: The act or process of calling something to the attention of the public; or a public notice, especially one published in the press or broadcast over the air. *Merriam-Webster's Collegiate Dictionary* (10th ed. 1993). Black's Law Dictionary defines "advertisement" as a "[n]otice given in a manner designed to attract public attention. Information communicated to the public, or to an individual concerned. . . ." *Black's Law Dictionary* 54 (6th ed. 1990) (citation omitted). *See also B & B Coastal Enters., Inc. v. Demers*, 276 F. Supp. 2d 155, 159 n.3 (D. Me. 2003) (noting that local ordinance regulating advertising signs applied to any sign which "directs attention to the type of business or profession conducted, as well as to a commodity or service, sold, offered, or manufactured . . ."). As discussed below, the evidence amply demonstrates that the DCO materials at issue in this case constitute the dissemination of "advertisements" for purposes of Section 12.

First, information about the Challenged Products is disseminated to the public, over the Internet, through the websites www.danielchapterone.com, www.7herbformula.com, www.gdu 2000.com, www.dc1pages.com, and www.dc1store.com. F. 158, 161. Consumers can locate the DCO Website by entering the term "cancer" in a Google search. F. 162. In addition, information about the Challenged Products is disseminated to the public through printed materials, also available on the DCO Website, including the BioGuide, the Cancer Newsletter, and "The Most Simple Guide." F. 163-64, 169-70, 172. Information about the Challenged Products is also disseminated to the public through BioMolecular Nutrition Product Catalog, F. 91, 154. Finally, information about the Challenged Products is disseminated to the public, via the Monday through Friday, two hour radio program, "Daniel Chapter One HealthWatch." F. 175-77.

The information provided through these media promotes the Challenged Products. Respondent Feijo admits that DCO advertises on the DCO Website. F. 161. DCO's printed materials

also promote the attributes of the Challenged Products. For example, the "Most Simple Guide" describes the Challenged Products as "essential for cancer." F. 192. The DCO websites, the BioGuide, and the Cancer Newsletter promote the products through product descriptions and testimonials. F. 179-80, 183-88, 190, 195, 197-201, 203-10. The BioMolecular Nutrition Product Catalog also describes and promotes the characteristics of the Challenged Products. F. 91, 233, 256, 279. Finally, the radio program uses "health advice" to promote the products. F. 213-17. Accordingly, the DCO materials constitute "advertisements" within the scope of Section 12 of the FTC Act, 15 U.S.C. § 52.

2. The advertisements are for the purpose of inducing, and did induce, purchases of the Challenged Products in or affecting commerce

As noted in Section III B 7 above, Respondents' contention that their products are offered for suggested donations and not for purchase is contrary to the evidence. The DCO Website contains icons inviting consumers to "Buy Now." For example, the DCO Website touts the purported benefits of BioShark immediately adjacent to a link urging the viewer to "BUY NOW!" F. 106, 221. The BioGuide, Cancer Newsletter, and "Most Simple Guide" all prominently feature DCO's toll-free call center number. F. 90, 94, 163, 167, 174. Consumers are also given the toll-free call center number on the DCO radio program. F. 102, 111. In addition, DCO has spent money on advertising its products. F. 159-60. In these circumstances, it is clear that Respondents' advertisements are "intended to" induce sales. Moreover, there is no question that DCO in fact made sales, F. 9, 80-81, and that its sales are "in or affecting commerce." *See* F. 218; *supra* Section III B 7.

3. The Challenged Products are food and/or drugs

"Food" and "drug," for the purposes of Section 12, are defined in the FTC Act as follows:

> (b) Food. The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

> (c) Drug. The term "drug" means (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories.

15 U.S.C. § 55(b), (c).

Courts and the Commission have routinely treated dietary supplements as within the scope of Section 12. *See FTC v. National Urological Group, Inc.*, No. 1:04-CV-3294, 2008 U.S. Dist. LEXIS 44145 (N.D. Ga. June 4, 2008); *FTC v. Direct Marketing Concepts, Inc.*, 569 F. Supp. 2d 285, 297 (D. Mass. 2008); *FTC v. Garvey*, 383 F.3d 891 (9th Cir. 2004); *Shafe v. FTC*, 256 F.2d 661, 663 (6th Cir. 1958). There is no dispute that the Challenged Products are dietary supplements. RFF 11; Answer ¶¶ 6, 8, 10, 12. In accordance with the foregoing authorities, such articles constitute "food" and/or "drug[s]" within the scope of Section 12. *See In re General Nutrition, Inc.*, No. 9175, 113 F.T.C. 146, 1986 FTC LEXIS 74, at *4 (Feb. 24, 1986) (finding that, as advertised, dietary supplement tablets, "Healthy Greens," constituted a "food" and "drug" within the meaning of Section 12 of the FTC Act).

D. Respondents' Advertising Is Deceptive or Misleading

An "advertisement is deceptive under the Act if it is likely to mislead consumers, acting reasonably under the circumstances, in a material respect." *Kraft, Inc. v. FTC*, 970 F.2d 311, 314 (7th Cir. 1992) (citing *In re Thompson Medical Co.*, No. 9149, 104 F.T.C 648, 788, 1984 FTC LEXIS 6, at *311 (Nov. 23, 1984), *aff'd,* 791 F.2d 189 (D.C. Cir. 1986); *In re Cliffdale Assocs.*, No. 9156, 103 F.T.C. 110, 164-66, 1984 FTC LEXIS 71, at *104 (Mar. 23, 1984)). *See also* 15 U.S.C. § 55(a)(1) (defining "false

advertisement" as an advertisement "which is misleading in a material respect"). Proof of intent to deceive is not required, and "the subjective good faith of the advertiser is not a valid defense." *FTC v. Sabal*, 32 F. Supp. 2d 1004, 1007 (N.D. Ill. 1998); *FTC v. World Travel Vacation Brokers, Inc.*, 861 F.2d 1020, 1029 (7th Cir. 1988).

In determining whether advertising is deceptive, the Commission engages in a three-part inquiry to determine: (1) whether the advertisements convey the claims alleged; (2) whether the claims are false or misleading; and (3) whether the claims are material to prospective consumers. *Kraft v. FTC*, 970 F.2d at 314; *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1095 (9th Cir. 1994); *FTC v. Direct Marketing Concepts*, 569 F. Supp. 2d at 297. Applying that three-part inquiry to this case, it is clear that Respondents' advertising is deceptive.

1. The DCO advertisements make the claims alleged in the Complaint

The Complaint alleges that Respondents disseminated advertisements which claim that the Challenged Products prevent, treat, or cure cancer. Complaint ¶¶ 5, 7, 9, 11, 13. The Complaint further charges that Respondents' advertisements represent that:

> 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
> BioMixx heals the destructive effects of radiation and chemotherapy.

Complaint ¶ 14.

Respondents contend that DCO's advertising does not use the words "diagnose, mitigate, cure or prevent," that their "express statements" about the Challenged Products describe the products'

effects on the "structure or function" of the body, and that their "claims" consist of the language of the various product descriptions in their advertising. RPFF Nos. 22-26; *see also* RRFF No. 153 (replying that the "statement cited . . . specifically does not state that the products can cure, treat or prevent cancer"); RB at 9 ("Nowhere on the face of the actual statements by Respondents do Respondents state that their products diagnose, mitigate, treat, cure or prevent a specific disease or class of diseases. . . "). Respondents' arguments disregard both the law and common sense, which recognize that claims may be either express or implied. *In re Kraft, Inc.*, No. 9208, 114 F.T.C. 40, 120, 1991 FTC LEXIS 38, at *10 (Jan. 30, 1991), *aff'd,* 970 F.2d 311 (7th Cir. 1992); *In re Thompson Medical*, 104 F.T.C. at 788, 1984 FTC LEXIS 6, at *311. While express claims directly state the representation at issue, implied claims do so in an oblique or indirect way. *Kraft v. FTC*, 970 F.2d at 318 n.4; *In re Thompson Medical*, 104 F.T.C. at 788, 1984 FTC LEXIS 6, at *312 ("Implied claims are any claims that are not express.").

The primary evidence of the claims an advertisement conveys to reasonable consumers is the advertisement itself. *In re Telebrands Corp.*, No. 9313, 140 F.T.C. 278, 290, 2005 FTC LEXIS 178 (Sept. 19, 2005), *aff'd*, 457 F.3d 354 (4th Cir. 2006); *In re Novartis Corp.*, No. 9279, 127 F.T.C. 580, 680, 1999 FTC LEXIS 90, at *37-38 (May 13, 1999); *In re Kraft*, 1991 FTC LEXIS 38, at *12. Moreover, the Commission looks to the overall net impression created by the advertisement as a whole, by examining the interaction of all of the different elements in the advertisement, rather than focusing on the individual elements in isolation. *American Home Prods. Corp. v. FTC*, 695 F.2d 681, 687 (3d Cir. 1982); *In re Kraft*, 1991 FTC LEXIS 38, at *14; *In re Thompson Medical*, 104 F.T.C. at 323 n.17, 1984 FTC LEXIS 6, at *324 n.17. "[T]he cardinal factor is the probable effect which the advertiser's handiwork will have upon the eye and mind of the reader. It is therefore necessary in these cases to consider the advertisement in its entirety and not to engage in disputatious dissection. The entire mosaic should be viewed rather than each tile separately. 'The buying public does not ordinarily carefully study or weigh each word in an advertisement. . . .'" *FTC v. Sterling Drug, Inc.*, 317 F.2d 669, 674 (2d Cir. 1963) (quoting *Aronberg v. FTC*, 132 F.2d 165, 167 (7th Cir. 1942)).

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

In addition, an advertisement may convey numerous representations, and the same advertising elements may be amenable to more than one reasonable interpretation. *In re Kraft*, 1991 FTC LEXIS 38, at *11 n.8; *In re Thompson Medical*, 104 F.T.C. at 789 n.7, 1984 FTC LEXIS 6, at *312 n.7. Moreover, the representations alleged in the Complaint need not be the only reasonable interpretations of the challenged advertising. *In re Kraft*, 1991 FTC LEXIS 38, at *11 n.8; *In re Thompson Medical*, 104 F.T.C. at 789 n.7, 1984 FTC LEXIS 6, at *312 n.7; *In re Bristol-Myers Co.*, 102 F.T.C. at 320, 1983 FTC LEXIS 64, at *249. In addition, "[s]tatements susceptible of both a misleading and a truthful interpretation will be construed against the advertiser." *FTC v. Bronson Partners*, 564 F. Supp. 2d at 127 n.6 (quoting *Country Tweeds, Inc. v. FTC*, 326 F.2d 144, 148 (2d Cir. 1964)).

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

a. Claims regarding the Challenged Products collectively

(1) "Cancer News" webpage on www.danielchapterone.com

DCO advertises the Challenged Products as a group on the DCO Website on a page entitled "Cancer News." F. 179-88. Viewing the Cancer News webpage as a whole, the claim that the Challenged Products prevent, treat, or cure cancer is so strongly implied as to be virtually express. F. 189.

First, the title of the page, in bold type, is "Cancer News." F. 179. Then, the opening paragraph recommends the Challenged Products "[i]f you suffer from any type of cancer." F. 180. Next, the Challenged Products are prominently featured in a photograph adjacent to the bold type phrase "Daniel Chapter One Cancer Solutions." F. 180. Next, adjacent to the text and visual image are bold type instructions to read or listen to testimonials "about cancer." F. 182, 186-87. The audio testimonials include such titles as, "Marie - Dad's throat tumor cured - 7 Herb and more," "Nancy - Cured Breast Cancer in 3 months - 7 Herb and GDU," and "Robert - Prostate cured from DC1 products." F. 187. Written testimonials also appear on the webpage. F. 182-85. These include statements from "Tracey," a purported cancer patient on whom "doctors had . . . given up," that she took BioMixx, 7 Herb Formula, and BioShark, among other DCO products, and that she is "now in complete remission." F. 184. Another testimonial states: "After using 7 Herb and other DC1 products for precancerous growths," among other ailments, her X-ray "showed nothing there." F. 185.

The overall net impression from the interaction of the words, pictures, and testimonials is unmistakable – that the Challenged Products prevent, treat, or cure cancer. *See FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *50-52 (holding that advertisement which included statements that herbal supplement was a "solution" for obesity and "Try Thermalean today and win the battle against obesity" clearly implied that the herbal supplement was an effective treatment for obesity).

(2) "Cancer Treatment" advertisement on www.dc1pages.com

The Challenged Products are advertised as a group on the DCO website www.dc1pages.com. F. 190. The words "Cancer Treatment," in bold and larger type, are featured prominently next to a picture of bottles of the Challenged Products and a listing of their product names. F. 190. The overall net impression of these words and visual images is that the Challenged Products are effective in the treatment of cancer. F. 191.

Respondents contend that use of the phrase "supporting products" at the top of the webpage "indicate[s] that these products are 'supporting products' that can be used in conjunction with cancer treatments, whatever those may be." RRFF No. 137. This contention is belied by the words of the advertisement itself, which states: "To enhance *7 Herb Formula's healing quantities* Daniel Chapter One advises to get familiar with *the supporting products below*." F. 190 (emphasis added). It is clear from this language that the only "cancer treatment" that the Challenged Products are advertised to "support" is DCO's 7 Herb Formula.

(3) "The Most Simple Guide to the Most Difficult Diseases"

The Challenged Products are promoted collectively in the DCO publication, "The Most Simple Guide to the Most Difficult Diseases: The Doctors' How-To Quick Reference Guide." F. 192. The page of the Guide that is dedicated to cancer, which word appears in large, bold type, lists the four Challenged Products in bold type, along with dosing instructions, such as: "7*Herb Formula ™ 2 ounces in juice or water (minimum intake) 2 times daily." F. 192. Each product listing is preceded by a "sun" symbol which, according to the advertisement, means that this product is "essential" for cancer. F. 192. Through the interaction of these words and visual images, the message that the Challenged Products treat or cure cancer is so strongly implied as to be virtually express. F. 193.

(4) Cancer Newsletter

The Cancer Newsletter, viewed as a whole, conveys the overall net impression that the Challenged Products prevent, treat, or cure cancer. First, the title of the publication, "How to fight cancer is your choice," F. 194, sets the stage by strongly implying, if not expressly stating, that the products described in the newsletter will "fight" cancer. *See FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *50-52 (holding that advertisement which included statement regarding herbal supplement, "Try Thermalean today and win the battle against obesity" clearly implied that the herbal supplement was an effective treatment for obesity). In addition, the preface to the Cancer Newsletter quotes a book entitled "Back to Eden," in which the writer states that his "cure for cancer" includes herbs. This in turn implies that the herbal supplements featured in the Cancer Newsletter can cure cancer. F. 196. Against this backdrop, featuring the Challenged Products, as four of only eight products featured in the Cancer Newsletter, implies that the Challenged Products treat or cure cancer. F. 195, 197, 202.

Further creating and reinforcing this overall net impression are the numerous testimonials to the successful use of the Challenged Products for cancer. F. 197-201. While there are only eight product descriptions, there are seventeen testimonials, which at times appear two to a page. The testimonial titles stand out in large, bold type: "Lump is gone without dangerous surgery!," "7 Herb Formula battles cancer," "7 Herb eliminates pre-cancerous growth," "Ancient cancer remedy improved upon," "Doctors gave up on Michigan man," "Pre-Cancerous Growths & Acid and Heartburn," "Tumor Free!," and "Declared Free of Cancer." F. 198. The testimonials include such statements as: "I started taking the 7 Herb and that tumor was shrinking . . . there has been massive tumor shrinkage." F. 199 ("Doctors gave up on Michigan man"); "Tricia convinced [them] that [the] best hope was to take natural remedies rather than go under the knife. . . . The growth is gone. . . ." F. 199 ("Cancer Success a Lie!"); and, "With stage 4 cancer and given only 6 months to live, Joe's dad was not doing well. . . . With 4 ounces of 7*Herb a day, in just 2 days . . . the family watched dad's color come back. . . . GDU to

the rescue! . . . PSA 3.3, no pain, alive. . . .” F. 199 (“Not too late!”).

By including the Challenged Products prominently and referring to them in the testimonials, the Cancer Newsletter implies that the Challenged Products, individually or in combination with one another, prevent, treat, or cure cancer. F. 202.

(5) BioGuide

Like the Cancer Newsletter, the BioGuide makes prominent, overwhelming use of testimonials claiming the successful use of the Challenged Products for cancer. F. 203. The clear implication of the BioGuide, through the words, photographs, and testimonials in particular, is that the Challenged Products prevent, treat, or cure cancer. F. 211. For example, on the page immediately following an advertisement for 7 Herb Formula, there is a picture of a smiling woman and the heading in large, colored, and bold type, “Cancer Brain Tumor.” Next to that entry is the colored, italicized text:

> *The doctors had pretty much given up on Tracey. She had leukemia and tumors on the brain, behind the heart and on her liver.*

The testimonial then claims that the speaker took “*BIOMIXX* and *7 HERB FORMULA,*” which resulted in “complete remission.” It further claims that a tumor above the brain stem “completely disappeared,” a “tumor on my liver is shrinking and the tumor behind my heart has shrunk over 50%. . . .” F. 204.

Similarly styled claims, complete with photographs of smiling people, are made in testimonials entitled: “Lowered PSA,” in which the speaker announces the “GOOD NEWS” of a lowered PSA, and states his belief that 7 Herb Formula and GDU “did the trick,” F. 205; “Prostate Cancer,” in which the author claims that he took 7 Herb Formula and BioMixx, has a lowered PSA, and plans to “stay on [7 Herb Formula] forever!” apparently to keep his cancer at bay, F. 206; and “Renal Cell Cancer,” in which the speaker claims to be taking 7 Herb Formula, GDU, and BioShark,

and that "no further activity" in his kidney tumor has occurred. F. 207. The BioGuide also includes a testimonial from a doctor who claims to have given 7 Herb Formula, BioShark, and GDU to his own child and claims the child's tumor has "begun to shrink. . . . Four months later the whole family is using the products, as well as my patients," F. 209, with the clear implication that these products have the ability not only to cure cancer, but to prevent it as well. Read as a whole, through the interaction of the product descriptions, the visual images, such as highlighted text and photographs, and the testimonials, the BioGuide clearly implies, if not expressly states, that the Challenged Products prevent, treat, or cure cancer. F. 211.

b. Claims regarding BioShark

(1) Website advertising

The product description of BioShark on the DCO Website states in pertinent part:

> 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. . . .

F. 221. Respondents assert that the foregoing statements comprise their entire advertising "claim" for BioShark. *See* RPFF No. 22. Even standing alone, the product description, through the use of such phrases as "inhibits angiogenesis" and "can stop tumor growth," strongly implies that BioShark inhibits tumors. F. 222. The language does not stand alone, however, and must be interpreted in the context of the other elements of the advertisement to determine the overall net impression. *See American Home Prods. v. FTC*, 695 F.2d at 687 (stating that advertisement must be interpreted as a whole, without emphasizing isolated words or phrases apart from their context). In this advertisement, the product webpage specifically promotes BioShark, in bold letters, for "Tumors & Cysts." F. 221. Adjacent to the product description is the message: "Read our clients [sic] testimonials on BioShark & Tumors," and a link to a

bulleted title, "Cancerous Tumor." F. 221. At the bottom of the webpage is a link to "Stop Tumor Growth & Cysts Top." F. 221. Considering these additional elements, the overall net impression of the product webpage for BioShark is that BioShark inhibits cancerous tumors and is an effective treatment for cancer. F. 224.

Adding to the overall net impression of the DCO Website that BioShark inhibits cancerous tumors and is an effective treatment for cancer, is that BioShark is featured as one of the "cancer solutions" for "any type of cancer" on the Cancer News webpage. F. 180. The website www.dc1pages.com also expressly advertises BioShark, along with the other Challenged Products, as a "Cancer Treatment." F. 190.

Further adding to that overall net impression is the following statement, set forth under the BioShark heading, which implies that BioShark inhibits tumors: "In 1983, two researchers at the Massachusetts Institute of Technology published a study showing that shark cartilage contains a substance that significantly inhibits the development of blood vessels that nourish solid tumors, thereby limiting tumor growth. This effect is called anti-angiogenesis." F. 225.

It is not a defense that the advertisements attempt to tie claims to the constituent ingredients of BioShark, i.e., "skeletal tissue of sharks" and "shark cartilage," as opposed to BioShark itself because, despite this word parsing, the overall net impression is that Respondents' claims pertain to the BioShark product itself. *See FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *53-55 (holding that even though express language of the advertising attempted to tie a claim to components of herbal supplement product and not to the product itself, the overall net impression was a claim as to the effectiveness of the product itself).

(2) Cancer Newsletter

The overall net impression from the Cancer Newsletter is that BioShark inhibits tumors and is effective in the treatment of cancer. F. 232. BioShark is among the products that the Newsletter's title represents will "fight" cancer. F. 195, 197.

Moreover, BioShark is specifically included in numerous testimonials. E.g., F. 184 ("7 Herb Formula battles cancer" ("[M]y 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 Pur, Siberian Ginseng, and Bio*Shark. I am now in complete remission.")); F. 200 ("Texas businessman has true friends for life" (Friends send a bladder cancer sufferer a package that "included 7 Herb Formula . . . Bio*Shark and Bio*Mixx"), and "Tumor Free!" (claiming that brain cancer sufferer takes "7 HERB FORMULA . . . BIO MIXX, BIO SHARK, and GDU Caps. . . . [T]he tumors were completely gone.")).

In addition, the Cancer Newsletter includes representations implying that BioShark has been scientifically proven to inhibit tumors, repeating the statement from the Cancer News webpage on the DCO Website: "In 1983, two researchers at the Massachusetts Institute of Technology published a study showing that shark cartilage contains a substance that significantly inhibits the development of blood vessels that nourish solid tumors, thereby limiting tumor growth. This effect is called anti-angiogenesis." F. 231. Adding to and strengthening this impression is the placement of this paragraph in the midst of the large, bold, and highlighted type testimonial titles, "Doctors gave up on Michigan Man" and "Pre-Cancerous Growth & Acid and Heartburn." F. 231.

(3) BioGuide

The BioGuide contains the same product description for BioShark as that found on its product webpage on the DCO Website. F. 221, 228. For the same reasons as those stated above, that product description strongly implies that BioShark inhibits tumors. F. 229. Adding to and reinforcing that implied claim are the testimonials, complete with photographs of smiling people, claiming that BioShark effectively treated cancer. For example, the testimonial "Cancer Brain Tumor" includes the statement: "[M]y 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 BioShark. I am now in complete remission." F. 204.

Similarly, the testimonial entitled "Renal Cell Cancer" includes the following: "I had Renal Cell Cancer in my left kidney, with a tumor attached that was slightly larger than a baseball. I went on 7 Herb Formula and GDU. . . . I continue to drink the 7-Herb and take Bio-Shark, and GDU. . . . [N]o further activity has occurred." F. 207. Another testimonial claims: "After switching to DC1 products – 7-Herb Formula, BioShark, GDU, Garlic Pur, Siberian Ginseng, Ezekiel Oil and BioMixx – [the skin cancer] cleared up quickly. . . . [T]hree weeks ago [I] was told I was completely clear of all types of cancer." F. 208. Accordingly, the BioGuide, taken as a whole, through the interaction of the product descriptions, the visual images such as highlighted text and photographs, and the testimonials, not only represents that BioShark inhibits tumor growth, but that BioShark prevents, treats, or cures cancer. F. 230.

(4) BioMolecular Nutrition Product Catalog

The BioMolecular Nutrition Product Catalog includes a similar product description for BioShark as that set forth on the DCO Website and in the BioGuide, stating: "Shark Cartilage protein inhibits angiogenesis, stops tumor growth, and halts eye diseases. Reduces pain, inflammation, joint stiffness of arthritis, inflammatory bowel disease, and reverses psoriasis. Affects the formation of new blood vessels." F. 233; *see* F. 221, 228. The overall net impression of this description is that BioShark inhibits tumor growth. F. 235. Indeed, the phrase "stops tumor growth" expressly claims that BioShark inhibits tumor growth. F. 234.

c. Claims regarding 7 Herb Formula

(1) Website advertising

The product page for 7 Herb Formula includes in the description, "purify the blood and promote cell repair. The ingredients in this tea concentrate work to clear skin, cleanse the liver, decrease cell mutation, and fight pathogenic bacteria and tumor formation." F. 237. The product is also featured on the Cancer News webpage of the DCO Website with a similar description, stating that 7 Herb Formula "purifies the blood, promotes cell repair, fights tumor formation [and] fights

pathogenic bacteria." F. 238. Respondents focus on these statements, asserting that the statements comprise their website "claim" regarding 7 Herb Formula. Relying on these statements alone, Respondents assert that they did not claim that 7 Herb Formula treats, cures, or prevents cancer. RPFF No. 23. Contrary to Respondents' position, such statements as "fights tumor formation" and "decrease[s] cell mutation," by themselves clearly do imply that 7 Herb Formula inhibits tumors and treats cancer. F. 239.

Moreover, the words do not appear in isolation, but interact with other elements in the advertisement. First, the product description appears under a bold type heading including the words "Cancer Help." F. 237. Next, a picture of the product with its description appears first on the Cancer News webpage, where the phrase "fights tumor formation" is highlighted in bold type. F. 238. Next, after the product description and a photograph of the product along with the other Challenged Products, is the admonition, "How to fight cancer is your choice!" F. 240. In addition, there are links to testimonials "about cancer," with titles that include specific references to 7 Herb Formula, such as "7 Herb Formula battles cancer" and "7 Herb eliminates pre-cancerous growth." F. 241. These elements interact to create a strong impression that 7 Herb Formula not only inhibits tumor growth, but is an effective treatment for cancer.

The text of testimonials strengthens this impression. For example, in the testimonial entitled "7 Herb Formula Battles Cancer," the speaker claims taking 7 Herb Formula, among other DCO products, for cancer and experiencing a "complete remission," thereby creating the impression that 7 Herb Formula cured her. F. 184; *see also* F. 243 (describing Michigan man's claim of taking 7 Herb Formula and experiencing "massive tumor shrinkage"). In addition, the testimonial entitled "7 Herb Eliminates Pre-cancerous Growth" states in part, "I had a pre-cancerous 'wart' on the back of my leg and drinking 7 Herb Formula made it go away," thereby creating the impression that 7 Herb Formula prevents cancer. F. 242.

Other material on the DCO Website further contributes to the overall net impression that 7 Herb Formula is an effective cancer

treatment. The Cancer News webpage article, "Ancient Cancer Remedy is Improved Upon," includes statements that "Jim improved upon the ancient Ojibway Indian Tribe remedy known as Essiac. . . . As a result of his research, Jim found that by adding Siberian Ginseng and Cat's Claw to the Essiac formula, he could attain remarkable healing results. . . ." F. 242; *see also* F. 244 ("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."). Such statements clearly imply, if not expressly represent, that 7 Herb is an effective cancer remedy. *See FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *51-52 (holding that advertisement which included statements that herbal supplement was the "most complete . . . nutriceutical ever developed for the diet industry" implied that the herbal supplement was an effective treatment for obesity).

The DCO website www.dc1pages.com expressly advertises 7 Herb Formula, along with the other Challenged Products, as a "Cancer Treatment" and specifically refers to its "healing qualities." F. 190. In addition, the question and answer portion of this site, similar to that on the DCO Website, makes the claim that 7 Herb Formula is the "most effective and potent formula available in the battle against tumors," F. 246, and therefore similarly represents that 7 Herb Formula is an effective cancer remedy. *See FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *51-52 (holding that advertisement which included statements that herbal supplement product was the "most complete . . . nutraceutical ever developed for diet industry" implied that the herbal supplement was an effective treatment for obesity). Finally, the website www.dc1pages.com states that 7 Herb Formula has been used in cancer clinics and provided in doctor's offices, thereby creating the impression that 7 Herb Formula is a cancer treatment. F. 247. Viewed in its entirety, the overall net impression of the advertising for 7 Herb Formula on www.dc1pages.com is that the product inhibits tumors and is effective for the treatment of cancer. F. 248.

(2) Cancer Newsletter

The product description for 7 Herb Formula in the Cancer Newsletter states that 7 Herb Formula "fights . . . tumor

formation." F. 251. Accordingly, the advertisement clearly implies that the product inhibits tumor formation. Combined with the statements that "7 Herb Formula has been created to . . . promote cell repair . . . fights pathogenic bacteria . . . [t]he ingredients . . . decrease cell mutation," the product description also implies that 7 Herb Formula is effective in treating cancer. F. 251, 255. The advertisement also states, immediately below the product description under a heading, in large, bold type, "esophageal cancer?" that the ingredients of 7 Herb Formula "may prevent and even heal cancer." F. 252. These statements strongly imply, if not expressly state, that 7 Herb Formula prevents or cures cancer. *See FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *53-55 (holding that even though the express language of advertising attempted to tie a claim to components of herbal supplement product and not to the product itself, overall net impression was a claim as to the effectiveness of the product itself).

Moreover, the above product descriptions must be interpreted with reference to other elements of the Cancer Newsletter. First, 7 Herb Formula is included among the eight products that the Cancer Newsletter's title represents will "fight" cancer. F. 195, 197. In fact, the Cancer Newsletter particularly highlights 7 Herb Formula, devoting an entire page to the product and prominently featuring its logo. F. 251. In addition, several testimonial titles specifically refer to 7 Herb Formula. E.g., F. 184 ("7 Herb Formula battles cancer"); F. 198 ("7 Herb Formula Eliminates Pre-Cancerous Growth"); F. 253 (same); F. 204 ("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. . . . I am now in complete remission"); F. 242 ("I had a pre-cancerous 'wart' on the back of my leg and drinking 7 Herb Formula made it go away"); and F. 253 ("7 Herb Formula Helps Battle Cancer" ("Within 60 days [of being on 7 Herb Formula] . . . PSA level dropped from 256 to 5. . . . [Thereafter, n]o evidence of . . . tumor.")).

The interaction of all of the elements of the Cancer Newsletter, including the title of the publication, the prominent featuring of 7 Herb Formula in text, visual imagery, and testimonials, and the content of the product descriptions and

testimonials, creates an overall net impression that 7 Herb Formula inhibits tumors and is effective to prevent, treat, or cure cancer. F. 255.

(3) BioGuide

The product description for 7 Herb Formula in the BioGuide, mirroring that on the DCO Website, includes the statements: "Herbs to purify the blood and promote cell repair. The ingredients in this tea concentrate work to clear skin, cleanse the liver, decrease cell mutation, and fight pathogenic bacteria and tumor formation." F. 237, 249. As on the DCO Website, these statements do not stand alone.

The product description is repeated twice in the three pages devoted to 7 Herb Formula. F. 249. Moreover, in between these pages is a page containing two testimonials to 7 Herb Formula. The first testimonial, "Cancer Brain Tumor," shows a smiling woman next to text highlighting the use of 7 Herb Formula in sending her cancer into "complete remission" and shrinking other tumors. F. 249. The placement and title of the second testimonial, "Lowered PSA," itself implies that 7 Herb Formula is related to the reported improvement in that cancer indicator. The testimonial features a photograph of a smiling man and text expressly stating the speaker's belief that the DCO products he took, including 7 Herb Formula, "did the trick." F. 205. Other testimonials in the BioGuide make similar claims as to the effectiveness of 7 Herb Formula to prevent, treat, or cure cancer. *See, e.g.*, F. 206 (testimonial entitled "Prostate Cancer," stating that the speaker took 7 Herb Formula "every day . . . . [It] did such a good job fighting cancer, 2 ounces is a good prophylaxis!"); F. 207 (testimonial entitled "Renal Cell Cancer," stating that the speaker with cancerous kidney tumor went on 7 Herb Formula and the oncologist is "amazed that no further activity has occurred"); F.208 (testimonial entitled "Skin Cancer," in which the speaker switches to DCO products, including 7 Herb Formula, and is "completely clear of all types of cancer").

The overall net impression from the BioGuide, through the interaction of the words of the product descriptions, the visual images such as highlighted text and photographs, and the

testimonials, is that 7 Herb Formula inhibits tumors and is effective to prevent, treat, or cure cancer. F. 250.

(4) BioMolecular Nutrition Product Catalog

The BioMolecular Nutrition Product Catalog describes 7 Herb Formula in virtually the same manner as the DCO Website, the BioGuide, and the Cancer Newsletter, stating that the herbs in 7 Herb Formula "purify the blood and promote cell repair, clear skin, cleanse the liver, decrease cell mutation, [and] fight pathogenic bacteria and tumor formation." F. 237, 249, 251, 256. As noted above, use of the phrase, "fights . . . tumor formation" strongly implies, if not expressly states, that the product inhibits tumor formation. Combined with the phrases "promote cell repair," "decrease cell mutation," and "fight pathogenic bacteria," the product description as a whole implies that 7 Herb Formula is effective in treating cancer. *See FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *53-55 (holding that even though express language of advertising attempted to tie a claim to components of herbal supplement product and not to the product itself, overall net impression was a claim as to the effectiveness of the product itself).

d. Claims regarding GDU

(1) Website advertising

The product page for GDU on the DCO Website includes statements that the ingredients of GDU "digest protein – even that of unwanted tumors and cysts" and that GDU is used "as an adjunct to cancer therapy." F. 262-63. These statements imply that GDU inhibits tumors and is a cancer treatment. F. 264. In addition, the product webpage has links to testimonials with various cancer-related titles, including, "Breast Mass" and "Prostate Cancer." F. 265. The interaction of the product description and cancer-related testimonial titles gives this DCO Website advertisement a strong overall net impression that GDU not only inhibits tumors, but is an effective cancer treatment or cure. F. 269.

Other features on the DCO Website strengthen this impression. GDU is featured as a "Cancer Solution" for "any type of cancer" on the Cancer News webpage on the DCO Website, further reinforcing the implication that GDU is an effective cancer treatment. F. 266. Testimonials on that webpage, or linked to the webpage, also claim that taking GDU, along with other DCO products, effectively treated cancer. F. 267; F. 268 ("Nancy – Cured Breast Cancer in 3 months – 7 Herb and GDU" and "Mel – Breast Mass [illegible] and GDU"). This website advertising also creates the impression that GDU is an effective cancer treatment. F. 269.

The DCO website www.dc1pages.com also claims that GDU is an effective treatment by expressly advertising GDU, among the other Challenged Products, as a "Cancer Treatment." F. 190.

(2) Cancer Newsletter

The product description for GDU in the Cancer Newsletter appears under the headline in large, bold type: "Enzymes attack growths." F. 276. The advertisement goes on to explain how the enzymes in GDU "can aid the body in breaking down a tumor." F. 276. It emphasizes the importance of enzymes "in treating cancer," stating that such enzymes can return leukemia cells "to a normal state," and help "to destroy cancer cells." F. 276. While these statements ostensibly refer only to the enzyme ingredient in GDU, they impliedly represent that GDU itself has these cancer treating qualities. F. 277. *See FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *53-55 (holding that overall net impression was a claim as to the effectiveness of the product itself, even though express language of advertising attempted to tie claims to components of herbal supplement product and not to the product itself).

Even though the language of the product description for GDU in the Cancer Newsletter attempts to relegate GDU's claimed effectiveness to a supporting role in "helping" or "aiding" the body, "[t]he entire mosaic should be viewed rather than each tile separately." *FTC v. Sterling Drug*, 317 F.2d at 674. In this case, the entire mosaic of the advertisement belies a merely "supporting" role for GDU. The overall net impression is that

GDU itself inhibits tumors and is an effective cancer treatment. F. 278.

GDU is one of the eight products that the Cancer Newsletter's title represents will "fight" cancer. F. 195, 197. The product description appears under the heading in large, bold type: "Enzymes attack growths." F. 276. Adjacent to the GDU headline, photograph, and product description are two testimonials with large type, highlighted and bold headlines: "Lump is gone without dangerous surgery" and "Cancer Success a Lie!" F. 276. Other testimonials in the Cancer Newsletter claim that taking GDU, along with other DCO products, effectively treats cancer. F. 200 ("Tumor Free!" claims brain cancer sufferer takes "7 HERB FORMULA . . . , BIO MIXX, BIO SHARK, and GDU Caps . . . [and thereafter] the tumors were completely gone"); and F. 199 ("Not too late!" in which a stage-four cancer patient with six months to live announces, "GDU to the rescue!").

The interaction of all of the elements of the Cancer Newsletter, including the title of the publication, the featuring of GDU, the product description headline and text, and the titles and content of its testimonials, creates an overall net impression that GDU inhibits tumors and is an effective cancer treatment. F. 278.

(3) BioGuide

The BioGuide features the product description for GDU on two pages. F. 270. The descriptions track those on the DCO Website and in the Cancer Newsletter, stating that GDU contains enzymes "to help digest protein - even that of unwanted tumors and cysts," and that GDU has a variety of uses, including "as an adjunct to cancer therapy." F. 263, 270-71. The former statement is repeated in large, bold type, thereby emphasizing the purported ability of GDU to "digest . . . tumors and cysts." F. 271. Taken as a whole, this product description implies that GDU inhibits tumors and implies that GDU is a cancer treatment. F. 272.

There are additional elements in the BioGuide that create the overall net impression that GDU inhibits tumors and is an effective treatment for cancer. The product name "GDU," in large, bold type, and the statement, also in large, bold type,

regarding its effect on "tumors and cysts," appear above a photograph of a smiling man, and the large, bold type testimonial title, "Prostate Cancer." F. 271.

Moreover, testimonials in the BioGuide discuss the use of GDU in treating cancer. For example, on the page immediately following the GDU product description, the testimonial entitled "Breast Mass" claims that after discovering a breast mass, the speaker "began taking GDU six times a day . . . . I got another bottle of GDU and the Superior Herbal Fat Burners, which I took twice a day. In April I had my 6-month examination and the letter read: 'We are pleased to inform you that the results of your recent breast evaluation are normal.'" F. 273. Similarly, the testimonial entitled "Renal Cell Cancer" describes the speaker's use of GDU for a kidney tumor: "I went on 7 Herb Formula and GDU . . . . I continue to drink the 7-Herb and take Bio-Shark, and GDU. . . . To date, my oncologist is amazed that no further activity has occurred." The latter statement is repeated in large, bold type. F. 207. In addition, the testimonial entitled "Lowered PSA" announces the speaker's "GOOD NEWS" of a lowered PSA after taking "7 Herb formula, in combination with your Bio C 1000, GDU and other minerals and vitamins. I believe it was your products that did the trick." F. 274; *see also* F. 208 ("Skin Cancer": "After switching to DC1 products – 7-Herb Formula, BioShark, GDU, Garlic Pur, Siberian Ginseng, Ezekiel Oil and BioMixx – it cleared up quickly . . . completely clear of all types of cancer"); F. 209 ("My son was diagnosed with a tumor on his left temple. . . . Jim and Trish . . . suggested 7-Herb, BioShark and GDU, which we bought and started him on. . . . [T]he tumor had already begun to shrink. . . . Four months later the whole family is using the products, as well as my patients, and you would never know my son had a tumor"); F. 210 ("One lady, who had a history of cancer, used the 7 Herb Formula, GDU & BioShark and was blessed to get rid of a large breast tumor.").

The interaction of all of the elements of the BioGuide regarding GDU, including the product descriptions, the visual images, such as highlighted text and photographs, and the testimonials, create the overall net impression that GDU inhibits tumors and is an effective cancer treatment. F. 275.

(4) BioMolecular Nutrition Product Catalog

The product description for GDU in the BioMolecular Nutrition Product Catalog mirrors that in the other DCO publications, stating that GDU contains enzymes "to help digest protein, even that of unwanted tumors and cysts. Helps to relieve pain, inflammation, and as an adjunct to cancer therapy." F. 263, 270, 276, 279. As stated above, taken as a whole, this product description implies that GDU inhibits tumors and is a cancer treatment. F. 280-81.

e. Claims regarding BioMixx

(1) Website advertising

Both the DCO Website and the website www.dc1pages.com imply that BioMixx is effective in treating or curing cancer. The Cancer News webpage on the DCO Website expressly advertises BioMixx, along with the other Challenged Products, as a "Cancer Solution" for "any type of cancer." F. 283. The Cancer News webpage also includes a testimonial representing that BioMixx effectively treated cancer: "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. . . . I am now in complete remission." F. 284. The website www.dc1pages.com also claims that BioMixx is an effective cancer treatment by expressly advertising BioMixx, among the other Challenged Products, as a "Cancer Treatment." F. 285.

(2) Cancer Newsletter

The product description for BioMixx in the Cancer Newsletter claims that BioMixx "is used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatments." F. 293. As with the similar word parsing used for the product descriptions for GDU (*see* F. 276), Respondents' attempt to relegate BioMixx's effectiveness to a supporting role in assisting the body fails. It is necessary to consider the advertisement "in its entirety and not to engage in

disputatious dissection." *FTC v. Sterling Drug*, 317 F.2d at 674. In this case, the "entire mosaic" of the Cancer Newsletter creates the overall net impression that BioMixx is an effective cancer treatment and ameliorates the adverse effects of radiation and chemotherapy. F. 294.

BioMixx is one of the eight products that the Cancer Newsletter's title represents will "fight" cancer. F. 195, 197. In addition, BioMixx is among the products referred to in the testimonial "7 Herb Formula Battles Cancer," in which the speaker is quoted as saying: "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. . . . I am now in complete remission." F. 292. Viewing the Cancer Newsletter as a whole, and considering the interaction of the publication's title, the BioMixx product description, and the testimonial, the overall net impression is that BioMixx is an effective cancer treatment and heals the adverse effects of radiation and chemotherapy. F. 294.

(3) BioGuide

The lengthy product description for BioMixx in the BioGuide states in relevant part that BioMixx "[h]elps detoxify the body [and] boosts immunity and energy. . . . 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. . . . This scientifically designed formula provides your body with [herbs and nutrients] . . . for cell, organ, and tissue health . . . . Whether you're losing weight battling illness, or are weakened due to intense training, BioMixx is the best." F. 287. This description conveys the clear message that BioMixx is an effective treatment for the adverse effects of chemotherapy and radiation. F. 288. By juxtaposing the promotion of BioMixx for this purpose with the promotion of BioMixx for "cell" health and to "battle illness," the advertisement also conveys the impression that BioMixx is effective for cancer. F. 291.

The impression that BioMixx is an effective cancer treatment, as well as an antidote to the adverse effects of chemotherapy and radiation, is strengthened by the message of testimonials. For example, the testimonial entitled "Cancer Brain Tumor" appears prominently, next to a photo of a smiling woman, and includes the statements: "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. . . . I am now in complete remission. . . ." F. 204, 289. BioMixx is also featured in a prominent testimonial entitled "Prostate Cancer," which states in part: "I had beam radiation for prostate cancer. I also took 7 Herb Formula . . . 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!" F. 290.

Viewed as a whole, considering the product descriptions, the visual images, such as highlighted text and photographs, and the testimonials, the BioGuide conveys the overall net impression that BioMixx is effective in the treatment of cancer and in healing the adverse effects of radiation and chemotherapy. F. 291.

f. Disclaimer language

Respondents assert that their website advertising contains the following disclaimer: "These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent disease." RFF 16 (citing CX 17 at FTC-DCO 0073, 0076, 0080, 0084, 0089, 0095, 0098). Respondents' cited disclaimer appears on certain shopping cart webpages on the website www.dc1store.com. F. 301. Relatively similar disclaimers, but briefer and without the FDA reference, appear on the bottom of certain webpages from www.dc1pages.com, at the bottom of webpages on danielchapterone.com, at the end of the BioGuide, and on the last page of the Cancer Newsletter. F. 296-300.

"Disclaimers or qualifications in any particular ad are not adequate to avoid liability unless they are sufficiently prominent and unambiguous to change the apparent meaning of the claims

and to leave an accurate impression. Anything less is only likely to cause confusion by creating contradictory double meanings." *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1497 (1st Cir. 1989) (citing *Giant Food, Inc. v. FTC*, 322 F.2d 977, 986 (D.C. Cir. 1963)); *accord FTC v. U.S. Sales Corp.*, 785 F. Supp. 2d. 737, 751 (N.D. Ill. 1992). Applying these standards to evaluate the above disclaimer, as well as similar disclaimers in the DCO advertising materials, it is readily apparent that the disclaimers are ineffective to alter the overall net impression of the advertisements or to leave an accurate impression.

The purported disclaimers are not prominent in any advertisement. In each case, the disclaimer appears well after the conclusion of the advertising claims. F. 296-300. In each instance, the disclaimer appears in type that is the same size, or smaller, than the surrounding type. F. 296-301, 303. The disclaimer in the Cancer Newsletter is virtually infinitesimal. F. 299, 303. In each instance, except for the webpages cited by Respondents, the disclaimer is buried in copyright disclosures. F. 296-300. Such small-print disclaimers at the bottom of advertisements are insufficient. *See FTC v. Medlab, Inc.*, No. C 08-822 SI, 2009 U.S. Dist. LEXIS 33917, at *15 (N.D. Cal. Apr. 21, 2009) ("Defendants cannot inoculate themselves from the representations that appear in the body of the text by including cautionary statements at the foot of the advertisements.").

Moreover, the language disclaiming any intent to "treat" any disease only serves to confuse in this case by interjecting a message that is contradictory to the overall net impression that the Challenged Products do treat cancer. For example, the disclaimer language appearing on one of the pages of www.dc1pages.com is followed on the next page, in bold type font far larger than that used for the disclaimer, by language touting:

> CANCER TREATMENT
>
> 7 Herb Formula
> Bio*Shark
> BioMixx
> GDU Caps

F. 304.

Because the purported disclaimers are not prominent or unambiguous, and create confusion with messages that contradict the advertisements' overall messages, the disclaimers are ineffective. *See In re Giant Food*, No. 7773, 61 F.T.C. 326, 1962 FTC LEXIS 85, at *51-52 (July 31, 1962) (holding that small print disclaimers that were inconsistent and contradictory to the content of the advertisements were ineffective to cure deceptive advertising), *aff'd, Giant Food, Inc. v. FTC*, 322 F.2d 977, 986 (D.C. Cir. 1963); *FTC v. QT, Inc.*, 448 F. Supp. 2d at 924 n.15 (stating that inconspicuous, periodic, on-screen statement in infomercial that "'this product is not intended to diagnose, treat, cure or prevent disease' [was] wholly inadequate to change the net impression of the pain relief claims made"). Accordingly, the disclaimers in Respondents' advertisements in this case are not adequate to avoid liability. *See FTC v. Phoenix Avatar, LLC*, No. 04 C 2897, 2004 U.S. Dist. LEXIS 14717 (N.D. Ill. July 29, 2004) (holding that disclaimer on the back of product packaging, that "[t]hese statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease," did not foreclose liability for deceptive advertising of weight-loss product).

g. Extrinsic evidence is not required

Respondents contend that their advertisements cannot be interpreted through a facial analysis alone, and that extrinsic evidence of consumer perceptions is required in order to find implied claims. RB at 5, 7, 10. Both the Commission and the courts, however, have squarely rejected the notion that extrinsic evidence is always necessary in order to prove an implied claim. As the Commission explained in *Thompson Medical*:

> [T]he Commission employs two different techniques in evaluating whether an advertisement contains implied claims. One is to look at evidence from the advertisement itself. We often conclude that an advertisement contains an implied claim by evaluating the conten[t] of the advertisement and the circumstances surrounding it. This technique is primarily useful in evaluating advertisements whose language or

> depictions are clear enough, though not express, for us to conclude with confidence after examining the interaction of all the different elements in them that they contain a particular implied claim. If our initial review of evidence from the advertisement itself does not allow us to conclude with confidence that it is reasonable to read an advertisement as containing a particular implied message, we will not find the ad to make the implied claim unless extrinsic evidence allows us to conclude that such a reading of the ad is reasonable.

104 F.T.C. at 789, 1984 FTC LEXIS 6, at *312-13.

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

> Courts, including the Supreme Court, have uniformly rejected imposing such a requirement on the FTC, and we decline to do so as well. We hold that the Commission may rely on its own reasoned analysis to determine what claims, including implied ones, are conveyed in a challenged advertisement, so long as those claims are reasonably clear from the face of the advertisement. . . . The implied claims Kraft made are reasonably clear from the face of the advertisements. . . . Hence the Commission was not required to utilize consumer surveys in reaching its decision. 970 F.2d at 319-20 (citing *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 391-92 (1965) (stating that the FTC is not required to conduct consumer surveys before determining that a commercial has a tendency to mislead) (other citations omitted)).

In this case, Respondents' advertising claims are even more clearly implied than those in *Kraft*. The interaction of product

descriptions, advertisement headings, visual images, testimonial titles, and testimonial texts, among other elements, is more than sufficient to conclude with confidence that the advertisements at issue make the claims alleged in the Complaint. The implied claims in Respondents' advertising are beyond "reasonably clear." They are clear and conspicuous from the advertising itself. Accordingly, no extrinsic evidence is necessary to interpret the claims. *See FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *42 n.12 (entering summary judgment in false advertising case where facial analysis of dietary supplement advertisements showed clearly implied claims of effectiveness for treatment of erectile dysfunction, holding that extrinsic evidence of consumer perceptions was unnecessary as a matter of law). *See also FTC v. QT, Inc.*, 448 F. Supp. 2d at 958 (stating: "'The courts and the FTC have consistently recognized that implied claims fall along a continuum from those which are so conspicuous as to be virtually synonymous with express claims to those which are barely discernible. It is only at the latter end of the continuum that extrinsic evidence is necessary.'") (quoting *FTC v. Febre*, No. 94 C 3625, 1996 U.S. Dist. LEXIS 9487, at *14 (N.D. Ill. July 3, 1996)).

Respondents contend that extrinsic evidence is particularly necessary in this case because the advertising was targeted at a particular group, defined by Respondents as individuals devoted to natural health in general and the constituents of Respondents' religious ministry in particular. RB at 6-7. While it is true that, if an advertisement is targeted at a particular group, the Commission analyzes the advertisements from the perspective of reasonable consumers within that group, *In re Telebrands*, 140 F.T.C. at 291, in this case there is insufficient evidence to conclude that Respondents' advertising was directed only at the target group Respondents allege. Rather, the evidence shows that anyone can access the advertisements. The DCO publication, "The Most Simple Guide," is available on the DCO Website and anyone can download it. F. 163. The BioGuide and the Cancer Newsletter are also available on-line through the DCO Website. F. 169, 172. Consumers can locate the DCO Website by entering the term "cancer" in a Google search. F. 162. Moreover, nothing on the DCO Website indicated to the FTC investigator who made the undercover purchase in this case that a consumer would have to

be part of any religious community in order to purchase the Challenged Products. F. 149. Accordingly, it is not necessary to interpret Respondents' claims from the perspective of Respondents' purported target group and extrinsic evidence is not necessary for that purpose.

2. Respondents' claims are misleading

There are two theories to prove that an advertisement is deceptive or misleading: (1) the "falsity" theory[4] or (2) the "reasonable basis" theory. *FTC v. Pantron I*, 33 F.3d at 1096; *In re Thompson Medical*, 104 F.T.C. at 818-19, 1984 FTC LEXIS 6, at *380-81. The Complaint in this case makes allegations only under the reasonable basis theory (Complaint ¶¶ 15, 16) and thus the analysis in this decision considers the reasonable basis theory only.

The reasonable basis theory holds that claims about a product's attributes, performance, or efficacy ("objective" product claims[5]) carry with them the express or implied representation that the advertiser had a reasonable basis substantiating the claims at the time the claims were made. *In re Thompson Medical*, 104 F.T.C. at 813, 1984 FTC LEXIS 6, at *367; *FTC v. Direct Marketing Concepts*, 569 F. Supp. 2d at 298; *In re Kroger*, No. C-9102, 1978 FTC LEXIS 332, at *15 (May 17, 1978). Respondents' advertising claims, including claims that the Challenged Products are "Cancer Treatments" and "Cancer Solutions," are objective product claims because the claims are stated in positive terms and are not qualified to be statements of opinion. *See Koch v. FTC*, 206 F.2d 311, 318 (6th Cir. 1953). In addition, Respondents' testimonials constitute objective claims that the products inhibit tumors or are otherwise effective in the treatment of cancer. *See id.* Accordingly, Respondents implied

[4] Under the "falsity" theory, in order to prevail, the government must carry the burden of proving that the express or implied message conveyed by the ad is false. *Pantron I v. FTC*, 33 F.3d at 1096; *In re Thompson Medical*, 104 F.T.C. at 818-19, 1984 FTC LEXIS 6, at *379-80.

[5] Claims regarding a product's attributes, performance, or efficacy are considered "objective" claims, as opposed to mere sales "puffery," because such claims can be objectively verified. *In re Thompson Medical*, 104 F.T.C. at 788-89 n.6, 1984 FTC LEXIS 6, at *312 n.6.

that they had a reasonable basis to substantiate these claims. *See In re Thompson*, 104 F.T.C. at 813, 1984 FTC LEXIS 6, at *367. *See also* Answer ¶ 15 (admitting that Respondents relied upon a reasonable basis that substantiated the challenged representations).

In determining whether an advertiser has satisfied the reasonable basis requirement, it must be determined (1) what level of substantiation the advertiser is required to have for its advertising claims, and then (2) whether the advertiser possessed and relied on that level of substantiation. *FTC v. Pantron I*, 33 F.3d at 1096; *FTC v. QT, Inc.*, 448 F. Supp. 2d at 959. Respondents have the burden of establishing what substantiation they relied on for their product claims and Complaint Counsel has the burden of proving that Respondents' purported substantiation is inadequate. *FTC v. QT, Inc.*, 448 F. Supp. 2d at 959.

If an advertiser does not have a reasonable basis substantiating its claims, the representations are deceptive or misleading. *FTC v. Pantron I*, 33 F.3d at 1096; *FTC v. Sabal*, 32 F. Supp. 2d at 1007; *FTC v. QT, Inc.*, 448 F. Supp. 2d at 959-60. As further discussed below, the appropriate level of substantiation for health-related efficacy claims, such as those made by Respondents here, is "competent and reliable scientific evidence." Because Respondents did not possess or rely upon such evidence, Respondents' advertising claims are misleading.

a. Competent and reliable scientific evidence is needed for health-related efficacy claims

The level of substantiation required depends on whether the advertising claims at issue are (1) establishment claims or (2) non-establishment claims. *Thompson Medical Co. v. FTC*, 791 F.2d 189, 194 (D.C. Cir. 1986). Establishment claims are those that contain representations regarding the amount of support the advertiser has for its product claims. *Id.; FTC v. Direct Marketing Concepts*, 569 F. Supp. 2d at 298 (citing FTC Policy Statement on Advertising Substantiation, appended to *In re Thompson Medical*, 104 F.T.C. at 839, 1984 FTC LEXIS 6, at *434 (hereinafter "Policy on Advertising Substantiation")). "They are in effect statements 'that scientific tests establish that a

product works.'" *FTC v. Direct Marketing Concepts*, 569 F. Supp. 2d at 298 (citing *Removatron v. FTC*, 884 F.2d at 1492 n.3). Common examples of establishment claims include statements such as "tests prove," "doctors recommend," or "studies show." *Id.* at 298-99 (citing Policy on Advertising Substantiation; *Thompson Medical Co. v. FTC,* 791 F.2d at 194) (other citations omitted). Where the challenged advertisements contain establishment claims, the Commission expects the advertiser to have at least the amount and type of substantiation it claimed to have had. *Thompson Medical Co. v. FTC*, 791 F.2d at 194. *See Removatron v. FTC*, 884 F.2d at 1498 (holding that advertiser lacked reasonable basis for establishment claim as to product's hair removal effects, as a matter of law, because advertiser did not have any well-controlled scientific studies supporting the claim).

By contrast, a non-establishment claim is simply a claim about a product's attributes, performance, or efficacy, without indicating any particular level of support for such claim. *In re Thompson Medical*, 104 F.T.C. at 815, 1984 FTC LEXIS 6, at *370. For non-establishment claims, what constitutes sufficient substantiation may depend on multiple factors, such as the type of claim, the type of product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation that experts in the field believe is reasonable. *FTC v. Direct Marketing Concepts*, 569 F. Supp. 2d at 299 (citing *Removatron v. FTC*, 884 F.2d at 1492 n.3); *accord FTC v. QT, Inc.*, 448 F. Supp. 2d at 959 (citing Policy on Advertising Substantiation). In *Thompson Medical*, the Commission stated that determining the appropriate level of substantiation for non-establishment claims requires weighing the following factors: (1) the product involved; (2) the type of claim; (3) the benefits of a truthful claim; (4) the ease of developing substantiation for the claim; (5) the consequences of a false claim; and (6) the amount of substantiation experts in the field would agree is reasonable. 104 F.T.C. at 821, 1984 FTC LEXIS 6, at *387 (citing *In re Pfizer, Inc.* 81 F.T.C. 23 (1972), *aff'd,* 791 F.2d 189 (D.C. Cir. 1986) (hereinafter the "*Pfizer* factors").

The DCO advertising at issue represents that the Challenged Products, individually or collectively, prevent, treat, or cure

cancer, inhibit tumors, or ameliorate the adverse effects of chemotherapy or radiation. F. 189, 191, 193, 202, 211, 222, 224, 227, 229, 230, 232, 234, 235, 239, 245, 248, 250, 255, 257, 258, 269, 272, 275, 277-78, 280-81, 286, 288, 291, 294. The advertisements do not represent that the claims have been proven by scientific testing, except in a very few cases. *E.g.*, F. 225, 231, 247. Complaint Counsel has not alleged or argued that Respondents' advertisements constitute establishment claims. Accordingly, the claims at issue are deemed non-establishment claims, and will be evaluated as such.

As discussed below, the challenged claims made by Respondents are health-related efficacy claims. It is well established that health-related efficacy claims, including those made about dietary supplements specifically, must be substantiated by "competent and reliable scientific evidence." *FTC v. Natural Solution, Inc.*, No. CV 06-6112-JFW, 2007 U.S. Dist. LEXIS 60783, at *11-12 (C.D. Cal. Aug. 7, 2007) (requiring competent and reliable scientific evidence to substantiate claims that liquid botanical dietary supplement Knutric was a treatment to prevent and fight various forms of cancer); *FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *43-44 (requiring competent and reliable scientific evidence to substantiate claims that dietary supplements under the brand names Thermalean, Lipodrene, and/or Spontane-ES, were effective for weight loss and sexual enhancement); *FTC v. Direct Marketing Concepts*, 569 F. Supp. 2d at 300, 303 (requiring competent and reliable scientific evidence to substantiate claims that dietary supplements, Coral Calcium and Supreme Greens, were effective to prevent, treat, or cure cancer); *see also FTC v. QT, Inc.*, 448 F. Supp. 2d at 961 (requiring competent and reliable scientific evidence to substantiate claims that the Q-Ray bracelet provided immediate, significant, or complete relief from various types of pain).

The foregoing authorities concluded that competent and reliable scientific evidence was the appropriate level of substantiation for health-related efficacy claims without first considering each of the *Pfizer* factors. However, to the extent specific application of the *Pfizer* factors is necessary for health-related efficacy claims, such application yields the same result:

Respondents must have possessed and relied upon competent and reliable scientific evidence to substantiate the health-related efficacy claims that they made. Each of the *Pfizer* factors is considered below.

(1) The type of product

Products related to consumer health require a high level of substantiation, such as scientific tests. *In re Removatron Int'l Corp.*, No. 9200, 111 F.T.C. 206, 1985 FTC LEXIS 21, at *212 n.20 (Nov. 4, 1988), *aff'd*, 884 F.2d 1489; *In re Thompson Medical*, 104 F.T.C. at 822, 1984 FTC LEXIS 6, at *388. Claims that the Challenged Products prevent, treat, or cure cancer, inhibit tumors, or ameliorate the adverse effects of radiation and chemotherapy relate to consumer health. F. 219, 236, 259, 282, 295. Accordingly, a high level of substantiation is required.

(2) The type of claim

Claims that are difficult or impossible for consumers to evaluate for themselves require a high level of substantiation, such as scientific tests. The "placebo" effect of consumer expectations when taking a purported remedy makes it difficult for consumers to verify product effectiveness for themselves. *In re Removatron*, 1985 FTC LEXIS 21, at *212 n.20; *In re Thompson Medical*, 104 F.T.C. at 822-23, 1984 FTC LEXIS 6, at *389; *FTC v. Pantron I*, 33 F.3d at 1090 n.1. In this case, for example, consumers cannot effectively determine for themselves the accuracy of the claim that BioShark inhibits tumors. Similarly, consumers reading "Tracey's" testimonial cannot evaluate whether the claimed "complete remission" of Tracey's cancer is due to her consumption of the Challenged Products or some other factor. Therefore, a high level of substantiation is required.

Respondents maintain that the challenged advertising does not state that the Challenged Products prevent, treat, or cure disease or tumors, and that Respondents' "express statements" constitute "structure/function" claims. RPFF No. 27, 36, 42, 43. Respondents state that the phrase "structure or function," in the context of dietary supplements claims, refers to representations

about a dietary supplement's effect on the structure or function of the body for maintenance of good health and nutrition. RB at 3-4 (citing the FTC's Guide, *Dietary Supplements: An Advertising Guide for Industry*, at 26 n.2). As discussed in Section III D 1, *supra*, the words used in an advertisement cannot be viewed in isolation, but must be viewed along with all the other elements of the advertisement to obtain the overall net impression. The evidence demonstrates that the overall net impression of Respondents' advertising is that the Challenged Products, individually or collectively, prevent, treat, or cure cancer, inhibit tumors, or ameliorate the adverse effects of chemotherapy or radiation. F. 189, 191, 193, 202, 211, 222, 224, 227, 229, 230, 232, 234, 235, 239, 245, 248, 250, 255, 257, 258, 269, 272, 275, 277-78, 280-81, 286, 288, 291, 294. These are health-related claims. F. 219, 236, 259, 282, 295. Therefore, Respondents' argument that they should be held to a lower standard of substantiation because they made "structure/function" claims is without merit. *See FTC v. QT, Inc.*, 448 F. Supp. 2d at 962 ("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. The choice belonged to Defendants.").

(3) The benefits of a truthful claim and the ease of developing substantiation for the claim

These two factors – the benefits of a truthful claim and the ease of developing substantiation for the claim – are typically considered together. The consideration of these factors seeks to ensure that the level of substantiation required is not likely to deter product development or prevent disclosure of potentially valuable information about product characteristics to consumers. *In re Removatron*, 1985 FTC LEXIS 21, at *212 n.20; *In re Thompson Medical*, 104 F.T.C. at 823-24, 1984 FTC LEXIS 6, at *391.

The fact that cancer patients could benefit from truthful claims of effective treatments is obvious. Respondents contend that developing "competent and reliable scientific evidence" is too costly for dietary supplements, and that such products should be held to a lower standard. RPFF No. 27, 36, 42, 43. However, as noted above, courts have required competent and reliable

scientific evidence for claims about dietary supplements when such products are advertised to treat diseases or medical conditions. *E.g.*, *FTC v. Natural Solution*, 2007 U.S. Dist. LEXIS 60783, at *11-12; *FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *43-44; *FTC v. Direct Marketing Concepts*, 569 F. Supp. 2d at 300, 303. Although Respondents deny they "stated" that the Challenged Products prevent, treat, or cure cancer or tumors, the evidence shows that the advertising clearly conveyed these claims. F. 189, 191, 193, 202, 211, 222, 224, 227, 229, 230, 232, 234, 235, 239, 245, 248, 250, 255, 257, 258, 269, 272, 275, 277-78, 280-81, 286, 288, 291, 294.

(4) The consequences of a false claim

The consequences of a false claim weigh in favor of requiring a higher level of substantiation in this case. The evidence shows that foregoing a proven cancer treatment in favor of an ineffective treatment would be injurious to a patient's health. F. 355-56. In addition, side effects and/or inappropriate dosing of a dietary supplement can cause harmful interactions that interfere with cancer treatment. F. 357-61. Furthermore, the Challenged Products are costly. F. 126-27, 135-37, 139-40, 143-44. Spending money on an ineffective remedy causes economic injury. *In re Schering Corp.*, No. 9232, 1991 FTC LEXIS 427, at *134 (Sept. 16, 1991); *In re Removatron*, 1985 FTC LEXIS 21, at *212 n.20.

(5) The amount of substantiation experts in the field believe is reasonable

Dr. Miller was the only witness in this case qualified as an expert in cancer research and cancer treatment. F. 326. His opinions, which were thorough and well-reasoned, were that competent and reliable scientific evidence is required to demonstrate that a cancer treatment is effective; that competent and reliable scientific evidence means controlled clinical studies; that animal and in vitro studies are insufficient; and that testimonials have no scientific validity. F. 343-53. Respondents contend that the relevant field is dietary supplements, and that in this regard, Drs. Duke and LaMont are more qualified than Dr. Miller. RB at 8-9. Where, as here, a dietary supplement is

claimed to have medical effects, however, it is appropriate to rely on the opinion of an expert in the medical field. *See FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *78-79 (accepting opinion of an expert in the field of erectile dysfunction as to level of substantiation required for claims that a dietary supplement was an effective treatment).

In any event, while Drs. Duke and LaMont each opined that there was a "reasonable basis" for the statements submitted to them for evaluation, neither witness even offered an opinion as to the amount or type of substantiation that is reasonable to support a claim that the Challenged Products prevent, treat, or cure cancer. F. 338, 387-88, 395-98. Accordingly, neither witness disputed Miller's opinion that competent and reliable scientific evidence is the appropriate standard for substantiating cancer claims. *See FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *78-79. Although LaMont would include studies of animals and cell culture lines in her definition of competent and reliable scientific evidence, she also included human clinical trials in her definition. F. 344. Accordingly, the expert testimony supports holding advertising claims, such as those made by Respondents, to the "competent and reliable scientific evidence" standard of substantiation.

b. Respondents did not possess or rely upon competent and reliable scientific evidence to substantiate their advertising claims

Respondents did not possess or rely upon competent and reliable scientific evidence to substantiate their claims that any of the Challenged Products is effective, either alone or in combination with other DCO products, in the prevention, treatment, or cure of cancer, in inhibiting tumor formation, or in ameliorating the adverse effects of radiation and chemotherapy, and in fact, no such evidence exists. F. 362-86. Claims that a dietary supplement treats a medical condition must be substantiated by clinical or scientific testing on the product itself; testing only component ingredients of the product is insufficient, unless the testing is on an exact duplicate of the product's combination of active ingredients. F. 367; *see FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *79; *FTC v.*

Natural Solution, 2007 U.S. Dist. LEXIS 60783, at *14-15 n.6 (holding on summary judgment that reliance on articles on the Internet, including the Mayo Clinic, website did not constitute adequate substantiation of claims that dietary supplement prevented or treated cancer where articles only addressed potential effects of particular herbs and did not demonstrate that the formula actually prevents or treats cancer). In the instant case, the Challenged Products were not tested to determine if they had the claimed effects. F. 308-14. Studies upon which Respondents relied evaluated isolated compounds that are present in certain of the Challenged Products and showed nonspecific immunostimulatory activities or suggested cancer preventive effects. F. 367. As in *National Urological Group* and *Natural Solution*, however, and as stated by Dr. Miller, testing only certain components of a Challenged Product does not substitute for an actual evaluation of each of the Challenged Products itself. For example, one cannot extrapolate from results of a published non-clinical study of curcumin that GDU can eliminate tumors. GDU itself, or each active ingredient in GDU, must be subjected to the same experimental conditions as those to which the curcumin was subjected. F. 367.

In addition, the materials relied upon by Respondents as substantiation consisted of author opinions and reviews of literature on the use of herbal medicines for a number of different diseases, including cancer. F. 365. Mere compilations of citations, which do not contain independent analysis or support for claims made in advertising, do not constitute substantiation. *FTC v. Direct Marketing Concepts*, 569 F. Supp. 2d at 300-01. Most of the studies referenced by Respondents are not peer-reviewed papers. F. 365. Respondents' substantiation materials did not include any controlled clinical trials. F. 365. Respondents' substantiation included non-clinical in vitro or animal studies, which serve only to demonstrate potential activity and safety. F. 345, 366. Such potential activity is not sufficient substantiation for claimed anti-cancer effects. *See FTC v. Natural Solution*, 2007 U.S. Dist. LEXIS 60783, at *14-15 (holding that reliance on Internet articles which addressed potential effects of herbs in Knutric and stated that further research was required did not substantiate anti-cancer claims). Instead, competent and

reliable scientific evidence to substantiate Respondents' claims requires controlled, clinical studies. F. 343-48.

Finally, Respondents' testimonials do not constitute valid scientific evidence because, among other reasons, it cannot be confirmed that the speakers had cancer, or that the speakers' reported responses were not due to other treatment modalities. *See Koch v. FTC*, 206 F.2d 311, 315-16 (6th Cir. 1953) (giving case histories no weight in verifying treatment claims, where the clinical data were based upon insufficient diagnosis or indicated use of conventional treatment along with the product). An individual's report that he or she "felt better," standing alone, does not scientifically measure response to a particular product. F. 351-53. For these and other reasons, cases consistently hold that testimonials do not constitute adequate substantiation for health-related efficacy claims in advertising. As Judge Easterbrook explained in *Federal Trade Commission v. QT, Inc.*:

> [A] person who promotes a product that contemporary technology does not understand must establish that this "magic" actually works. Proof is what separates an effect new to science from a swindle. . . . [D]efendants have no proof of the Q-Ray Ionized Bracelet's efficacy. The "tests" on which they relied were bunk. . . . What remain are testimonials, which 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 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.).

512 F.3d 858, 862 (7th Cir. 2008). *See also Simeon Mgmt. Corp. v. FTC*, 579 F.2d 1137, 1143-44 (9th Cir. 1978) (stating that anecdotal evidence, such as testimonials by satisfied customers, does not constitute adequate and well-controlled investigation, and therefore does not support claims that drug was effective for weight loss); *In re Warner-Lambert Co.*, No. 8891, 86 F.T.C. 1398, 1496, 1975 FTC LEXIS 12, at *213 (Dec. 9, 1975) ("Since there may be a divergence between what the user thinks the product will do for him and what the product actually does (or

does not do), evidence of consumer beliefs has little probative value for determining whether" a product works in the manner claimed), *aff'd*, 562 F.2d 749 (D.C. Cir. 1977).

Respondents argue that the literature upon which they relied constitutes "reasonable" support for their "express statements" which they contend are "structure/function" claims. RFF Nos. 26, 40; RCOL Nos. 18, 19. As discussed in Section III E 1-5 *supra*, the overall net impression of the DCO advertising is that each of the Challenged Products, either alone or in combination with other DCO products, is effective in the prevention, treatment, or cure of cancer, in inhibiting tumor formation, or in ameliorating the adverse effects of radiation and chemotherapy. F. 189, 191, 193, 202, 211, 222, 224, 227, 229, 230, 232, 234, 235, 239, 245, 248, 250, 255, 257, 258, 269, 272, 275, 277-78, 280-81, 286, 288, 291, 294. The fact that there may have been some basis to support the "express" words of product descriptions, taken out of context, is immaterial because Respondents had no competent and reliable scientific evidence to substantiate the overall net impression conveyed by their advertisements. *See FTC v. Bronson Partners*, 564 F. Supp. 2d at 133-34 (holding that expert report that included conclusions that Chinese Diet Tea "could lead to weight reduction," "can be a useful part of a weight reduction program," and "can help reduce fat absorption," while supporting the generalized notion that the product could be a useful part of a weight reduction program, did not support advertising claims that the product will lead to rapid and substantial weight loss).

It bears mentioning that Respondents' strategy throughout this case, despite clear and well-established law, has been to ignore each component of their advertising *except* the "express" words of their product descriptions, as though those statements stand alone. Following this strategy, Respondents did not seek, nor did any of their proffered experts offer, an opinion as to whether there was competent and reliable scientific evidence to support the claims that were alleged in the Complaint. F. 339-40, 387-89, 397, 399-400, 405, 408-09, 418, 420-21, 422, 424-25. Respondents' proffered experts were not asked to review, and none of them did review, any of the DCO advertising at issue. F. 338, 387, 395-96, 404, 410, 418, 422. None of Respondents' proffered experts, with the possible exception of Roy, opined as to what level of

substantiation is necessary or appropriate for claims that a dietary supplement prevents, treats, or cures cancer. F. 387-88, 397-98, 405-07, 418-19, 422-23. None of Respondents' proffered experts had any expertise in treating cancer, or in testing the efficacy of proposed cancer treatments. F. 330-37, 414-17. The result of Respondents' strategy is that none of Respondents' proffered experts offered any opinions on any material, contested issue in the case, and the opinions that Respondents' proffered experts did offer are entitled to little, if any, weight.

c. Respondents' claims are deceptive or misleading

Complaint Counsel can show that a representation is deceptive or misleading by showing that the advertiser lacked a reasonable basis for asserting that the message was true. *FTC v. Pantron I*, 33 F.3d at 1096; *FTC v. Sabal*, 32 F. Supp. 2d at 1007; *FTC v. QT, Inc.*, 448 F. Supp. 2d at 959-60. Complaint Counsel has demonstrated that Respondents lacked a reasonable basis for their claims that the Challenged Products, individually or collectively, prevent, treat, or cure cancer or inhibit tumors, or ameliorate the adverse effects of chemotherapy and radiation. Accordingly, Complaint Counsel has demonstrated that Respondents' claims are deceptive or misleading.

3. Respondents' advertising claims are material

"A claim is considered material if it 'involves information that is important to consumers and, hence, likely to affect their choice of, or conduct regarding a product.'" *Kraft v. FTC*, 970 F.2d at 322 (citations omitted). Health-related efficacy claims are consistently held to involve information that is important to consumers. *FTC v. Direct Marketing Concepts*, 569 F. Supp. 2d at 299-300; *FTC v. QT, Inc.*, 448 F. Supp. 2d at 966; *accord FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *45-46. Furthermore, the Commission is entitled to presume materiality for claims involving health concerns. *Kraft v. FTC*, 970 F.2d at 323. *Accord Novartis Corp. v. FTC*, 223 F.3d 783, 786 (D.C. Cir. 2000) (noting that information has been presumed material where it "concerns the purpose, safety, efficacy, or cost of the product or service") (quoting FTC Policy Statement on

Deception, appended to *In re Cliffdale Assocs.*, 103 F.T.C. 110, 182, 1984 FTC LEXIS 71, at *189 (Mar. 23, 1984)); *FTC v. QT, Inc.*, 448 F. Supp. 2d at 966. The presumption may be rebutted with extrinsic evidence indicating that the claims are not material. *FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *81.

Respondents' advertising claims that the Challenged Products, individually or collectively, prevent, treat, or cure cancer or inhibit tumors, or ameliorate the adverse effects of chemotherapy and radiation unquestionably relate to health concerns. F. 219, 236, 259, 282, 295. Claims that relate to health concerns are material. *FTC v. Direct Marketing Concepts*, 569 F. Supp. 2d at 299-300 (holding that claims that dietary supplements could prevent or treat cancer and other diseases were health-related efficacy claims which were "clearly material"); *FTC v. QT, Inc.*, 448 F. Supp. 2d at 966 (stating that claims that the Q-Ray bracelet provides immediate, significant, or complete relief from various types of pain were "[w]ithout question" medical, health-related claims that were material to consumers); *FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *46 (applying presumption of materiality to claims that dietary supplements were effective to treat weight loss and sexual dysfunction). Therefore, Respondents' claims are clearly material. In addition, Respondents did not make any argument, or attempt to introduce any evidence, that their claims are not material to consumers. Accordingly, Respondents' claims are deemed material.

E. Respondents' Defenses

Respondents have raised numerous defenses. Some of these defenses have been addressed in other sections of this Initial Decision.[6] Only a few of Respondents' remaining defenses merit discussion, and these are addressed below. Regardless of whether a defense is specifically addressed in this Initial Decision, each of

[6] *See, e.g.*, Sections III B (jurisdiction); III D 1 (interpretation of advertisements); III D 1 f (disclaimers); III D 1 g (extrinsic evidence); III D 2 a (level of substantiation).

Respondents' defenses has been fully considered, and rejected as being without sufficient basis in fact and/or law.

1. Claims regarding insufficient proof

a. Proof of unfair trade practices under Section 5(n) of the Act

Respondents argue that Complaint Counsel must prove that Respondents' acts or practices are not only deceptive, but also "unfair," as defined under Section 5(n) of the FTC Act. That Section provides:

> (n) Definition of unfair acts or practices. The Commission shall have no authority under this section or section 18 [15 U.S.C. § 57a] to declare unlawful an act or practice on the grounds that such act or practice is unfair unless the act or practice causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition. In determining whether an act or practice is unfair, the Commission may consider established public policies as evidence to be considered with all other evidence. Such public policy considerations may not serve as a primary basis for such determination.

15 U.S.C. § 45(n).

Respondents' argument fails. Respondents cite no authority for their contention that the evidence must show that deceptive trade practices are also unfair because of substantial consumer injury. Moreover, the law is contrary to Respondents' position. It is well established that proof of deception does not require proof of actual consumer injury. *FTC v. Direct Marketing Concepts*, 569 F. Supp. 2d at 297; *In re Kraft*, 1991 FTC LEXIS 38, at *38. This is because misrepresentations harm consumer choice, and in this regard, injure both consumers and competition. *In re Novartis Corp.*, 1999 FTC LEXIS 63, at *26. Accordingly, the harm resulting from a deceptive practice renders such practice "unfair" as well. *In re Southwest Sunsites, Inc.*, No. 9134, 105 F.T.C. 7, 1980 FTC LEXIS 86, at *338 n.81 (Jan. 15, 1985).

Indeed, the provisions of Section 12(b) of the FTC Act recognize this principle, by providing that false advertising is, by definition, an "unfair or deceptive" act or practice within the meaning of Section 5 of the FTC Act. 15 U.S.C. § 52(b). Therefore, there is no legal or logical reason to require additional, independent proof of unfairness under Section 5(n), 15 U.S.C. § 45(n).

b. Proof of inadequate substantiation

(1) Requirement of placebo-controlled, double-blind studies

Respondents assert that placebo-controlled, double-blind studies are not required for adequate substantiation under the FTC Act. RB at 2-3 (citing *FTC v. QT, Inc.*, 512 F.3d 858). Respondents correctly note that the court in *Federal Trade Commission v. QT, Inc.* stated: "Nothing in the Federal Trade Commission Act . . . requires placebo-controlled, double-blind studies. . . . Placebo-controlled, double-blind testing is not a legal requirement for consumer products." 512 F.3d at 861. However, Respondents ignore the fact that the appellate court affirmed the district court's holdings that substantiation for health-related efficacy claims must be based on competent and reliable scientific evidence, and that the studies upon which defendants relied were inadequate under that standard. *Id.* at 862. Moreover, the appellate court held that its conclusion regarding double-blind, placebo-controlled studies was of no help to the defendants because, as the district court had found after exhaustive analysis of the defendants' studies, "defendants ha[d] no proof" to support their advertising claims. *Id.*

In the instant case as well, the language in *Federal Trade Commission v. QT, Inc.* regarding placebo-controlled, double-blind studies does not help Respondents because, as discussed in Section III D 2 *supra*, Respondents did not possess or rely upon any adequate substantiation for their claims that the Challenged Products prevent, treat, or cure cancer. Respondents had no studies whatsoever of the effects of the Challenged Products themselves. F. 308-14. Respondents' substantiation materials included studies on isolated compounds that are present in some of the Challenged Products, rather than studies of the exact

combinations of constituent ingredients in the Challenged Products. F. 367. Respondents' own proffered expert, Dr. LaMont, admitted that because the products have not been tested, the effectiveness of BioShark, 7 Herb Formula, GDU, and BioMixx to prevent, treat, or cure cancer is not known. F. 364. Most of the substantiation materials upon which Respondents relied were not peer-reviewed papers. F. 365. Respondents' substantiation materials did not include controlled clinical human trials. F. 365. Respondents' substantiation materials included author opinions and reviews of literature on the use of herbal medicines. F. 365. Many of the studies cited in Respondents' reference materials were in vitro or animal studies. F. 366. Ultimately, like the defendants in *QT, Inc.*, Respondents here relied on testimonials (F. 316), "which are not a form of proof." 512 F.3d at 862.

(2) Substantiation for "structure-function" claims under DSHEA

Respondents further contend that a high level of substantiation, such as placebo-controlled, double-blind studies, is not required because, according to Respondents, Respondents made "structure-function" claims under the Dietary Supplement Health and Education Act, Pub. L. No. 103-417, 108 Stat. 4325 (DSHEA). RB at 3, 7-8. Respondents cite 21 U.S.C. § 343(r)(6)(A), which relaxes certain DSHEA misbranding rules for statements on labels that "describe . . . the role of a nutrient or dietary ingredient intended to affect the structure or function in humans." In this case, the evidence demonstrates that Respondents made health-related efficacy claims. *See supra* Section III D 1-2. Such claims would not be deemed "structure-function" claims under DSHEA, even according to the cases cited by Respondents. *See Pearson v. Shalala*, 164 F.3d 650, 652 (D.C. Cir. 1999) (stating that claims that consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers, consumption of fiber may reduce the risk of colorectal cancer, consumption of omega-3 fatty acids may reduce the risk of coronary heart disease, and 8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form constitute "health claims" under FDA regulations); *United States v. Lane*

Labs-USA, Inc., 324 F. Supp. 2d 547, 568 (D.N.J. 2004) (holding that claims that shark cartilage products were an effective treatment for cancer and HIV/AIDS were not structure-function claims). In any event, this case does not present issues relating to labeling under DSHEA, but advertising and unfair acts or practices under the FTC Act. Complaint ¶¶ 7-14, 16; 15 U.S.C. §§ 45(a), 52.

(3) FTC Guidelines for Dietary Supplement Advertising

Next, Respondents argue that Complaint Counsel ignored FTC guidelines regarding the advertising of dietary supplements. RB at 4, 8 (citing the FTC's Guide, *Dietary Supplements: An Advertising Guide for Industry*, available at http://www.ftc.gov/bcp/edu/pubs/business/adv/bus09.shtm (hereinafter, "Guidelines")). Respondents contend that the Guidelines state that: (1) the evaluation of substantiation for dietary supplement claims must be flexible to ensure consumers have access to information about emerging areas of science; (2) there is no requirement that dietary supplement claims be supported by a specific number of studies; and (3) research concerning the biological mechanism underlying the claimed action of a dietary supplement is acceptable substantiation for dietary supplement claims. RB at 4, 8.

Respondents misconstrue the Guidelines. The first statement from the Guidelines that Respondents contend was ignored introduces a discussion of the five factors relevant in evaluating substantiation, which are the same as the five *Pfizer* factors. *See* Guidelines at 8-9; *In re Thompson Medical*, 104 F.T.C. 648, 821, 1984 FTC LEXIS 6, at *387. The *Pfizer* factors were considered and applied in this case. *See supra* Section III D 2 a. The second statement from the Guidelines, to which Respondents referred, is preceded by important qualifying statements, which Respondents ignore, including that "the [amount and type of] evidence needed depends on the nature of the claim," that "all competent and reliable scientific research" should be considered, and that "the quality of studies [is] more important than quantity." Guidelines at 10. The nature of Respondents' claims was thoroughly considered in determining the level of substantiation required.

See supra Section III D 1-2 a. The quality of Respondents' substantiation was fully evaluated and determined to not constitute competent and reliable scientific evidence. *See supra* Section III D 2 b. Finally, regarding Respondents' third statement, the Guidelines simply do not state that "research concerning the biological mechanism underlying the claimed action of a dietary supplement is acceptable substantiation for dietary supplement claims." The Guidelines state: "When a clinical trial is not possible (e.g., in the case of a relationship between a nutrient and a condition that may take decades to develop), *epidemiologic evidence may be* an acceptable substitute for clinical data, especially when supported by other evidence, such as research explaining the biological mechanism underlying the claimed effect." Guidelines at 10 (emphasis added). To the extent Respondents' substantiation materials included any "research explaining the biological mechanism" of the Challenged Products, it was determined that such materials did not constitute adequate substantiation for the claim that the Challenged Products prevent, treat, or cure cancer. *See supra* Section III D 2 b.

2. Due process claim

Although Respondents' due process claim is difficult to discern, it appears to be based upon what Respondents contend is a lack of evidence. Respondents assert that: Under DSHEA, dietary supplements must be proved harmful; there is no evidence of unfairness or consumer injury; and extrinsic evidence is necessary to determine the overall net impression of their advertising. RB at 10-11. To find liability without such evidence, according to Respondents, violates their procedural due process rights, under *Mathews v. Eldridge*, 424 U.S. 319 (1976) and *Stanley v. Illinois*, 405 U.S. 645 (1972). Neither cited opinion has any bearing on this case legally or factually. Moreover, each alleged evidentiary deficiency has been proved erroneous. As noted in *supra* Sections III D 1 g and III E 1 a-b, DSHEA law does not govern this deceptive advertising case, consumer injury is not an element of proof in a deceptive advertising case, unfairness is not an element of proof in a deceptive advertising case, and extrinsic evidence is not necessary to determine the overall net impression of advertisements where, as here, the

meaning is sufficiently clear on the face of the advertisements. Accordingly, Respondents' due process argument has no merit.

3. *United States v. Johnson*

Respondents rely on the near-century-old case of *United States v. Johnson*, 221 U.S. 488 (1911) to argue that unsubstantiated claims regarding product effectiveness are not unlawful because such claims are matters of opinion, not fact. *See, e.g.,* Respondents' Motion to Dismiss, Jan. 11, 2009, at 6-8. *Johnson* involved the question of whether medicine bottles, whose labels contained false and misleading representations that the medicine was effective in curing cancer, were "misbranded" within the meaning of Section 8 of the Food and Drug Act of 1906. 221 U.S. at 495-97. The Court held that the Act was not intended to cover all possible false or misleading statements regarding medicine, but only those related to the identity of the contents of the medicine. *Id*. On its face, *Johnson* has no application to this case. In addition, Congress implicitly overruled *Johnson* by amending the Food and Drug Act to expressly include claims regarding curative effectiveness. Act of June 30, 1906, as amended, 37 Stat. 416 (1912). Finally, as noted in Section III D 2 *supra*, Respondents' advertising claims, including claims that the Challenged Products are "Cancer Treatments" and "Cancer Solutions," are stated in positive terms, and not qualified by opinion. *See Koch v. FTC*, 206 F.2d at 318 (holding that representations concerning the therapeutic value of certain medicinal preparations were within jurisdiction of FTC). Respondents' claims are representations of fact because they are subject to objective verification. *See In re Thompson Medical*, 104 F.T.C. 648, 788-89 n.6, 1984 FTC LEXIS 6, at *312 n.6 (stating that claims that can be objectively verified do not constitute mere "puffery"). Thus, *Johnson* does not support Respondents' position.

4. First Amendment defense

Respondents assert that their statements about the Challenged Products reflect both their religious view of life grounded in the Christian Bible and their political beliefs concerning allopathic drugs and pharmaceutical companies. RB at 12-13. Thus,

Respondents maintain, their statements about the Challenged Products constitute religious and political speech protected by the First Amendment to the U.S. Constitution. RB at 12-13. Respondents further argue that even if their statements are found to be commercial speech, they are protected by the First Amendment. RB at 13. Respondents also assert that the FTC has the burden of showing that Respondents' statements are misleading and the burden of proving that suppression of those statements is necessary to achieve a substantial government interest. RB at 16. In addition, Respondents assert that the First Amendment doctrine of prior restraint would prohibit an FTC order enjoining Respondents' representations. RB at 14.

Complaint Counsel asserts that Respondents' representations constitute commercial speech. CCB at 32. Complaint Counsel further states that the evidence demonstrates that the challenged advertisements and promotional materials, which are broadly disseminated on the Internet to draw consumers, contain little or no religious commentary. CCB at 32-33. Complaint Counsel also contends that this commercial speech is deceptive and, therefore, not protected by the First Amendment. CCB at 34-35. In addition, Complaint Counsel maintains that the FTC's action does not constitute a prior restraint. CCB at 35.

Supreme Court decisions "have recognized 'the "common-sense" distinction between speech proposing a commercial transaction, which occurs in an area traditionally subject to government regulation, and other varieties of speech.'" *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 64 (1983) (quoting *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 455-56 (1978)). Thus, the Supreme Court has held that the Constitution accords less protection to commercial speech than to other constitutionally safeguarded forms of expression. *Id.* at 64-65 (citing *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of New York*, 447 U.S. 557, 562-563 (1980); *Virginia Pharm. Bd. v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 771-72 n.24 (1976)).

"[A]s a general matter, 'the First Amendment means that government has no power to restrict expression because of its message, its ideas, its subject matter, or its content.'" *Id.* at 65

(quoting *Police Dep't of Chicago v. Mosley*, 408 U.S. 92, 95 (1972)). Thus, with respect to noncommercial speech, the Supreme Court has "sustained content-based restrictions only in the most extraordinary circumstances." *Id.* "By contrast, regulation of commercial speech based on content is less problematic." *Id.* "In light of the greater potential for deception or confusion in the context of certain advertising messages, content-based restrictions on commercial speech may be permissible." *Id.* (citing *In re R. M. J.*, 455 U.S. 191, 200 (1982); *Friedman v. Rogers*, 440 U.S. 1 (1979)).

"Because the degree of protection afforded by the First Amendment depends on whether the activity sought to be regulated constitutes commercial or noncommercial speech," *id.*, a determination must first be made as to whether Respondents' challenged representations constitute commercial speech. Once it is determined that the language at issue is commercial speech, case law makes clear that misleading or deceptive commercial speech is not protected by the First Amendment.

a. Respondents' statements constitute commercial speech

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) (citations omitted); *In re R.J. Reynolds Tobacco Co.*, No. 9206, 111 F.T.C. 539, 1988 FTC LEXIS 9, at *9 (Mar. 4, 1988) ("The Supreme Court has referred to the 'core notion' of commercial speech as speech which proposes a commercial transaction.") (citations omitted). As a result, the determining factor is whether the speech at issue "propose[s] a commercial transaction." *Board of Trustees of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 473-74 (1989).

Whether the speaker has an economic motivation for the speech is germane to the issue of whether the speech is commercial. *In re Primus*, 436 U.S. 412, 438 n.32 (1978) (stating that the line between commercial and noncommercial speech is "based in part on the motive of the speaker"); *Bolger*, 463 U.S. at

66. Another consideration is whether the statements refer to specific products. *Bolger*, 463 U.S. at 66; *In re R.J. Reynolds*, 1988 FTC LEXIS 9, at *14 ("[I]nformation about attributes of a product or service offered for sale, such as type, price, or quality, is also indicative of commercial speech.") (citing *Friedman v. Rogers*, 440 U.S. 1, 11 (1979)). The Federal Trade Commission has specifically stated: "[I]nformation about health effects associated with the use of a product can properly be classified as commercial speech." *In re R.J. Reynolds*, 1988 FTC LEXIS 9, at *14 (citing *Bolger*, 463 U.S. at 66-67; *National Comm'n on Egg Nutrition v. FTC*, 570 F.2d 157, 163 (7th Cir. 1977)).

In this case, the evidence very clearly shows that Respondents' speech is economically motivated and proposes a commercial transaction by urging consumers to purchase specific products. Respondent James Feijo conceded at trial that the DCO Website constitutes advertising. F. 161. Moreover, the content of Respondents' advertising promotes specific products and their attributes, and urges consumers to purchase those products. For example, in the BioMolecular Nutrition Product Catalog, Respondents list and describe the Challenged Products and state, "Call Toll FREE 1-800-504-5511 or shop online at www.danielchapterone.com." F. 91. There is no mention of a DCO ministry in the BioMolecular Nutrition Product Catalog. F. 93. In the exhibits attached to the Complaint, and admitted into evidence, Respondents clearly propose commercial transactions. F. 179-80 (webpage from the DCO Website, entitled "Cancer News," which contains a picture of 7 Herb Formula and states regarding the Challenged Products as a group: "If you suffer from any type of cancer, Daniel Chapter One suggests taking 7*Herb Formula™, Bio*Shark™, BioMixx™, GDU Caps™." Immediately following this text is a prominent picture of bottles of BioMixx, 7 Herb Formula, Bio*Shark, and GDU, and adjacent to that is a statement in bold type, "Daniel Chapter One's Cancer solutions," and text that states: "To Buy the products click here. How to fight cancer is your choice!") (emphasis omitted); F. 220-21 (printout of the webpage for BioShark on the DCO Website, with a heading in bold type, "Immune Boosters," a picture of bottles of BioShark, and a shopping cart icon with the instruction, "BUY NOW!") (emphasis omitted); F. 262-63 (webpage for GDU on the DCO Website, which begins with a heading in bold

type, "Immune Boosters," depicts bottles of GDU, with text that includes "[t]his formula also helps to relieve pain and heal inflammation," and provides a link to "buy now."). Further, Respondents' representations convey information about the health effects that are purportedly associated with the use of their products. *See supra* Section III D 1-2. *E.g.*, F. 180 (DCO Website stating: "If you suffer from any type of cancer, Daniel Chapter One suggests taking [the Challenged Products]").

In addition to evaluating the content of the speech, the Supreme Court has found that the means used to publish speech is relevant to how speech should be classified. *In re R.J. Reynolds*, 1988 FTC LEXIS 9, at *15. For example, the Court has recognized that commercial speech frequently takes the form of paid-for advertising. *Id.* (citing *Bolger*, 463 U.S. at 66; *Bates v. State Bar of Ariz.*, 433 U.S. 350, 363-64 (1977); *Virginia State Board of Pharmacy*, 425 U.S. at 761). Respondents operate the DCO Website, www.danielchapterone.com, and the websites www.dc1pages.com, www.dc1store.com, www.7herbformula .com, and www.gdu2000.com, through which they accept consumers' orders. F. 103-04. Respondents have spent money to have the DCO websites and written publications created and for cable advertising services. F. 159-60.

Given the foregoing, the religious or political views, upon which Respondents' advertising was assertedly based, do not convert Respondents' commercial speech to constitutionally protected religious or political speech. In *Bolger*, the Supreme Court found that mailings constituted "commercial speech notwithstanding the fact that they contain discussions of important public issues such as venereal disease and family planning." *Bolger*, 463 U.S. at 67-68. "We have made clear that advertising which 'links a product to a current public debate' is not thereby entitled to the constitutional protection afforded noncommercial speech." *Id.* at 68 (quoting *Central Hudson*, 447 U.S. at 563 n.5). The Supreme Court further held: "A company has the full panoply of protections available to its direct comments on public issues, so there is no reason for providing similar constitutional protection when such statements are made in the context of commercial transactions. Advertisers should not be permitted to immunize false or misleading product information from government

regulation simply by including references to public issues." *Id.* *See also Central Hudson*, 447 U.S. at 563 (stating that failing to honor distinction between commercial and noncommercial speech "could invite dilution, simply by a leveling process, of the force of the [First] Amendment's guarantee with respect to the latter kind of speech") (quoting *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. at 456). Thus, even though Respondents assert that their representations are based on their religious view of life grounded in the Christian Bible and positioned as a political argument against drugs and pharmaceutical companies, RB at 12-13, it is clear from the foregoing examples that Respondents' speech seeks to promote sales of the Challenged Products. Accordingly, Respondents' challenged representations constitute commercial speech.

b. Misleading commercial speech may be prohibited

For commercial speech to receive the protections of the First Amendment, "it at least must concern lawful activity and not be misleading." *Central Hudson*, 447 U.S. at 566. As the Supreme Court has explained:

> The First Amendment's concern for commercial speech is based on the informational function of advertising. Consequently, 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, or commercial speech related to illegal activity.

Id. at 563-64. It is well settled that "[t]he States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading." *Zauderer*, 471 U.S. at 638; *In re R. M. J.*, 455 U.S. at 203 (noting that the government may prohibit false or misleading commercial advertising entirely).

Restrictions on deceptive advertising of food and drugs have repeatedly been upheld against First Amendment challenges.

Association of Nat'l Advertisers v. Lungren, 44 F.3d 726, 734 n.3 (9th Cir. 1994) (citing *Kraft v. FTC*, 970 F.2d at 324-26 (upholding FTC ban on deceptive claims about the calcium content of processed cheese products); *Bristol-Myers Co. v. FTC*, 738 F.2d 554, 562 (2d Cir. 1984) (upholding FTC prohibitions on certain types of advertising claims about analgesics)). *See also FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *29-30 (citing *Bristol-Myers v. FTC*, 738 F.2d at 562 ("deceptive advertising enjoys no constitutional protection")). "Even in the absence of a finding of actual deception, agencies may properly regulate speech that is merely potentially deceptive." *Bristol-Meyers v. FTC*, 738 F.2d at 562 (citing *Friedman v. Rogers*, 440 U.S. 1, 15 (1979)). Respondents' representations have been found to lack adequate substantiation and therefore have been determined to be deceptive or misleading. *See supra* Section III D 2. Accordingly, the deceptive commercial speech at issue in this case is not protected by the First Amendment.

c. *Central Hudson* does not apply

Respondents argue that even if their statements are found to be commercial speech, they are protected by the First Amendment under *Central Hudson*. RB at 13, 16, 22. In *Central Hudson*, the Supreme Court set out the standards applicable to governmental restrictions on commercial speech: The State must assert a substantial interest to be achieved by restrictions on commercial speech; the regulatory technique must be in proportion to that interest; and the limitation on expression must be designed carefully to achieve the State's goal. *Central Hudson*, 447 U.S. at 564. The *Central Hudson* test, however, is applied "if the communication is neither misleading nor related to unlawful activity." *Id.*; *Grolier Inc. v. FTC*, 699 F.2d 983, 988 (9th Cir. 1983). Where, as here, Respondents' practices are unlawful or misleading, First Amendment protections do not apply. *Grolier v. FTC*, 699 F.2d at 988; *National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *30 (stating that *Central Hudson* test did not apply to the FTC deceptive advertising case before the court). Therefore, the *Central Hudson* test does not apply to this deceptive advertising case.

d. Other cases relied upon by Respondents do not apply

Respondents cite numerous First Amendment commercial speech cases involving advertisements for accountants and attorneys to show how the Supreme Court "restated its *Central Hudson* test." RB at 16-18. Respondents' reliance upon these cases is misplaced. The accountant and attorney advertisement cases that Respondents cite all involve commercial speech that was not misleading or that did not involve unlawful activity. *See Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 620-24 (1995) (holding that the Florida Bar Rules prohibiting personal injury lawyers from sending targeted direct-mail solicitations to victims and their relatives for thirty days following an accident or disaster did not violate the First Amendment); *Ibanez v. Fla. Dep't of Bus. and Prof'l Regulation Bd. of Accountancy*, 512 U.S. 136, 139, 142 (1994) (concluding that the Board's decision censoring petitioner was incompatible with the First Amendment, but recognizing that "false, deceptive, or misleading commercial speech may be banned"); *Edenfield v. Fane*, 507 U.S. 761, 765-66 (1993) (holding that Florida's rule prohibiting certified public accountants from engaging in "direct, in-person, uninvited solicitation" is inconsistent with the free speech guarantees of the First Amendment when the speech involved is truthful and nondeceptive); *Peel v. Attorney Registration and Disciplinary Comm'n of Ill.*, 496 U.S. 91, 100, 110-11 (1990) (stating that an attorney's letterhead was not actually or inherently misleading, because a lawyer has a constitutional right, under the standards applicable to commercial speech, to advertise his or her certification, but stating that "[m]isleading advertising may be prohibited entirely"); *In re R. M. J.*, 455 U.S. at 206-07 (stating that there is "no finding that appellant's speech was misleading" but noting that "the States retain the authority to regulate advertising that is inherently misleading or that has proved to be misleading in practice"). In the instant case, Respondents' challenged speech is misleading and unlawful. Accordingly, the commercial speech cases upon which Respondents rely are inapposite.

e. The FTC's action does not constitute a prior restraint

Respondents have asserted that this administrative proceeding and the issuance of a cease and desist order impose a prior restraint, in violation of their First Amendment rights, because there has been no proof that any consumer was actually misled or "physically harmed." RRB at 13-15. 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.'" *Alexander v. United States*, 509 U.S. 544, 550 (1993) (citations omitted). Courts have consistently held that a FTC cease and desist order prohibiting representations about performance of products without substantiation is not an unconstitutional "prior restraint," but a reasonable sanction, imposed after a hearing establishes a violation of the FTC Act. *E.g., Jay Norris, Inc. v. FTC*, 598 F.2d 1244, 1252 (2d Cir. 1979) ("[B]ecause the FTC here imposes the requirement of prior substantiation as a reasonable remedy for past violations of the Act, there is no unconstitutional prior restraint of petitioners' protected speech."); *Sears, Roebuck & Co. v. FTC*, 676 F.2d 385, 399 (9th Cir. 1982) ("[T]he Commission may require prior reasonable substantiation of product performance claims after finding violations of the Act, without offending the [F]irst [A]mendment."). Thus, the cease and desist order entered here, only after an administrative trial where the evidence conclusively showed that Respondents' advertising was misleading, does not constitute a prior restraint.

The defenses advanced by Respondents are without merit. Accordingly, they do not provide a basis for holding that Respondents are not liable for the proven violations of the FTC Act.

F. Summary of Liability

The Complaint charges that the acts and practices of Respondents, as alleged in the Complaint, constitute deceptive advertising in violation of Sections 5(a) and 12 of the FTC Act. Complaint Counsel has presented reliable, probative, and

substantial evidence in support of the Complaint's charges. The defenses raised by Respondents have been considered and rejected. Accordingly, Respondents DCO and James Feijo are hereby found liable for violating Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a), 52.

G. Remedy

On determination that a challenged act or practice is prohibited by Section 5 of the FTC Act, the appropriate remedy is an order requiring respondents to cease and desist from such act or practice. 15 U.S.C. § 45(b); *FTC v. National Lead Co.*, 352 U.S. 419, 428 (1957). Courts have long recognized that the Commission has considerable discretion in fashioning an appropriate remedial order, subject to the constraint that the order must bear a reasonable relationship to the unlawful acts or practices. *See, e.g., FTC v. Colgate-Palmolive Co.*, 380 U.S. at 394-95; *FTC v. Ruberoid Co*., 343 U.S. 470, 473 (1952); *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 612-13 (1946).

As held above, DCO is liable for the violations of the FTC Act alleged in the Complaint. Further, as set forth below, James Feijo is individually liable and an Order against him, as well as DCO, is appropriate. The Order attached herewith is reasonably related to the proven violations.

1. Individual liability

When both a corporation and an individual are named in the complaint, to obtain a cease and desist order against the individual, Complaint Counsel must prove violations of the FTC Act by the corporation and that the individual either directly participated in the acts at issue or had authority to control them. *FTC v. Amy Travel Serv., Inc.*, 875 F.2d at 573; *see also FTC v. Standard Educ. Soc'y*, 302 U.S. 112, 119-20 (1937) (finding it proper for Commission to include individuals who were in charge and control of the affairs of respondent corporations in the Commission's cease and desist order). As summarized in Section III F, DCO violated the FTC Act. As summarized in Section III B 6, Respondent James Feijo both participated directly in and had the authority to control and, in fact, did direct and control the

deceptive representations at issue. Accordingly, James Feijo is individually liable for acts or practices of Respondent DCO that violate Sections 5 and 12 of the FTC Act, and the entry of a cease and desist order against James Feijo is appropriate.

2. Specific provisions of the Order

The Order attached to this Initial Decision is substantially the same as the proposed order that accompanied the Complaint in this matter. The only substantive change in this Order from the proposed order attached to the Complaint is to the language in the letter, appended as Attachment A to the Order, that Respondents are required by this Order to send to consumers of the Challenged Products. That change is discussed below.

As a result of the Findings and Conclusions in this case, the Order prohibits Respondents from making the types of misrepresentations challenged in the Complaint. The Order also provides fencing-in relief, requiring Respondents to possess competent and reliable scientific evidence supporting certain future claims about any dietary supplement, food, drug, or other health-related product, service, or program. These provisions are discussed below. In addition, the Order contains standard provisions regarding record-keeping, dissemination of the order to officers and employees, prior notification of corporate changes, filing compliance reports, and sunsetting of the Order.

a. Competent and reliable scientific evidence requirement

The Order prohibits Respondents from making representations that any health-related program, service, or product prevents, treats, or cures, or assists in the prevention, treatment, or cure of any type of tumor or cancer, unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation. "Competent and reliable scientific evidence" is defined in the Order to mean "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."

Commission orders requiring respondents to have competent and reliable scientific evidence, as defined in this Order, that is based on the expertise of professionals in the area and that has been conducted and evaluated by persons qualified to do so, are typical and have been consistently upheld. *E.g.*, *In re Telebrands*, 140 F.T.C. at 347, *aff'd,* 457 F.3d 354; *In re Kraft*, 114 F.T.C. at 149, *aff'd,* 970 F.2d 311 (7th Cir. 1992). *See also In re Thompson Medical*, 104 F.T.C. at 844, *aff'd,* 791 F.2d at 192 (upholding order requiring respondents to possess and rely upon a reasonable basis consisting of competent and reliable scientific or medical evidence to substantiate certain representations, and defining "'competent and reliable scientific evidence' [to] include at least two adequate and well-controlled, double-blinded clinical studies . . . by persons . . . qualified by training and experience to conduct such studies"); *In re Removatron*, 1985 FTC LEXIS 21, at *167, *aff'd*, 884 F.2d at 1498 (upholding order requiring respondents to possess and rely upon competent and reliable scientific evidence to substantiate representations and defining "'competent and reliable scientific evidence' . . . as adequate and well-controlled, double-blind clinical testing conforming to acceptable designs and protocols and conducted by a person or persons qualified by training and experience to conduct such testing").

b. Fencing-in provision

The Order entered herewith prohibits Respondents from making certain representations not only as to the Challenged Products, but also as to any substantially similar health-related program, service, or product, or any other Covered Product or Service. "Covered Product or Service" is defined in the Order to mean any dietary supplement, food, drug, or other health-related product, service, or program, including, but not limited to, BioShark, 7 Herb Formula, GDU, and BioMixx. Thus, the Order, by prohibiting Respondents from engaging in deceptive practices concerning products in addition to the Challenged Products, provides "fencing-in" relief.

"Fencing-in" relief refers to provisions in an FTC order that are broader than the conduct that is declared unlawful and may extend to multiple products. *Telebrands Corp. v. FTC*, 457 F.2d 354, 357 n.5 (4th Cir. 2006) (citing *In re Telebrands*, 140 F.T.C. at 281 n.3); *American Home Prods. v. FTC*, 695 F.2d at 705; *Kraft v. FTC*, 970 F.2d at 326 (citing *FTC v. Colgate-Palmolive*, 380 U.S. at 395; *Sears v. FTC*, 676 F.2d at 391-92). "Fencing-in remedies are designed to prevent future unlawful conduct." *Telebrands*, 457 F.2d at 357 n.5 (citing *In re Telebrands*, 140 F.T.C. at 281 n.3).

"Such an order must be sufficiently clear that it is comprehensible to the violator, and must be 'reasonably related' to a violation of the Act." *Kraft*, 970 F.2d at 326 (citation omitted). In determining whether a broad fencing-in order bears a "reasonable relationship" to a violation of the FTC Act, Courts and the Commission consider: (1) the deliberateness and seriousness of the violation; (2) the degree of transferability of the violation to other products; and, (3) any history of prior violations. *Telebrands*, 457 F.2d at 358; *Kraft*, 970 F.2d at 326. Applying these factors to the facts of this case, in order to provide adequate consumer protection, the fencing-in relief in this Order is appropriate.

(1) Deliberateness and seriousness of the violation

In weighing the deliberateness of the violation, the evidence shows that Respondents made numerous deceptive representations over the Internet, in their publications, and through the DCO radio program, over the course of several years. Respondents were aware that they were making representations that could be deemed unlawful by governing authorities. *See* F. 215 (DCO HealthWatch radio program, where 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"); F. 217 (DCO HealthWatch radio program, in which Patricia Feijo advised an individual 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, [to download] 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.").

In weighing the seriousness of the violation, the evidence shows that the representations are health-related claims, *see supra* III D 1-2, and in some instances suggested that individuals forego traditional cancer treatments in favor of purchasing and consuming the Challenged Products. *E.g.*, F. 260 (During the July 8, 2008 DCO HealthWatch radio program, in response to a caller's concern about colon cancer and whether the caller should follow her doctor's recommendation of a colonoscopy, James Feijo stated, "Polyps are nothing . . . Polyps should be left alone."); F. 214 (2008 DCO HealthWatch radio program, in which James Feijo stated, "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. [His] skin cleared up after a few months in the late 1980s [sic], early '99, [he] was told there was no trace of cancer."). There is a potential harm if a cancer patient foregoes potentially beneficial therapy and replaces it with one or more of the Challenged Products. F. 356. In addition, taking the Challenged Products could cause a dangerous interaction with drugs. F. 357. "When drug advertising is at issue, the potential health hazards may well justify a more sweeping order than would be proper were the Commission dealing with a less consequential area." *American Home Prods. v. FTC*, 695 F.2d at 706. Here, where Respondents intentionally represented that the Challenged Products could prevent, treat, or cure cancer, through numerous publications and websites, the deliberateness and seriousness of the violation weighs heavily in favor of the Order encompassing a broad range of products.

(2) Degree of transferability

A violation is transferrable where other products could be sold utilizing similar techniques. *FTC v. Colgate-Palmolive*, 380 U.S. at 394-95; *Sears v. FTC*, 676 F.2d at 392. For example, "misrepresenting that doctors prefer a product, or that tests prove the product's superiority, is a form of deception that could readily be employed for any non-prescription drug product." *American Home Prods. Corp. v. FTC*, 695 F.2d at 708. In this case, the claims that the Challenged Products prevent, treat, or cure cancer, and the use of testimonials by doctors and consumers to make such claims, could readily be employed for any dietary supplement. Thus, transferability is a significant factor in favor of provisions in the Order encompassing a broad range of products.

(3) History of violations

No evidence was introduced or argument made to indicate that Respondents have a history of prior violations of the FTC Act. However, "the more egregious the facts with respect to a particular element, the less important it is that another negative factor be present. In the final analysis, [courts] look to the circumstances as a whole and not to the presence or absence of any single factor." *Sears v. FTC*, 676 F.2d at 392; *see also Kraft v. FTC*, 970 F.2d at 327. In *Telebrands*, the Court of Appeals upheld the Commission's conclusion that the strength of the evidence as to the first two factors sufficiently established that there was a reasonable relationship between the remedy and the violation, and it was not necessary to also consider any prior consent orders. *Telebrands*, 457 F.2d at 362. Thus, while here there is no history of violations which would weigh against the Order encompassing a broad range of products, that factor is less important, taking into account the circumstances as a whole. Accordingly, weighing all of the factors, the fencing-in relief in the attached Order bears a reasonable relationship to Respondents' violations of the FTC Act.

c. Requirement of a letter to consumers

The proposed order requires Respondents to mail a letter to each consumer of the Challenged Products, to inform him or her

that the FTC has found that Respondents' advertising claims for these products were false and unsubstantiated and that the FTC has issued an Order prohibiting Respondents from making those claims in the future. It is appropriate to require Respondents to mail a letter to consumers to inform them of those findings. *E.g.*, *FTC v. Natural Solution, Inc.*, No. CV 06-06112-JFW (C.D. Cal. Sept. 4, 2007). However, the proposed letter attached to the Complaint will be modified in two respects.

First, the proposed letter attached to the Complaint could be seen as requiring Respondents to adopt as their own statements and opinions that are contrary to the beliefs to which Respondents testified at trial. Therefore, the letter is modified to make it clear that the information contained in the letter is information that the FTC has required Respondents to transmit to consumers. Second, the letter is modified to reflect the fact that consumers purchased the Challenged Products not only through the DCO websites, but also through the toll-free number to DCO's call center.

d. Summary of remedy

The Order entered herewith is sufficiently clear and precise and is reasonably related to the unlawful acts or practices found to exist.

IV. SUMMARY OF CONCLUSIONS OF LAW

1. Complaint Counsel bears the burden of proving jurisdiction and liability by a preponderance of evidence.

2. Respondent Daniel Chapter One ("DCO") engages in business for its own profit or that of its sole member, Respondent James Feijo.

3. Respondent Daniel Chapter One ("DCO") is a corporation, as "corporation" within the meaning of "corporation" in Section 4 of the Federal Trade Commission Act.

4. Respondent James Feijo directed and controlled the acts and practices of DCO and may be held liable under the FTC Act for the violations of DCO.

5. Respondents' sales of BioShark, 7 Herb Formula, GDU, and BioMixx, the "Challenged Products," are in or affect commerce, as required by the FTC Act, 15 U.S.C. § 45(a)(1).

6. The Commission has jurisdiction over Respondents, and the conduct challenged in the Complaint, under Sections 4 and 5 of the FTC Act. 15 U.S.C. § 44, 45.

7. The materials disseminated by Respondents over the Internet constitute advertisements under Section 12 of the FTC Act. 15 U.S.C. § 52.

8. The materials disseminated by Respondents over the Internet were for the purpose of inducing and did induce purchases of the Challenged Products in or affecting commerce, under Section 12 of the FTC Act. 15 U.S.C. §§ 52, 55.

9. The Challenged Products constitute "food" or "drugs," under Section 12 of the FTC Act. 15 U.S.C. § 55.

10. The overall, net impression created by the Respondents' advertisements is that the Challenged Products, either alone or in combination with each other or other DCO products, prevent, treat, or cure cancer, inhibit tumors, or ameliorate the adverse effects of radiation or chemotherapy.

11. The disclaimer language, which appears on some of the advertisements, is not prominent or unambiguous, creates confusion with contradictory messages, and thus is not adequate for Respondents to avoid liability.

12. Extrinsic evidence is not required to interpret Respondents' advertisements or to interpret the claims from the perspective of a particular targeted group.

13. Extrinsic evidence is not required to interpret Respondents' advertisements because the meaning of the advertisements is reasonably clear from a facial review.

14. The claims made by Respondents are objective claims that relate to the attributes, performance, or efficacy of the Challenged Products.

15. Objective product claims carry with them the express or implied representation that Respondents had a reasonable basis substantiating the claims at the time the claims were made.

16. The claims made by Respondents are non-establishment claims and relate to health and safety.

17. Health-related efficacy claims, including claims made about dietary supplements must be substantiated by competent and reliable scientific evidence on the product itself. Testing only component ingredients is insufficient, unless the testing is on an exact duplicate of the product's combination of active ingredients.

18. Respondents did not possess or rely upon competent and reliable scientific evidence to substantiate their claims that the Challenged Products are effective, either alone or in combination with each other or other DCO products, in the prevention, treatment, or cure of cancer, tumors, or side effects of radiation or chemotherapy.

19. By showing that Respondents lacked a reasonable basis for their claims, Complaint Counsel has demonstrated that Respondents' statements are deceptive or misleading.

20. Respondents' claims relate to health concerns, involve information that is important to consumers and likely to affect their choice of or conduct regarding the Challenged Products, and are therefore material.

21. Respondents' representations constitute commercial speech that is false, deceptive, or misleading, and are therefore not protected by the First Amendment.

22. The FTC's action and the Order entered herewith do not constitute an unconstitutional prior restraint.

23. All defenses raised by Respondents have been considered and rejected as lacking in merit, regardless of whether they are expressly addressed in this Initial Decision.

24. Respondents DCO and James Feijo are liable for violating Sections 5(a) and 12 of the FTC Act. 15 U.S.C. §§ 45(a), 52.

25. Individual Respondent James Feijo participated directly in and had the authority to control the deceptive representations at issue in this case. Accordingly, James Feijo is individually liable for practices of Respondent DCO found to be in violation of Sections 5 and 12 of the FTC Act.

26. The appropriate remedy is an order requiring Respondents to cease and desist from making the types of misrepresentations challenged in the Complaint.

27. Fencing-in relief is appropriate where, after examining circumstances of the case as a whole, it bears a reasonable relationship to a violation of the FTC Act.

28. The Order also provides fencing-in relief, requiring Respondents to possess competent and reliable scientific evidence supporting certain future claims about any dietary supplement, food, drug, or other health-related product, service, or program.

29. The Order attached herewith is clear and reasonably related to the proven violations.

ORDER

For purposes of this order the following definitions apply:

A. "Competent and reliable scientific evidence" shall mean 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.

B. "Covered Product or Service" shall mean any dietary supplement, food, drug, or other health-related product, service, or program, including, but not limited to, BioShark, 7 Herb Formula, GDU, and BioMixx.

C. "Food" and "drug" shall mean "food" and "drug" as defined in Section 15 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 55.

D. "Advertisement" means any written or verbal statement, illustration, or depiction that is designed to effect a sale or to create interest in the purchasing of goods or services, whether it appears in a book, brochure, newspaper, magazine, pamphlet, leaflet, circular, mailer, book insert, letter, catalogue, poster, chart, billboard, public transit card, point of purchase display, packaging, package insert, label, film, slide, radio, television or cable television, video news release, audio program transmitted over a telephone system, infomercial, the Internet, e-mail, or in any other medium.

E. Unless otherwise specified, "Respondents" shall mean Daniel Chapter One and its successors and assigns, affiliates, or subsidiaries, and its officer, James Feijo, individually and as an officer of the corporation; and each of the above's agents, representatives, and employees.

F. "Commerce" shall mean "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

G. "Endorsement" shall mean "endorsement" as defined in 16 C.F.R. § 255.0(b).

Initial Decision

I.

IT IS HEREBY ORDERED that Respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of BioShark, 7 Herb Formula, GDU, and BioMixx, or any substantially similar health-related program, service, or product, or any other Covered Product or Service, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of product or program names or endorsements, that such health-related program, service, product, or Covered Product or Service prevents, treats, or cures or assists in the prevention, treatment, or cure of any type of tumor or cancer, including but not limited to representations that:

A. BioShark inhibits tumor growth;

B. BioShark 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; or

H. BioMixx heals the destructive effects of radiation or chemotherapy;

unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that Respondents, directly or through any person, corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product or Service, in or affecting commerce, shall not make any representation, in any manner, directly or by implication, including through the use of a product name, endorsement, depiction, or illustration, about the efficacy, performance, or health-related benefits of any Covered Product or Service unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

IT IS FURTHER ORDERED that:

A. Nothing in this order shall prohibit Respondents from making any Representation for any drug that is permitted in labeling for such drug under any tentative or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and

B. Nothing in this order shall prohibit Respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

IV.

IT IS FURTHER ORDERED that:

A. Respondents shall, within seven (7) days after the date of service of this order, deliver to the Commission a list, in the form of a sworn affidavit, of all consumers

who purchased BioShark, 7 Herb Formula, GDU, and/or BioMixx, on or after January 1, 2005 through the date of service of this order. Such list shall include each consumer's name and address, the product(s) purchased, and, if available, the consumer's telephone number and email address;

B. Within forty-five (45) days after the date of service of this order, Respondents shall send by first class mail, postage prepaid, an exact copy of the notice attached as Attachment A to all persons identified in Part IV.A. above. The face of the envelope containing the notice shall be an exact copy of Attachment B. The mailing shall not include any other documents; and

C. Except as provided in this order, Respondents, and their officers, agents, servants, employees, attorneys, and representatives shall not sell, rent, lease, transfer, or otherwise disclose the name, address, telephone number, credit card number, bank account number, e-mail address, or other identifying information of any person who paid any money to any Respondent, at any time prior to the issuance of this order, in connection with the purchase of BioShark, 7 Herb Formula, GDU, and/or BioMixx. *Provided, however,* that Respondents may disclose such identifying information to the FTC pursuant to Part IV.A., above, or any law enforcement agency, or as required by any law, regulation, or court order.

V.

IT IS FURTHER ORDERED that for a period of five (5) years after the last date of dissemination of any representation covered by this order, Respondents shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:

A. All advertisements and promotional materials containing the representation;

B. All materials that were relied upon in disseminating the representation; and

C. All tests, reports, studies, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question such representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

VI.

IT IS FURTHER ORDERED that Respondents shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

VII.

IT IS FURTHER ORDERED that Respondent Feijo, for a period of ten (10) years after the date of issuance of this order, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment. The notice shall include the individual Respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Paragraph shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

VIII.

IT IS FURTHER ORDERED that Respondent DCO and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation(s) that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. *Provided, however*, that, with respect to any proposed change in the corporation about which Respondent DCO learns less than thirty (30) days prior to the date such action is to take place, Respondent DCO shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Paragraph shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

IX.

IT IS FURTHER ORDERED that Respondents shall, within sixty (60) days after the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

X.

IT IS FURTHER ORDERED that this order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

A. Any paragraph in this order that terminates in less than twenty (20) years;

B. This order's application to any Respondent that is not named as a defendant in such complaint; and

C. This order if such complaint is filed after the order has terminated pursuant to this paragraph.

Provided further, that if such complaint is dismissed or a federal court rules that the Respondents did not violate any provision of this order, and the dismissal is either not appealed or upheld on appeal, then the order will terminate according to this paragraph as though the complaint was never filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

ATTACHMENT A

LETTER TO BE SENT BY FIRST CLASS MAIL

[To be printed on letterhead of Daniel Chapter One]

[Name and address of recipient] [Date]

Dear [Recipient]:

Our records show that you bought **[name of products]** from our website **[name of website]** or through our call center using our toll free number. We are writing to tell you that the Federal Trade Commission ("FTC") has found that our advertising claims for these products were false or unsubstantiated, and has issued an Order prohibiting us from making those claims in the future.

The Order entered against us by the FTC also requires that we send you the following information about the scientific evidence on these products:

> Very little scientific research has been done concerning shark cartilage, cat's claw, burdock root, Siberian ginseng, sheep sorrel, slippery elm, watercress, Turkey rhubarb root, bromelain, turmeric, quercetin, feverfew, boron, goldenseal, echinacea, and ginseng as a means of prevention, treatment, or cure for cancer in humans. The scientific studies that have been done do not demonstrate that any of these ingredients, which are included in BioShark, 7 Herb Formula, GDU, and BioMixx, are effective when used for prevention or treatment for cancer in humans.
>
> It is very important that you talk to your doctor or health care provider before using any alternative or herbal product, including shark cartilage, cat's claw, burdock root, Siberian ginseng, sheep sorrel, slippery elm, watercress, Turkey rhubarb root, bromelain, turmeric, quercetin, feverfew, boron, goldenseal, echinacea, and ginseng. Speaking with your doctor is important to make sure that all aspects of your medical treatment work

together. Things that seem safe, such as certain foods, herbs, or pills, may interfere or affect your cancer or other medical treatment, or other medicines you might be taking. Some herbs or other complementary or alternative treatments may keep your medicines from doing what they are supposed to do, or could be harmful when taken with other medicines or in high doses. It also is very important that you talk to your doctor or health care provider before you decide to take any alternative or herbal product, including shark cartilage, cat's claw, burdock root, Siberian ginseng, sheep sorrel, slippery elm, watercress, Turkey rhubarb root, bromelain, turmeric, quercetin, feverfew, boron, goldenseal, echinacea, and ginseng, instead of taking conventional cancer treatments that have been scientifically proven to be safe and effective in humans.

If you would like further information about complementary and alternative treatments for cancer, the following Internet web sites may be helpful:

1. The National Cancer Institute: www.cancer.gov/cancer topics/pdq; or

2. The National Center for Complementary and Alternative Medicines: www.nccam.nih.gov.

You may also contact the National Cancer Institute's Cancer Information Service at 1-800-4-CANCER or 1-800-422-6237.

Sincerely,

ATTACHMENT B

Daniel Chapter One
1028 East Main Road
Portsmouth, Rhode Island, 02871

[name and address of purchaser]

GOVERNMENT ORDERED NOTICE

OPINION OF THE COMMISSION

By ROSCH, Commissioner, For A Unanimous Commission:

Upon consideration of the record and the arguments of counsel, the Commission denies the Respondents' appeal and affirms the Initial Decision of the Administrative Law Judge both as a matter of fact and as a matter of law. The Commission finds the order entered below to be proper, but modifies the language in Attachment A of the Order, the prescribed notice that the Respondents are required to send to consumers who purchased the products at issue.

I. Background and Proceedings Below

The Commission issued the Complaint in this matter on September 16, 2008 against Daniel Chapter One ("DCO") and

James Feijo (collectively, "Respondents"). The Complaint alleged that Respondents engaged in deceptive acts or practices, in or affecting commerce, in violation of Sections 5(a) and 12 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. §§ 45(a) and 52. Compl. ¶ 17.

The Complaint alleged that these deceptive acts or practices occurred in connection with the Respondents' advertising, promotion, offering for sale and distribution of four DCO products: BioShark, 7 Herb Formula, GDU and BioMixx (collectively, "the Challenged Products"), which purport to prevent, treat, or cure cancer or tumors and other serious medical illnesses. *Id.* ¶¶ 3-13.

More specifically, the Complaint alleged that advertisements for the Challenged Products represented, expressly or by implication, that:

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

Id. ¶ 14. The Complaint alleged that those representations were deceptive in that Respondents represented, directly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations when in fact Respondents lacked a reasonable basis to substantiate them. *Id.* ¶¶ 15-17.

Respondents filed their Answer on October 11, 2008. The Answer admitted that Respondents made the representations alleged in the Complaint about the efficacy of the Challenged Products. Answer ¶ 14. The Answer also admitted that

Respondents operated a website that provided information respecting the Challenged Products in a religious and educational context, but otherwise denied the allegations that they engaged in deceptive acts or practices in connection with the advertising or sale of the Challenged Products. *Id.* ¶¶ 5, 7, 9, 11, 13-15. The Answer affirmatively averred that Respondents possessed and relied upon a reasonable basis that substantiated the representations made about the Challenged Products at the time the representations were made. *Id.* ¶ 16.

Respondents filed two motions to amend their Answer. Chief Administrative Law Judge D. Michael Chappell ("ALJ"), who presided over all pretrial proceedings and the trial, denied those motions on the grounds, *inter alia*, that the proposed amendments, coming after the close of discovery and approximately two months before trial, would have been unduly prejudicial to Complaint Counsel. Respondents also filed two motions to dismiss, and cross-motions for summary judgment were filed by Respondents and Complaint Counsel. Those motions were denied.

An evidentiary hearing on jurisdiction was held on April 21, 2009. Thereafter, the ALJ issued a ruling that Complaint Counsel had demonstrated, by a preponderance of evidence, that jurisdiction existed in the case. Respondents' motion for an interlocutory appeal from that ruling was denied.

The final pre-trial conference was held on April 22, 2009, with trial commencing immediately thereafter. Following trial, Respondents and Complaint Counsel filed concurrent post-trial briefs, proposed findings of fact and conclusions of law, and replies to each other's post trial briefs and proposed findings. Closing argument was held on July 9, 2009. The ALJ issued his Initial Decision and Proposed Order on August 5, 2009.

As set forth in the Initial Decision, the ALJ found that the record showed that DCO, described by the Respondents as a house ministry, was led by Respondent James Feijo, with his wife Patricia Feijo, and that DCO engaged in business for profit for itself or for its member, James Feijo. The ALJ found that, although DCO's activities included spiritual counseling to

individuals, they also included advertising and selling the dietary supplements BioShark, 7 Herb Formula, GDU and BioMixx to the public.

The ALJ also found that Respondents disseminated advertisements for the purpose of inducing, and which did induce, the purchase of a food or drug, in or having an effect on commerce within the meaning of Sections 5(a) and 12 of the FTC Act, and that those advertisements claimed that the Challenged Products, individually or collectively, prevent, treat, or cure cancer, inhibit tumors, or ameliorate the adverse effects of radiation and chemotherapy. The ALJ also found that Respondents did not have a reasonable basis to substantiate these claims and that the claims made were material to consumers.

The ALJ held that Complaint Counsel had carried its burden of proving that Respondents are liable under Sections 5(a) and 12 of the FTC Act. The ALJ considered the defenses raised by the Respondents and concluded that they were not meritorious. The ALJ imposed a cease and desist order that, *inter alia*, enjoins Respondents from making any representation, expressly or by implication, that any dietary supplement, food, drug, or other health-related product, service, or program, including but not limited to the Challenged Products, prevents, treats, cures or assists in the prevention, treatment, or cure of any type of tumor or cancer, unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

The order also enjoins the Respondents from making any representation about the efficacy, performance, or health-related benefits of any dietary supplement, food, drug, or other health-related product, service, or program, including but not limited to the Challenged Products, unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

The order also requires the Respondents to send a prescribed notice to all consumers who purchased the Challenged Products

that informs those consumers that the FTC has found that the advertising claims at issue were false and unsubstantiated, that the FTC has issued an order prohibiting those claims from being made in the future, and that informs those consumers about the scientific evidence on the Challenged Products.

Respondents filed a timely appeal and Complaint Counsel did not cross-appeal. The decision of the ALJ is subject to *de novo* review by the Commission. *See* 16 C.F.R. § 3.54. Accordingly, the Commission on appeal may consider the entire record and determine whether there is a sufficient evidentiary basis for the ALJ's findings of fact.

The Commission has reviewed the ALJ's findings of fact, as well as the record underlying them. The Commission has also reviewed the advertisements at issue to determine the overall net impressions conveyed by them. The Commission sees no reason to disturb the ALJ's findings of fact and adopts them as the Commission's own insofar as they are consistent with those set forth in this Opinion. Otherwise, the findings of fact in this Opinion are those of the Commission.

II. Respondents' Claims on Appeal

Respondents make three fundamental claims in their appeal: (1) Respondents claim that the FTC did not have jurisdiction over them (RAB at 11, 29-40);[1] (2) Respondents claim that the ALJ misinterpreted various statutes, including, among others, Section 5 of the FTC Act, as well as the Due Process Clause and the First Amendment of the United States Constitution, by banning truthful statements about dietary supplements, improperly shifting the burden of proof to Respondents, applying an incorrect standard of

[1] References to the record are abbreviated as follows:

IDF	Initial Decision Finding
ID	Initial Decision
RAB	Respondents' Appellate Brief
CAB	Complaint Counsel's Answering Brief
RRB	Respondents' Reply Brief
Tr.	Transcript of Trial Testimony
CX	Complaint Counsel's Exhibit
RX	Respondents' Exhibit

proof, and permitting "evidence by presumption" (RAB at 11-29, 40-55); and (3) Respondents argue that the ALJ's remedy not only prohibits truthful speech, but also illegally compels Respondents to engage in government-mandated speech. RAB at 12, 55-65.

The Commission considers the Respondents' arguments in Part III in the following order: Section A considers the Respondents' jurisdictional argument; Sections B through E consider Respondents' statutory and constitutional arguments; and Section F considers the Respondents' argument concerning the remedy.

III. Analysis

A. The FTC Has Jurisdiction.

Findings of Fact.

Prior to 2002, DCO was a for-profit corporation organized in 1990 under the laws of Rhode Island. IDF 22. Its Articles of Incorporation stated that its purposes 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." IDF 23. Subsequent annual reports, which were signed by Respondent James Feijo, described the character of the business in substantially the same way. IDF 24, 25. James Feijo sold BioShark, 7 Herb Formula, GDU and BioMixx while DCO was registered as a for-profit corporation. IDF 27.

DCO is currently a "corporation sole" organized in 2002 under the laws of the State of Washington. IDF 1; RAB at 30, 32. DCO's Articles of Incorporation do not specifically declare that DCO was organized exclusively for charitable or other clearly nonprofit purposes. IDF 30. The Articles do not provide for distribution of its assets upon dissolution solely to other nonprofit entities or prohibit distribution of its earnings to the benefit of any individual or for-profit corporation. *Id*. Nor do its advertising or promotional materials specifically refer to DCO as a nonprofit entity. IDF 32.

Respondent James Feijo is the sole "overseer" and trustee of DCO's assets and all of its funds, and he is DCO's sole "member." IDF 5, 6; RRB at 8. As such, he is responsible for all of its activities and for directing all of its funds. IDF 5, 6. James Feijo and his wife, Patricia, are the only officers of DCO. IDF 7.

DCO has a number of bank accounts, including accounts that are described as "Business Partner" accounts. IDF 42. DCO's revenue is deposited into the Business Partners Checking accounts, and from there the revenue is distributed at James Feijo's discretion to other DCO bank accounts. IDF 42. Patricia Feijo is a signatory to DCO's bank accounts and writes checks from the DCO accounts. IDF 48. The Business Partners Money Market Fund showed a balance during the period from December 19, 2006 to February 20, 2008 in excess of $1 million, but on February 21, 2008, a debit of over $800,000 was posted. IDF 45.

DCO or its affiliate own the Rhode Island and Florida homes in which James and Patricia Feijo live, as well as two Cadillacs that James Feijo uses. ID at 75; IDF 55-57. DCO paid for all of the Feijos' living expenses, including pool and gardening expenses, tennis and golf club expenses, as well as the Feijos' expenditures on retail items and at restaurants. IDF 58, 61-70.

DCO currently sells 150 to 200 products, including BioShark, 7 Herb Formula, GDU and BioMixx. IDF 8. James Feijo has been solely responsible for the development, creation, production, and pricing of the Challenged Products. IDF 37. James and Patricia Feijo have been solely responsible for creating, drafting and approving directions for the usage, and developing recommended dosages, for the Challenged Products. IDF 38, 39.

Sales of the 150 to 200 products sold by DCO, all of which are dietary supplements, have generated approximately $2 million in annual gross sales. IDF 9, 10. DCO's sales of BioShark, 7 Herb Formula, GDU and BioMixx constituted 20 to 30 percent of DCO's sales during the period from 2006 through 2008. IDF 80. The acquisition costs for those products is about 30 percent of the sale price. IDF 83.

Over a thousand people have purchased the Challenged Products, including people who do not belong to any DCO religious community and people who do not believe in God. IDF 81, 82. Respondents sell the four Challenged Products through publications, a call center, a radio program, over the Internet, and through stores and other resellers. IDF 84, 158. Any consumer could be directed to the DCO website by entering the term "cancer" in a Google internet search. IDF 162.

DCO's publications are fourfold. The first is entitled "Bioguide: The BioMolecular Nutrition Guide to Natural Health" ("BioGuide"), which was prepared by James Feijo, describes "two aspects of BioMolecular Nutrition, the spiritual and the physical" and promotes all four Challenged Products. IDF 203-211, 228, 229, 249, 270-274, 287-290. The second publication is the BioMolecular Nutrition Product Catalog ("Product Catalog"), which describes all of DCO's products including the four Challenged Products, but does not mention the existence of a DCO ministry. IDF 91, 233, 234, 256, 257, 279, 280. The third publication is a newsletter entitled "How to Fight Cancer is Your Choice!!!" ("Newsletter"), which promotes all four of the Challenged Products. IDF 94-96, 194-201, 231, 251, 253, 254, 276, 277, 292, 293. The fourth publication is entitled "The Most Simple Guide to the Most Difficult Diseases: The Doctors' How-To Quick Reference Guide" ("Most Simple Guide"). It also promotes the four Challenged Products. IDF 192. The Most Simple Guide, the BioGuide, and the Newsletter are all available to anyone by download from DCO's website. IDF 163, 169, 172.

Each of these publications promotes DCO's call center and the toll-free number to access it, as well as DCO's principal website address. IDF 90, 91, 94, 167, 174. The Newsletter promotes the BioGuide and the Most Simple Guide. IDF 168, 175. All except the Product Catalog promote the radio program. IDF 177.

As previously mentioned, DCO has a toll-free number and a call center for consumers to buy their products. IDF 99. They were created, managed and maintained by James Feijo, who has supervised the call center and taken consumer orders. IDF 100, 101. DCO also has several websites at which it takes consumers'

orders, the principal one of which invites consumers to shop at DCO's "On-Line Store" and to "Buy Now." IDF 103-107. These websites promote all four of the Challenged Products. IDF 179-190, 220-226, 237-244, 246, 247, 262-268, 283-286.

DCO also has a radio program, which is co-hosted by James and Patricia Feijo for two hours a day. IDF 108, 109. On that program, the Feijos have promoted the Challenged Products. IDF 213-217, 260, 261. They have also counseled individuals who have identified themselves as cancer patients, and they (and the website) have provided listeners with the toll-free number they can use to buy DCO's products. IDF 102, 110, 111.

A number of retail stores and chiropractic centers in various states sell DCO products. IDF 116-119. Respondents have prepared a brochure entitled "The Truth Will Set You Free" for retailers of DCO products. Among the benefits listed in that brochure are financial rewards, and the brochure makes the representation that DCO is "the ONLY nutrition company where the owners personally tell thousands of people to visit your office or store." IDF 122. Respondents also promote an "affiliate program" on their principal web page where they offer website owners "a means of profiting from their websites" by "generat[ing] sales for commercial websites" in order to "earn a commission." IDF 123.

To promote its products, DCO offers consumers coupons for their next online order, and discounts when products are purchased in volume. IDF 113-115. Moreover, in addition to the revenue derived from sale of its products, DCO charges shipping and handling fees totaling $20.95. IDF 112.

Legal Analysis.

On appeal, Respondents argue that the ALJ was mistaken and incorrect in concluding that the FTC had jurisdiction over DCO. In support of this contention, Respondents rely on several alleged Due Process errors and misapplications of law by the ALJ. RAB at 31. Specifically, Respondents argue that the ALJ misapplied the applicable law regarding jurisdiction; disregarded DCO's status as a corporation sole, a legitimate entity outside the FTC's

jurisdiction; failed to require Complaint Counsel to prove that DCO is a corporation "organized to carry on business for its own profit or that of its members;" and failed to prove that DCO or its members "derived a profit from DCO's activities." RAB 31-40. These arguments are each considered below.

As Respondents acknowledge in their appellate briefs, *California Dental Ass'n v. FTC*, 526 U.S. 756 (1999) and *Community Blood Bank v. FTC*, 405 F.2d 1011 (8th Cir. 1969), are controlling authorities respecting their challenge to the FTC's jurisdiction. RAB at 31, 34; RRB at 17. Both cases, following the language of § 4 of the FTC Act, hold that the Commission's jurisdiction extends to a corporation organized to carry on business for its own profit or that of its members. *See California Dental*, 526 U.S. at 766-67 ("The FTC Act is at pains to include not only an entity 'organized to carry on business for its own profit,'. . . but also one that carries on business for the profit 'of its members'"); *Community Blood Bank*, 405 F.2d at 1022 (holding the Commission has jurisdiction over nonprofit corporations without shares of capital, which engage in business for their own profit or that of their members); *see also* 15 U.S.C. § 44.

Respondents try to distinguish these cases from the instant case by parsing the definition of "profit" and by arguing that, contrary to the teaching of *California Dental*, DCO did not make a profit and has no for-profit subsidiaries. RAB at 32. Specifically, Respondents quote *California Dental* for the proposition that "according to a generally accepted definition 'profit' means gain from business or investment over and above expenditures, or gain made on business or investment where both receipts or payments are taken into account." RAB at 32 (*quoting California Dental*, 526 U.S. at 768 n.6 (*citing Community Blood Bank*, 405 F.2d at 1017)). However, the ALJ cited to the same *California Dental* language in evaluating the evidence and reaching his conclusion that by engaging in commercial activities, DCO operates a commercial enterprise and thereby is not a business organized or engaged in only charitable purposes. ID at 70-71. In addition, Respondents failed to include the conclusion of the quoted sentence where the Court noted that "the 'term's meaning must be derived from the context in which it is used.'"

California Dental, 526 U.S. at 768 n.6 (*citing Community Blood Bank*, 405 F.2d at 1016).

Respondents contend that they are a religious ministry organized and operated for charitable purposes. RAB at 2, 31. Respondents argue that by acknowledging that DCO was a religious ministry, but still concluding that the FTC had jurisdiction over DCO, the ALJ's conclusions are "unprecedented, legally incorrect and unsupported by the facts." RAB at 4, 29-30. But *Community Blood Bank* specifically holds that such a finding does not foreclose the FTC from exercising jurisdiction over a respondent. 405 F.2d at 1017-18; s*ee also id.* at 1018 ("Congress took pains in drafting § 4 to authorize the Commission to regulate so-called nonprofit corporations, associations and all other entities if they are in fact profit-making enterprises."). Nonprofit status insulates an entity from FTC jurisdiction when the entity is engaged in business for "only charitable purposes." *Id*. at 1022. Whatever else may be said about DCO's religious status and activities, the findings of fact, supported by extensive evidence, establish that DCO conducted business for the purpose and with the effect of selling its products, including the four Challenged Products. IDF 80-84, 91, 94, 96, 98-101, 110-113, 116-119, 123, 158, 174-190, 192, 194-201, 203-211, 213-217, 220-229, 231, 233, 234, 237-244, 246, 247, 249, 253, 254, 256, 257, 260-268, 270-274, 276, 277, 279, 280, 283-290, 292, 293. Thus, the ALJ did nothing to impeach his conclusion that the FTC had jurisdiction over Respondents.

The Respondents also argue that the ALJ failed to require proof that DCO was organized and operated to carry on business for its own profit or that of its members. RAB at 30, 34-35. In support of this contention, Respondents insist that DCO was not a for-profit corporation because it did not "make a profit" and that "the evidence showed the DCO operates at a breakeven point or less." RAB at 30, 35. Whether or not that is true, it is beside the point. As the ALJ pointed out, it is not necessary to show that the entity was actually successful in running its business or turning a profit. ID at 71 (*citing California Dental*, 526 U.S. at 768 n.6 ("the FTC Act does not require for Commission jurisdiction that members of an entity turn a profit on their membership, but only that the entity be organized to carry on business for members'

profit"); *In re Ohio Christian College*, 80 F.T.C. 815, 849-50 (1972) (stating that the fact that respondents "were apparently not very successful in their enterprise" was of "little consequence")). As discussed above, Respondents' activities, as described in the findings of fact, and supported by extensive evidence, establish that DCO conducted business for the purpose and with the effect of selling its products.

Moreover, in *In re College Football Ass'n*, 117 F.T.C. 971, 994 (1994), the Commission stated that *Community Blood Bank* thus established a two-part test looking to "the source of the entity's income, *i.e.*, to whether the corporation is 'organized for and actually engaged in business for only charitable purposes,' and to the destination of the income, *i.e.*, to whether either the corporation or its members derive a profit." Respondents contend that the FTC must also show the "destination" of DCO's income, and argue that the ALJ improperly shifted the burden of proof from the FTC to the Respondents to show that the income did not profit either DCO or Mr. Feijo. RAB at 35-36. However, the ALJ's findings of fact, supported by ample evidence, show that the "destination" of the profits of DCO's for-profit activities was James Feijo. ID at 74-76. As DCO's sole "member," "overseer," and "trustee," James Feijo was responsible for all of DCO's activities, including the distribution of its funds; he distributed those funds to himself and his wife for their benefit. The record also shows that DCO or its affiliate owned the Feijos' Rhode Island and Florida homes and two Cadillacs, and was the source of all of their living expenses, including their tennis, golf and restaurant expenses. IDF 5, 6, 42, 48, 55-58, 61-70. Thus, it cannot be said that the ALJ's conclusion that the FTC had jurisdiction over DCO was "unprecedented." RAB at 11; RRB at 12, 14, 21-22. To the contrary, it was fully supported by *California Dental* and *Community Blood Bank*.

Finally, it cannot be said that the ALJ was "mistaken" in exercising jurisdiction over DCO and Mr. Feijo despite the existence of various statutes and regulations that allow churches to carry on "business activities" for purposes of exemption from federal income taxation or provide "religious workers' special exemptions." RAB at 38-40. Respondents argue that DCO's status as a church and Mr. Feijo's status as a minister entitle

Respondents to special tax treatment. RAB at 39. Similarly, Respondents contend that DCO was organized as a "corporation sole" in 2002 under the laws of the State of Washington, and, as such, has been a nonprofit corporation since 2002. RAB at 29-31. As recognized by the ALJ, however, "courts and the Commission look to the substance, rather than the form, of incorporation in determining jurisdiction under the FTC Act." ID at 71 (citations omitted). The Commission agrees with the ALJ's determination, supported by ample evidence in the record, that "DCO bears none of the substantive indicia of a corporation that is truly organized only for charitable purposes." *Id*.

B. Respondents Made the Claims Alleged in the Complaint.

Findings of Fact.

The text of the advertisements at issue here repeatedly links all four products collectively to the prevention, treatment or cure of cancer. IDF 179, 180, 183, 186, 190, 192, 195, 197, 200, 203, 204, 208, 213. Furthermore, the advertisements repeatedly link each product individually to the cure or treatment of cancer, the shrinkage of tumors, or, in the case of BioMixx, to the amelioration of the side effects of radiation and chemotherapy. IDF 182, 198, 199, 204, 206, 221, 222, 223, 225, 226, 228, 231, 233 (respecting BioShark); IDF 237-244, 246, 247, 249, 251- 254, 256, 257, 260 (respecting 7 Herb Formula); IDF 262, 264-268, 270-274, 276, 277, 279, 280 (respecting GDU); IDF 283-285, 287-290, 292, 293 (respecting BioMixx). Indeed, in some of these advertisements the linkage between these products and the treatment or cure of cancer is to a specific type of cancer such as breast cancer (IDF 182, 187, 265, 267, 268, 273); brain cancer (IDF 184, 200, 249, 289); prostate cancer (IDF 187, 206 253, 265, 271, 274, 290); skin cancer (IDF 208, 214); colon cancer (IDF 217, 260); leukemia (IDF 276, 284); bladder cancer (IDF 200); renal cancer (IDF 207); and esophageal cancer (IDF 252). Generally, these links were explicit, but even when they were implicit, the linkage was clear.

The linkage in these advertisements was frequently emphasized by testimonials, generally by consumers. IDF 180,

181, 183, 184, 186, 197-200, 203-210, 231, 242-244, 247, 249, 253, 265, 267, 268, 273, 276, 284, 290, 292. Again, the linkage in the testimonials between the products and the treatment or cure of cancer, the shrinkage of tumors or, in the case of BioMixx, to the healing effects on radiation or chemotherapy was generally explicit, but even where it was implicit, the linkage was clear. That linkage was also frequently stressed either by the use of bold-faced type, the use of italics or the use of capital letters. IDF 180, 182, 186, 187, 190, 192, 204-209, 221, 226, 228, 231, 237, 238, 240-243, 249, 252-254, 266, 271, 274, 276, 283, 285, 289. Additionally, the products or consumers purporting to use them were depicted in the advertisements. IDF 180, 184, 190, 204, 206-208, 210, 221, 237, 238, 240, 241, 251 (logo), 254 (logo), 256, 262, 263, 266, 271, 276, 279, 283-285, 290.

These advertisements did not exist in isolation from each other. As previously described, DCO's publications prominently displayed the existence of DCO's call center and the toll-free number by which the call center could be accessed, as well as DCO's principal website address. IDF 90, 91, 98, 167-169, 174. Also, the Newsletter promoted the BioGuide and The Most Simple Guide, and the call center promoted the DCO email address. IDF 168, 175-177. Thus, the overall net impressions left by these advertisements were mutually reinforcing.

Those overall net impressions were that: (1) BioShark inhibits tumor growth and is effective in the prevention, treatment, or cure of cancer (IDF 224, 227, 230, 232, 235); (2) 7 Herb Formula inhibits tumor formation and is effective in the prevention, treatment, or cure of cancer (IDF 245, 248, 250, 255, 258); (3) GDU eliminates tumors and is an effective treatment for cancer (IDF 269, 275, 278, 281); and (4) BioMixx heals the adverse effects of radiation and chemotherapy and is effective in the prevention, treatment, or cure of cancer. IDF 286, 291, 294.

Respondents' advertisements and materials sometimes included "disclaimers" of these overall net impressions. DCO's websites asserted, *inter alia*, that "[t]he information provided in this site is not intended to diagnose a disease;" that the information "is designed to support, not replace, the relationship that exists between a patient site visitor and his/her health

provider;" and that "this product is not intended to diagnose, treat, cure, or prevent disease." IDF 296, 297, 300, 301. The BioGuide and Newsletter stated, *inter alia*, that they were "not intended to diagnose or treat disease." IDF 298, 299. The Most Simple Guide contains no disclaimer language. IDF 302.

For the most part, these disclaimers were made in "mouse print" or type size significantly smaller than the type of the text contributing to those overall net impressions. IDF 296, 298-300, 303. They were often buried in copyright disclosures, and placed well after the conclusion of the advertising claims. IDF 296-300. Moreover, they disclaimed only Respondents' "intentions," not the representations themselves. They did not dispel the overall net impressions left by the advertisements and by the other contributing factors that the Challenged Products prevent, treat, or cure cancer. IDF 306.

Legal Analysis.

Respondents do not take issue with the ALJ's conclusion that the "overall net impression" of the advertising promoting the four Challenged Products determines what impression is conveyed by an advertisement. RAB at 4, 5, 11; RRB at 38. That acknowledgment is not gratuitous. The courts have long held that to be the test applied in determining what impressions are conveyed to consumers. *See, e.g., American Home Prods. Corp. v. FTC*, 695 F.2d 681, 687 (3rd Cir. 1982); *FTC v. Sterling Drug, Inc.*, 317 F.2d 669, 674 (2d Cir. 1963); *FTC v. Bronson Partners LLC*, 564 F. Supp. 2d 119, 125 (D. Conn. 2008); *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 920-21, 929, 932 (N.D. Ill. 2006), *aff'd*, 512 F.3d 858 (7th Cir. 2008). Moreover, Respondents admitted that they made the representations that the ALJ found were conveyed by the advertisements at issue (Answer ¶ 14), although now Respondents shrug off the admissions as "ministerial error" and stress that the ALJ did not consider them. RBB at 35.

However, Respondents repeatedly assert that in assessing those "overall net impressions," the ALJ was obliged by the Due Process Clause and the First Amendment of the Constitution to consider "extrinsic" evidence. RAB at 2, 4, 13, 48-49; RRB at 12-13, 30-31. More specifically, Respondents claim that

"Complaint Counsel should have been required to produce evidence that consumers were actually misled by Respondents' promotional efforts and representations," including testimony from the misled consumers themselves. RAB at 14, 23-24; RRB at 33, 34, 37-38, 57. Indeed, Respondents contend that the ALJ's failure to require Complaint Counsel to do so amounted to resorting to "presumptions" instead of evidence or at least "shifting the burden of proof" to Respondents in violation of the Due Process Clause and the First Amendment. RAB at 3, 11, 14, 24.

That is not the law. Federal courts have long held that the Commission has the common sense and expertise to determine "what claims, including implied ones, are conveyed in a challenged advertisement, so long as those claims are reasonably clear." *Kraft, Inc. v. FTC*, 970 F.2d 311, 319 (7th Cir. 1992); *accord FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 391-92 (1965); *Thompson Med. Co. v. FTC*, 791 F.2d 189, 197 (D.C. Cir. 1986); *Bronson Partners*, 564 F. Supp. 2d at 126; *FTC v. Nat'l Urological Group, Inc.*, No. 1:04-CV-3294-CAP, 2008 U.S. Dist. LEXIS 44145, at *41-43 (N.D. Ga. June 4, 2008) (extrinsic evidence "is only necessary when the asserted claims fall on the 'barely discernable' side of the continuum"); *QT, Inc*., 448 F. Supp. 2d at 958.

Moreover, in *Kraft*, the Seventh Circuit rejected Respondents' First Amendment argument. Like Respondents, Kraft contended that *Peel v. Attorney Registration & Disciplinary Commission*, 496 U.S. 91 (1990), held that the First Amendment required "extrinsic" evidence and prevented the Commission from determining the overall net impression conveyed by advertisements challenged as deceptive under the FTC Act. The Court of Appeals held that the restriction challenged in *Peel* is "a completely different animal than the one challenged here." *Kraft*, 970 F.2d at 317. It explained that in *Peel*, the issue was whether a "regulation applicable to all lawyers, completely prohibiting an entire category of potentially misleading speech, passed constitutional muster" in contrast to "whether an individualized FTC cease and desist order, prohibiting a particular set of deceptive ads, passes constitutional muster." *Id.*

In this case, the ALJ and the Commission itself have determined the "overall net impressions" of the representations made about the Challenged Products, based not only on the text of the advertisements itself, but also on the interaction of other factors that operate to create that impression, such as testimonials, bold type, visual images and mutually reinforcing language. ID at 82-83. Those are factors that the Commission and the courts have recognized are probative in determining what messages advertising is conveying. *In re Kraft*, 114 F.T.C. 40, 121 (1991), *aff'd*, 970 F.2d 311 (7th Cir. 1992); s*ee also Bronson Partners*, 564 F. Supp. 2d at 125; *In re Telebrands Corp.*, 140 F.T.C. 278, 290 (2005), *aff'd*, 457 F.3d 354 (4th Cir. 2006). The Commission therefore does not agree with Respondents that "evidence" has been supplanted by "presumptions" or that the ALJ shifted the "burden of proof" to Respondents so as to violate Due Process or the First Amendment of the Constitution in the determination of those overall net impressions.

As discussed below, the alleged "disclaimers" do not dispel these overall net impressions.

C. Respondents' Representations Were Deceptive Unless Properly Substantiated.

After reaching his findings on the overall net impressions of the Respondents's advertising respecting the efficacy of the four Challenged Products, the ALJ next examined whether those representations were deceptive under Commission and federal case law. He concluded that under that case law, the representations would be deceptive under Sections 5 and 12 of the FTC Act if they were either shown to be false or shown to lack a reasonable basis substantiating the claims made in the advertisement. ID at 99 (*citing FTC v. Pantron I*, 33 F.3d 1088, 1096 (9th Cir. 1994); *In re Thompson Med. Co.*, 104 F.T.C. 648, 818-19 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986)).

The ALJ focused on whether the advertisements at issue were deceptive or misleading under the "reasonable basis" theory because the Complaint only made "reasonable basis" allegations. *Id*. Again, citing Commission and federal case law, the ALJ stated that the "reasonable basis theory holds that claims about a

product's attributes, performance, or efficacy ('objective' product claims) carry with them the express or implied representation that the advertiser had a reasonable basis substantiating the claims at the time the claims were made." *Id*. (*citing In re Thompson Med. Co.*, 104 F.T.C. at 813; *FTC v. Direct Mktg. Concepts*, 569 F. Supp. 2d 285, 298 (D. Mass. 2008); *In re Kroger Co.*, No. C-9102, 1978 FTC LEXIS 332, at *15 (May 17, 1978)).

Respondents do not (and cannot) dispute that this is a correct reading of the case law. However, Respondents contend that in applying these principles, the ALJ again engaged in "presumptions" and shifted the "burden of proof" in a way that violated the Due Process Clause and the First Amendment of the Constitution. RRB at 34, 51.

First, Respondents contend that the representations made about the efficacy of the four Challenged Products cannot be challenged as deceptive, consistent with the First Amendment. Specifically, Respondents liken those representations to mere "ideas, opinions, beliefs and theories" involved in *In re Rodale Press, Inc.*, 71 F.T.C. 1184 (1967), to a ban on the words "natural," "organic" and "health food" which an FTC Presiding Officer condemned in connection with the Commission's Proposed Trade Regulation Rule on Food Advertising ("Food Rulemaking") (Report of the Presiding Officer, Proposed Trade Regulation Rule: Food Advertising, Pub. Rec. No. 215-40, at 239, Feb. 21, 1978), and with the representations about "matters of opinion" involved in *United States v. Johnson*, 221 U.S. 488 (1911). RAB at 5-11.

Respondents' representations are not matters of opinion, but, as the ALJ put it, "objective product claims . . . stated in positive terms and . . . not qualified to be statements of opinion." ID at 99. Or, to put the matter more baldly, Respondents' representations were representations of fact, not simply representations about ideas, opinions, beliefs or theories; Respondents made assertions not just about what they believed those products might do, but represented that the four Challenged Products would in fact treat or cure cancer, prevent or shrink tumors, and ameliorate the side effects of radiation and chemotherapy. *See, e.g.*, IDF 179, 180, 183,186, 190, 192, 195, 197, 200, 203, 204, 208, 213 (Challenged

Products collectively); IDF 221-223, 225, 226, 228, 231, 233 (BioShark); IDF 182, 198, 199, 204, 206, 237-244, 246, 247, 249, 251-254, 256, 257, 260 (7 Herb Formula); IDF 262, 264-268, 270-274, 276, 277, 279, 280 (GDU); IDF 283-285, 287-290, 292, 293 (BioMixx). Therefore, as a matter of law, there was an implied claim that there was a reasonable basis substantiating those representations. *In re Thompson Med. Co.*, 104 F.T.C. at 813 n.37 (noting that "objective product claims carry with them an express or implied statement that the advertiser has some amount of support for the claim").

Beyond that, *Rodale Press*, the Food Rulemaking, and the *Johnson* case were not decided on constitutional grounds. As Respondents acknowledge, the Commission simply voted to dismiss *Rodale Press*. RAB at 6. Similarly, the Commission abandoned its Proposed Trade Regulation Rule on Food Advertising on the ground that case-by-case scrutiny would be more appropriate. *See* Food Advertising, 45 Fed. Reg. 23705 (Apr. 8, 1980); Termination of Proposed Trade Regulation, 48 Fed. Reg. 23270 (May 24, 1983). In neither instance was the Commission's action compelled by the First Amendment. *See, e.g.*, 45 Fed. Reg. at 23706 (stating that "it is not clear that the claims under scrutiny are readily susceptible to the across-the-board remedies that have been proposed or that this approach represents the ideal solution for remedying deception or unfairness"); *Rodale Press, Inc. v. FTC*, 407 F.2d 1252 (D.C. Cir. 1968) (vacating Commission's order and remanding for further hearing and argument on new theory of violation); *In re Rodale Press, Inc.*, 74 F.T.C. 1429, 1430 (1968) (dismissing complaint because, "[f]urther continuation of these proceedings at this time appearing not to be in the public interest and the possibility appearing remote that the practices challenged in the complaint would be resumed in the future"). Respondents likewise acknowledge that "[t]he *Johnson* case did not reach the constitutional question because the majority disposed of it as a legislative interpretation case." RAB at 11. Indeed, as the ALJ pointed out, Congress effectively overruled *Johnson* by amending the Food and Drug Act to expressly include claims regarding curative effectiveness. ID at 111 (*citing* Act of June 30, 1906, as amended, 37 Stat. 416 (1912)).

Additionally, Respondents' representations are not protected by the First Amendment. It is well established under applicable Supreme Court precedent that commercial speech is accorded less protection than other constitutionally protected forms of speech. ID at 112 (*citing Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 562-63 (1980); *Va. Pharm. Bd. v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 771-72 n.24 (1976)). In determining whether speech is commercial, *Zauderer v. Office of Disciplinary Council*, 471 U.S. 626, 637-38 (1985), is instructive. *Zauderer* holds that 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.'" ID at 113 (citations omitted). Thus, as the ALJ pointed out in the Initial Decision, speech that "propose[s] a commercial transaction" necessarily constitutes commercial speech. *Id.* (*citing Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 US. 469, 473-74 (1989)).

As previously discussed in connection with Respondents' jurisdictional challenge, the primary purpose and effect of Respondents' representations concerning the four Challenged Products was to sell those products. Those representations constituted commercial speech, not simply practicing religion or engaging in "charitable solicitations." See RRB at 62. As a matter of law, including religious or political views in the commercial advertising at issue does not convert Respondents' commercial speech to constitutionally protected religious or political speech. ID at 114; *see also Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 67-68 (1983) (holding that mailings constituted "commercial speech notwithstanding the fact that they contain discussions of important public issues such as venereal disease and family planning"); *id.* at 68 (*quoting Central Hudson*, 447 U.S. at 563 n.5 ("[A]dvertising which 'links a product to a current public debate' is not thereby entitled to the constitutional protection afforded noncommercial speech.")).

Accordingly, the Supreme Court cases concerning *non-commercial* speech upon which Respondents rely – namely, *New York Times Co. v. Sullivan*, 376 U.S. 254 (1964); *Village of Schaumburg v. Citizens for a Better Environment*, 444 U.S. 620 (1980); and *West Virginia State Board of Education v. Barnette*,

319 U.S. 624 (1943) – do not apply at all. *Cf. Church of Scientology v. Richardson*, 437 F. 2d 214, 218 (9th Cir. 1971) (holding there was no First Amendment violation so long as the FDA "could determine the E-meter's [an instrument used in the practice of Scientology] intended use without evaluating the truth or falsity of any related 'religious' claims."). RRB at 56.

The Supreme Court's First Amendment cases involving commercial speech upon which Respondents rely – *Central Hudson*, 447 U.S. 557; *Edenfield v. Fane*, 507 U.S. 761 (1993); *Greater New Orleans Broadcasting Ass'n. v. United States*, 527 U.S. 173 (1999); *Ibanez v. Florida Department of Business & Professional Regulation, Board of Accountancy*, 512 U.S. 136 (1994); *In re R.M.J.*, 455 U.S. 191 (1982); *Peel v. Attorney Registration & Disciplinary Commission*, 496 U.S. 91 (1990); *Rubin v. Coors Brewery Co.*, 514 U.S. 476 (1995); *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002); *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976); and *Illinois ex rel. Madigan v. Telemarketers Ass'n.*, 538 U.S. 600, 619-20 (2003) – have all affirmed that misleading or deceptive commercial speech is not protected by the First Amendment. Those declarations are often included in the passages cited by Respondents. RAB at 18, 20-21; RRB at 51-52.

Respondents argue that *Central Hudson*, *Peel*, *Ibanez* and *Thompson*, *Madigan* and *Greater New Orleans Broadcasting* teach that under the First Amendment, the government (here the FTC) must identify a "substantial interest" in order to justify restricting their advertising. RAB at 20-23; RRB at 51-52. Respondents further cite *Edenfield*, 507 U.S. at 770-71, for the proposition that the "substantial interest" cannot be established by mere "speculation and conjecture." RAB at 22. But that gets things backward. In *Central Hudson*, the Supreme Court set forth the four-part analysis for determining whether regulation of commercial speech is constitutional. A first and threshold inquiry is whether the speech in question is false or misleading; for commercial speech to be afforded any First Amendment protection, "it at least must concern lawful activity and not be misleading." 447 U.S. at 566. Non-misleading commercial speech remains subject to reasonable regulation, under the

remaining three elements of the *Central Hudson* analysis: whether the regulation is based on a substantial governmental interest; "whether the regulation directly advances the governmental interest asserted;" and "whether it is not more extensive than necessary to serve that interest." *Id*.

The cases cited by Respondents all recognize that the latter three prongs of the test are reached if, and only if, Respondent's advertising is not misleading or deceptive. *See Edenfield*, 507 U.S. at 768 ("[O]ur cases make clear that the State may ban commercial expression that is fraudulent or deceptive without further justification."). The ALJ found Respondents' commercial speech deceptive. The record shows that the ALJ's findings were based on the text of the advertisements at issue, as well as the Respondents' use of testimonials, bold print, pictures and mutually reinforcing advertisements to create the "overall net impressions" conveyed by the advertisements. In reviewing the ALJ's findings, the Commission has also brought its expertise and experience to bear. Once reaching that finding, no further analysis is necessary.

Respondents also emphasize that *Thompson v. Western States Medical Center* held that under the First Amendment, even if the government has an interest in preventing misleading advertisements, it could not enjoin the compounding of drugs if disclaimers would be a less restrictive alternative. RAB at 60. In their Reply Brief, Respondents argue that *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), said the same thing about the use of disclaimers. RRB at 27-30. That case does not help Respondents either. Both in *Thompson* and in the portion of *Pearson* on which Respondents rely, the issue was not the condemnation of particular commercial speech found to have been actually misleading, but rather the regulation of broad categories of speech, subject to the latter three prongs of the *Central Hudson* analysis. *See Thompson*, 535 U.S. at 368; *Pearson*, 164 F.3d at 655-56. It was in the context of that analysis – assessing the "fit" between government regulation of non-misleading commercial speech and the interests sought to be served – that each court focused on the use of disclaimers as a substantially less restrictive alternative to outright bans. *See Central Hudson*, 535 U.S. at 376; *Pearson*, 164 F.3d at 657-58. Respondents offer no support for

their assertion that the *Central Hudson* "fit" analysis should be imported into cases like the present one, in which an administrative agency is adjudicating the deceptive nature of particular advertisements.[2]

Even if we were to adopt Respondents' unprecedented approach to this issue, their arguments fail on the record before us. Respondents' "disclaimers" here were ineffective, given the multiple techniques Respondents used to reinforce their overall advertising messages, the comparatively small print in which most of their "disclaimers" were printed (IDF 296, 298, 299, 300, 303), their ambiguity and lack of conspicuousness (IDF 305), and the fact that even those "disclaimers" only disclaimed Respondents' "intentions," not the messages themselves. Any one of these factors would blunt the effectiveness of the disclaimers. *See, e.g., Removatron Int'l v. FTC*, 884 F.2d 1489, 1497 (1st Cir. 1989) (holding that disclaimer that was not clear and conspicuous was ineffective). Considering these factors in combination, Respondents' "disclaimers" did not dispel the overall net impressions that the four Challenged Products would treat or cure the diseases and conditions that Respondents' representations conveyed.

Second, Respondents argue that none of this First Amendment jurisprudence applies to herbal supplements like the four Challenged Products because they are not "drugs" within the meaning of the Food and Drug Act. RAB at 8. As Respondents acknowledge, the Food and Drug Act "differs from" the FTC Act. RRB at 41 (*quoting FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008)). Respondents do not explain why or how the Food and Drug Act can be considered binding on the Commission in enforcing the Sections 5 and 12 of the FTC Act. Under the FTC Act, these products are embraced within Section 5, and, as the ALJ observed, the FTC Act defines the words "food" and "drug" broadly for purposes of Section 12. ID at 80. Accordingly, the courts have repeatedly held that that definition covers dietary

[2] Respondents further attempt to bootstrap from *Pearson*'s holding by equating the "potentially misleading" speech subjected to prescriptive regulation there with the implied claims that have been specifically adjudicated in the present case to be actually misleading. RRB at 28. As explained above, however, the two are "completely different animal[s]." *Kraft*, 970 F.2d at 317.

supplements. *See, e.g.*, *FTC v. Natural Solution, Inc.*, No. CV 06-6112-JFW, 2007 U.S. Dist. LEXIS 60783, at *11-12 (C.D. Cal. Aug. 7, 2007); *Nat'l Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *43-44; *Direct Mktg. Concepts*, 569 F. Supp. 2d at 300, 303; *see also* ID at 80-81, 103. Moreover, those same courts have specifically held that such products can be deceptive if they lack a reasonable basis substantiating the claims made for them. *Natural Solution*, 2007 U.S. Dist. LEXIS 60783, at *9-10; *Nat'l Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *76-79; *Direct Mktg. Concepts*, 569 F. Supp. 2d at 298.

Third, Respondents repeatedly assert that the Commission cannot challenge their efficacy representations for the four Challenged Products because those representations were simply "structure/function" claims that are permitted under the Dietary Supplement Health and Education Act, Pub. L. No. 103-417, 108 Stat. 4325 ("DSHEA"), which amended the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399a ("FDCA"). RAB at 3, 4, 12, 45, 46, 51, 52; RRB at 33, 40, 41, 45. Respondents' representations, however, are not "structure/function" claims under the DSHEA. Under the FDCA, such a claim is defined simply as one that describes "the role of a nutrient or dietary ingredient intended to affect the structure or function in humans." 21 C.F.R. § 101.93(f) (2009). The Respondents' representations that the four Challenged Products would treat or cure cancer, prevent or shrink tumors, and ameliorate the side effects of radiation and chemotherapy do not simply describe the "role" that those four products will play in affecting the structure or function in humans. *See United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547, 568 (D.N.J. 2004); *see also Pearson*, 164 F.3d at 652. Moreover, DSHEA expressly provides that even compliant "structure/function" claims are permitted only if they are "truthful and not misleading" and the manufacturer "has substantiation" that such claims are true. 21 U.S.C. § 343 (r)(6)(B) (2009). Thus, the DSHEA amendment to the FDCA is not inconsistent with the FTC case law as applied by the ALJ. Indeed, even if the FDCA departed from the FTC Act and its relevant case law, Respondents offer no authority that it would be binding on the Commission.

Fourth, Respondents argue that the ALJ failed to adopt a "flexible standard of substantiation" for their representations and

ignored numerous studies supporting those representations, contrary to the FTC's guidelines entitled, *Dietary Supplements: An Advertising Guide for Industry* ("Guide"). RAB at 47-48. The Commission does not agree. The Guide advises the Commission's standard of substantiation for dietary supplements is "flexible," because the standard depends upon the claims made for those products. Guide at 8. The Guide warns that the "FTC typically requires claims about the efficacy or safety of dietary supplements to be supported with 'competent and reliable scientific evidence.'" Guide at 9. Thus, where, as here, Respondents represented that the four Challenged Products would treat or cure cancer, prevent or shrink tumors, and/or ameliorate the destructive side effects of radiation or chemotherapy, the competent and reliable scientific standard applies under the Guide.

Fifth, Respondents maintain that they only intended to convey the impression that their "Biblical approach to health care – including use of the Challenged Products – could reinforce the naturally healing capability of the body, including the immune system, and thereby provide adjunct support for whatever path – drugs, surgery or other – an individual freely chose to take for their cancer care regimen." RAB at 44. That stated intent is at odds with almost all of the advertisements themselves, which generally did not mention the "naturally healing ability of the body" or that the four Challenged Products could be only an "adjunct" to traditional cancer treatments. But in any event, the courts have long held that "the subjective good faith of the advertiser is not a valid defense." *FTC v. Sabal*, 32 F. Supp. 2d 1004, 1007 (N.D. Ill. 1998); *see also FTC v. World Travel Vacation Brokers, Inc*., 861 F.2d 1020, 1029 (7th Cir. 1988).

Finally, Respondents contend that they cannot be held liable for deception because all of the elements of Section 5(n) of the FTC Act have not been proved. That is, Respondents argue Complaint Counsel failed to prove their acts were both unfair and deceptive. That argument is without merit. No case has ever held that deception claims are subject to Section 5(n).

D. Due Process Was Not Violated.

Despite Respondents' claims to the contrary, it cannot be said that the ALJ violated Due Process in reaching his findings of fact under a "preponderance of evidence" standard instead of a "clear and convincing evidence" standard. RAB at 11, 27-29. As the ALJ states in his Initial Decision, under both the Administrative Procedure Act and the Commission's rules, the proper standard to be applied in FTC Act cases challenging deceptive practices is the "preponderance of evidence" standard. ID at 66-67. Federal court and Commission decisions respecting those challenges have repeatedly so held. *In re Telebrands Corp.*, 140 F.T.C. 278, 426 (2004), *aff'd*, 140 F.T.C. 278 (2005), *aff'd*, 457 F.3d 354 (4th Cir. 2006); *In re Auto. Breakthrough Sciences, Inc.*, No. 9275, 1998 FTC LEXIS 112, at *37 n.45 (Sept. 9, 1998); *In re Adventist Health System/West*, 117 F.T.C. 224, 297 (1994); *In re Bristol-Myers Co. v. FTC*, 102 F.T.C. 21, 275 (1983), *aff'd*, 738 F.2d 554 (2d Cir. 1984). Moreover, contrary to Respondents' assertion in their Reply Brief (RRB at 47), those decisions do not simply concern the standard applicable to litigating over whether the FTC has jurisdiction. *Telebrands*, for example, concerned whether certain representations were conveyed in the advertising, and whether they were deceptive. 140 F.T.C. at 427, 449.

Other cases upon which the Respondents rely, *Addington v. Texas*, 441 U.S. 418 (1979); *Stanley v. Illinois*, 405 U.S. 645 (1972); and *Mathews v. Eldridge*, 424 U.S. 319 (1976) (RAB at 26-28), do not hold otherwise. Those cases did not consider the standard of proof applicable under the FTC Act or the standard of proof applicable when the FTC challenges deceptive acts or practices. Indeed, they are entirely inapposite. *Stanley* simply held that a State may not deprive an unwed father of custody of his children, on the basis of a statutory presumption of unfitness, but must afford an individualized fitness hearing. In the present case, Respondents have been afforded an extensive hearing on the specific charges against them. *Mathews* set forth general standards for due process procedures, but emphasized the flexibility of the constitutional standard. 424 U.S. at 334-35. The Court there upheld an administrative scheme for the termination of disability benefits without any pre-termination evidentiary hearing – a holding that offers the present Respondents no

support. *Id.* at 339-40. In *Addington* – the only case cited that addresses a constitutional requirement regarding the standard of proof – the Supreme Court held that due process requires "clear and convincing" evidence to support the indefinite, involuntary commitment of an individual to a mental institution. 441 U.S. at 431-32. The holding in *Addington*, respecting an extreme form of deprivation of personal liberty, has no bearing on the present case. Here, Respondents were afforded ample procedural protections, including adjudication under the established preponderance of evidence standard typical of civil litigation. Their assertions that due process required more than this are without merit.

E. There is No Reasonable Basis Substantiating the Representations.

Findings of Fact.

Respondents alleged in their Answer that they possessed and relied upon a reasonable basis that substantiated the representations they made for the four products at issue at the time those representations were made. Answer ¶ 16; RAB at 2. However, Respondents did not conduct or direct others to conduct any scientific testing of the effects of the four Challenged Products. IDF 308, 309, 311, 313, 315. The manufacturers of BioShark and BioMixx likewise did not conduct any testing on those products. IDF 310, 314. Respondents have not produced anything to show that they possessed and relied on any competent and reliable scientific evidence to support the overall net impressions conveyed by the advertisements at issue.

The ALJ considered the evidence presented by Complaint Counsel's expert, Dennis Miller, M.D. and Respondents' five experts, James Duke, Ph.D., Sally LaMont, N.D., Rustum Roy, James Dews and Jay Lehr, Ph.D. IDF 329-425. The only proffered expert who was a medical doctor, had specialized training or experience regarding cancer or cancer treatment, or had conducted clinical studies regarding cancer treatments was Dr. Miller. IDF 329-337. Dr. Miller is a board-certified pediatric hematologist/oncologist who, *inter alia*, has directed clinical care, education, laboratory and clinical research, and administration heading divisions or departments for over forty years at the

University of Rochester Medical Center, New York Hospital-Cornell Medical Center, Memorial Sloan-Kettering Cancer Center and Northwestern University Medical School. IDF 320-326.

Dr. Miller testified that "competent and reliable scientific evidence" is required to conclude that a cancer treatment is effective. IDF 343. Dr. Miller explained that in order to constitute competent and reliable scientific evidence that a product treats, cures, or prevents cancer, the products' efficacy and safety must be demonstrated through controlled clinical studies (tests on humans). IDF 344, 345. He further testified that studies performed in test tubes or in animals, testimonials and other anecdotal reports are not substitutes. IDF 345, 351-353. He testified that harm potentially may occur from remedies that are alternatives to those that have undergone clinical studies on humans. IDF 356-361. And, he testified that for these reasons, the need to substantiate a claim by clinical studies (*i.e.*, on humans) was the same whether the purported agent was a herbal medicine or a more conventional pharmaceutical agent. IDF 354.

Dr. Miller was asked to determine whether there was competent and reliable scientific evidence to substantiate each of the overall net impressions conveyed by the advertisements at issue about the Challenged Products, and he did so. IDF 327, 344, 345, 351-354. Dr. Miller concluded that the reference materials relied on by Respondents did not constitute competent and reliable scientific evidence that any of the Challenged Products prevent, treat or cure cancer; that most of those materials were not peer-reviewed papers but instead consisted of author opinions and literature reviews; that many of the studies involved *in vitro* or animal studies, not studies on humans; that others relied on the efficacy or safety of ingredients of the Challenged Products rather than the products themselves and that, absent, evidence that DCO's four products at issue here contained exactly those ingredients in the proportion tested, those studies were not probative; and that there is no competent and reliable scientific evidence that the Challenged Products are effective, either alone or in combination with other DCO products, in the prevention, treatment or cure of cancer, in inhibiting tumor formation, or in ameliorating the adverse effects of radiation and chemotherapy.

IDF 362-367. The reference materials on which Respondents relied were of the sort that Dr. Miller testified were not reliable. IDF 368-386.

Respondents did not ask any of their proffered experts to render an opinion as to whether Respondent's purported substantiation materials constituted competent and reliable scientific evidence substantiating any of the overall net impressions conveyed by the advertisements at issue about the Challenged Products. IDF 339. Neither did Respondents ask any of their proffered experts to render an opinion as to whether there existed any such substantiating evidence. IDF 340. Respondents' expert, Dr. Duke, made no effort to determine whether there were any studies of any sort regarding the Challenged Products; he did not analyze any of those products; and he did not know the ingredients of those products. IDF 392-394. Dr. LaMont likewise did not analyze any of the Challenged Products themselves, but only the ingredients in those products, and she did not know the concentration of those ingredients in those products. IDF 401-403. Mr. Roy did not review or obtain any of the Challenged Products or their labels, and he had no idea what ingredients those products contain. IDF 412, 413. None of the experts proffered by Respondents expressed any opinion about whether there was any competent and reliable scientific evidence to support the overall net impressions respecting the efficacy of the four products at issue created by the challenged advertisements. IDF 341, 389, 390, 398, 399, 408, 409, 419, 420, 423, 424.

Legal Analysis.

Respondents have repeatedly accused the ALJ of improperly engaging in "presumptions," "shifting the burden of proof" away from Complaint Counsel, as well as violating the Due Process Clause and the First Amendment of the Constitution. Thus, in reviewing the ALJ's conclusion that Respondents lacked a reasonable basis substantiating their representations concerning the efficacy of the Challenged Products, it is appropriate to analyze what the ALJ did not do, in addition to what he did do.

First, the ALJ did not treat Respondents' advertising as making "establishment" claims – that is to say, advertising that represents the amount and type of evidence substantiating the product claims made. ID at 100-101. Although the ALJ pointed out that a few of the advertisements did represent that the claims had been proven by scientific testing (ID at 101 (citing IDF 225, 231, 247)), he concluded, "Complaint Counsel has not alleged or argued that Respondents' advertisements constitute establishment claims. Accordingly, the claims at issue are deemed non-establishment claims, and will be evaluated as such." ID at 101.

The result of that conclusion, however, is that in determining the level of substantiation required, the ALJ did not "presume" the truth of Respondents' representations that their claims were supported a study conducted by "two researchers at the Massachusetts Institute of Technology" or "used by patients involved in clinical studies in cancer clinics." IDF 225 (CX 13); IDF 231 (CX 23 & 24); IDF 247 (CX 18). Instead, the ALJ found the claims to be "health-related efficacy claims," and as a result, under well-established precedent, such claims must be substantiated by "competent and reliable scientific evidence." ID at 101. In addition, to the extent that further analysis for determining the substantiation standard was necessary, the ALJ also analyzed them under the *Pfizer* factors: the type of claim involved, the benefits of a truthful claim, the consequences of a false claim, and the amount of substantiation experts in the field consider reasonable. ID at 102-104; *In re Pfizer, Inc.*, 81 F.T.C. 23 (1972); *QT, Inc.*, 448 F. Supp. 2d at 959; *Nat'l Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *43-44, 77-79; *In re Removatron*, 111 F.T.C. 206, 306 n.20 (1988); *In re Thompson Med. Co.*, 104 F.T.C. at 821.

Based upon his findings respecting the "overall net impressions" conveyed by Respondents' representations, the ALJ concluded that: (1) the representations made about the four Challenged Products were "health-related efficacy claims" in that they represented that the products would "treat or cure" cancer, eliminate or shrink tumors, and/or ameliorate the adverse effects of radiation and chemotherapy (ID at 101-102); (2) the benefits of truthful claims were substantial because cancer patients would benefit from truthful representations about effective treatment of,

or cure for, the disease (ID at 103); (3) the consequences of a deceptive claim were substantial not only because a patient might forego using products or therapies that were effective in treating or curing the relevant diseases, but also (as Respondents acknowledged in their "disclaimers"), because their products could be harmful if used with the other products or therapies (ID at 103); and (4) clinical studies respecting human beings were required because the representations Respondents made concerned the efficacy of the Challenged Products in treating or curing human beings, not animals, or their efficacy in vitro. ID at 103-104.

Taking those considerations into account, the ALJ concluded that Respondents' representations needed to be substantiated by "competent and reliable scientific evidence," including "controlled clinical studies" – *i.e.*, human studies. ID at 104. That conclusion is supported by numerous decisions describing the standard that should be applied when supplements like the Respondents' four products are represented to be effective to treat diseases or medical conditions. *See, e.g.*, *Natural Solution*, 2007 U.S. Dist LEXIS 60783, at *11-12; *Nat'l Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *43-44; *Direct Mktg. Concepts*, 569 F. Supp. 2d at 300, 303.

Second, the ALJ did not hold Respondents to the representation they made in their Answer that they had a reasonable basis substantiating their representations at the time the representations were made. The only explanation that the ALJ articulated for not requiring Respondents to tether their proof to "the time the representations were made" was that Complaint Counsel, rather than Respondents, had the burden of proof on all elements of their claim, including whether Respondents had a reasonable basis to substantiate their representations. ID at 67. The Commission considers that conclusion debatable. Respondents specifically averred that they had substantiation at the time their representations were made, and they were in the best position to support their averment. Again, the Commission is not prepared to second-guess the decision by the ALJ. The consequence of that conclusion, however, was that the ALJ considered abundant *ex post* expert testimony on the issue

whether there was *ever* a reasonable basis substantiating the representations.

Respondents repeatedly assert that in assessing the expert testimony the ALJ did not just embrace the substantiation standard he had held was applicable – namely "competent and reliable scientific evidence," including "controlled clinical studies" – but instead required that those studies be "double-blind" and "placebo controlled." RAB at 4, 8, 11-12, 15, 25, 43, 45; RRB at 12, 40-41, 53-54, 57, 59, 65. According to Respondents, that substantiation requirement, combined with the lack of a requirement that "extrinsic evidence" be produced, had the effect of creating a "presumption" that their representations were not adequately substantiated and, indeed, of turning the proceeding into "rulemaking by adjudication" in violation of *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), the Due Process Clause, and the First Amendment of the Constitution. RAB at 4, 11-12, 15-17, 25-26, 43-44, 54-55; RRB at 40, 54-55.

Respondents' claims are without merit. As previously discussed, "extrinsic" evidence to interpret the advertising is not required, as a matter of law. Respondents' reliance on *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), does not assist their argument either. As the ALJ explained in the Initial Decision, although the Seventh Circuit stated that nothing in the FTC Act required a placebo-controlled, double-blind study, it went on to affirm the district court's holding that substantiation for health-related efficacy claims must be based on competent and reliable scientific evidence. ID at 109. Because the ALJ in this case found the Respondents had not possessed or relied upon *any* adequate substantiation for their claims, the ALJ found their argument that *QT* does not require a placebo-controlled, double-blind study to be irrelevant. ID at 109. The Commission agrees.

The same thing is true of Respondents' assertion that this case involves "rulemaking by adjudication" of the sort condemned in the *Pearson* case. RAB at 15-16, 25-26; RRB at 27, 31-33, 44 n.24, 53-54. *Pearson* bears no resemblance to this case. Not only were the agency (the FDA) and the statute (the Food, Drug, and Cosmetic Act) different than the ones involved here, but the case involved formal rulemaking procedures by the FDA. In *Pearson*,

the FDA proposed a rule that would ban all health claims by dietary supplements unless there was "significant scientific agreement" about those claims, regardless of whether or not the claims were deceptive. RAB at 14-16. This case does not involve rule-making or even "amending or bypassing a pending rulemaking proceeding." RAB at 40. This case involves a purely adjudicatory challenge to specific deceptive representations made in advertisements that four specific products would "treat" or "cure" cancer, prevent or shrink tumors, and ameliorate the destructive side effects of radiation or chemotherapy. Most significantly, the substantiation standard used by the ALJ in this case, requiring competent and reliable scientific evidence, including studies on humans is neither "unconstitutionally vague" nor "impossibly high," as Respondents describe the "significant scientific agreement" standard in the FDA's proposed rule. RRB at 27, 31-32, 44 n.24. To borrow the language in *Kraft*, *Pearson* involved "a completely different animal" than the one involved here. *Kraft*, 970 F.2d at 317.

Nor did the ALJ otherwise use any "assumptions" or "shift the burden of proof" away from Complaint Counsel in his assessment of the expert testimony. RAB at 3, 11, 54-55. To the contrary, he found, *inter alia*, that Complaint Counsel's witness, Dr. Miller, a board-certified oncologist who had practiced for over forty years at some of the country's most eminent institutions, was the "only witness in this case qualified as an expert in cancer research and cancer treatment" (ID at 103), and that he was the only expert witness who offered an opinion as to whether there was competent and reliable scientific evidence to support Respondents' representations. ID at 103-106. By contrast, the ALJ found that Respondents and their experts had relied, *inter alia*, on in vitro and animal (not human) clinical reports, searches of literature, testimonials without confirmation that the speakers' treatments were not attributable to other clinical modalities or indeed that the speakers had cancer, and tests on the ingredients of the four Challenged Products without confirmation that the ingredients were present in those products in the same proportion to the ingredients tested. ID at 104-105.

Respondents do not contend that these findings lacked substantial supporting evidence in the record. As a result, as the

ALJ put it, "none of Respondents' experts offered any opinions on any material, contested issue in the case, and the opinions that Respondents' proffered experts did offer are entitled to little, if any, weight." ID at 106. Put differently, the ALJ simply weighed the evidence proffered by the experts. The way he weighed the evidence, moreover, was consistent with his earlier opinion that although Respondents might have the burden of production of some evidence to substantiate their representations, Complaint Counsel bore the burden of proving that the substantiation was inadequate. ID at 67. The ALJ concluded that Complaint Counsel had borne the burden of proving that Respondents' representations were not substantiated. There was no violation of either the Due Process Clause or the First Amendment involved.

F. The Remedy is Proper.

Respondents advance several arguments that the remedy is illegal. RAB at 55-65. The Commission has considered each of these arguments, has reviewed the applicable case law and the language of the proposed Order, and has concluded that these claims are without merit. The Commission considers each of these arguments in turn.

Respondents first argue that the recent unpublished decision in *FTC v. Lane Labs-USA, Inc.*, No. 00-CV-3174 (DMC) (D.N.J. Aug. 10, 2009) (appeal pending),[3] "should be instructive and considered here," (RAB at 56-57; *see also* RRB at 59-60), and that they are "identically situated" to the respondents in *Lane Labs*. RRB at 34. In doing so, Respondents focus on three statements made by the district court, which were based upon the specific facts and evidence presented in that case: 1) the district court considered the substantiation proffered by Lane Labs and noted, "[t]his is not a case of a company making claims out of thin air;" 2) the district court found that Lane Labs provided credible medical testimony that the products in question are good products and could have the results advertised; and 3) the district court noted that "there has been no physical harm to the public."

[3] The Commission is appealing this decision. *FTC v. Lane-Labs-USA, Inc.*, No. 00-CV-3174 (DMC) (D. N.J. Aug. 10, 2009), *appeal docketed*, No. 09-3909 (3rd Cir. Oct. 13, 2009).

Contrary to Respondents' assertion, they are not "identically situated" to the respondents in *Lane Labs*. *Lane Labs* was a civil contempt proceeding in which the FTC sought a $24 million compensatory contempt award from the defendants for violating a negotiated consent order. According to the district court, in order to establish contempt, the movant bears the burden of proving by clear and convincing evidence that the respondent violated a court order. *Lane Labs*, No. 00-CV-3174 (DMC), slip op. at 11. The district court declined to find contempt because he found that the FTC failed to show by clear and convincing evidence that the defendants had not substantially complied with the Orders. Accordingly, the standard of proof, as well as the proof required, differentiates the DCO Respondents from the Lane Lab respondents.

And, to the extent that *Lane Labs* – as an unpublished decision that is being appealed – can be considered "instructive," it does not help Respondents. As in the instant case, the *Lane Lab* Orders required defendants to possess "competent and reliable scientific evidence" (as defined in the DCO remedy) to substantiate any claims made about the health benefits of a product.[4] The *Lane Labs* court specifically found the Orders to be valid and controlling. *Id*. at 12. However, in contrast to the case before us, the medical experts proffered in *Lane Labs* were medical doctors that the district court qualified and found "credible and knowledgeable in their respective fields of expertise." *Id*. at 8-10. The DCO respondents' experts were not medical doctors and the ALJ found that none of these proffered experts had "specialized training or experience regarding cancer or cancer treatment." IDF 335, 336. Indeed, in contrast to *Lane Labs*, in preparing their opinions, none of Respondents' experts here had reviewed the advertising claims at issue. IDF at 338. Furthermore, Respondents did not ask their experts to render an opinion as to whether their purported substantiation materials constituted competent and reliable scientific evidence that would substantiate

[4] "Competent and scientific evidence" was defined as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate results." *Lane Labs*, slip op. at 12. This is the same definition the ALJ uses in the proposed Order.

a claim that any of the Challenged Products prevent, cure or treat, cancer (IDF 339), or whether any such evidence existed. IDF 340.

Second, Respondents argue that the remedy is an arbitrary, capricious and retaliatory attack on their constitutional rights. Respondents make many general allegations regarding this claim, but do not cite any case law or other precedent in support of it. Respondents assert that the ALJ used "Respondents' political and religious speech as a weapon against them when he turned to issuing the Remedy." RRB at 36; *see also* RAB at 57. Respondents also claim that the ALJ took the Respondents' political and religious speech and activities into consideration when crafting the remedy, but not when "portraying Respondents as being engaged purely in commerce." RAB at 57.

As a preliminary matter, the Commission notes that the ALJ did not "portray[] Respondents as being engaged purely in commerce." As the Commission has stated already, this misstates the law and the legal conclusions of the Initial Decision; the ALJ found that Respondents were not a business organized for or engaged in "only" charitable purposes. These two conclusions are not the same. In addition, as discussed earlier in this Opinion, the Commission has already found that the ALJ performed the proper legal analysis in determining the FTC's jurisdiction, *see* section III.A, and Respondents' liability, *see* sections III.C and E. The Commission likewise finds that the ALJ applied the proper standard in drafting the proposed order.[5] Accordingly, the Commission declines to characterize the remedy as "arbitrary, capricious and retaliatory."

Third, Respondents claim that the proposed remedy would violate the Religious Freedom Restoration Act of 1993 (P.L. 10-

[5] Once the determination is made that Respondents violated Section 5 of the FTC Act, the Commission has the authority to issue an order requiring respondents to cease and desist from such acts and or practices. *FTC v. Nat'l Lead Co.*, 352 U.S. 419, 428 (1957). The Commission has considerable discretion in fashioning the remedial order, so long as the order bears a reasonable relationship to the unlawful acts or practices. *See, e.g., FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 394-95 (1965); *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 612-13 (1946).

141) ("RFRA"). RAB at 57-60. The Commission disagrees. As Respondents concede, the RFRA only applies to government statutes that "substantially burden a person's exercise of religion." RAB at 58; RRB at 15, 60-61. The Order imposes no burden on Respondents' exercise of religion; it only applies to their commercial advertising. Although Respondents argue the remedy imposes an unconstitutional prior restraint on "truthful speech," (RAB at 61; RRB at 60-63), the speech at issue here was found to be deceptive. As noted in *Central Hudson*, "there can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity." 447 U.S. at 563.

Far from prohibiting truthful speech, Paragraphs II and III of the Order permit Respondents to make any efficacy claims for those products so long as the representations are "true, non-misleading, and, at the time [they are] made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation." In other words, Respondents are only obliged to do that which the case law under Sections 5 and 12 of the FTC Act has defined as necessary to avoid deception. To be sure, that requirement embraces not just the four Challenged Products, but other dietary supplements, foods, drugs or other health and related programs, services or products. However, the case law holds that this is appropriate "fencing in," given the kinds of representations Respondents made and the frequency with which they made those representations. *Telebrands Corp. v. FTC*, 457 F.3d 354, 358 (4th Cir. 2006); *Kraft*, 970 F.2d at 326.[6] The proposed order limits what Respondents may say without substantiation relating to the sale of certain products, but it does not otherwise reach into the Respondents' religious speech or practices.

[6] The Commission generally considers three factors in determining whether an order bears a reasonable relationship to a particular violation: (1) the seriousness and deliberateness of the violation; (2) the ease with which the violation may be transferred to other products; and (3) whether the respondent has a history of prior violations. *See In re Stouffer Foods Corp*., 118 F.T.C. 746, 811 (1994). All three elements need not be present to warrant fencing-in. *See Sears, Roebuck & Co. v. FTC*, 676 F.2d 385, 392 (9th Cir. 1982). The ALJ considered these factors and found the relief ordered was reasonably related to the Respondents' violations of the FTC Act. Respondents do not seem to challenge the ALJ's analysis of these elements. ID at 120-21.

Finally, Respondents claim that the requirement that they send a letter to their customers – even as modified by the ALJ – would unconstitutionally encroach on their rights under the religious guarantees of the First Amendment and the RFRA. RAB at 61-65; RRB at 63. Specifically, Respondents claim that the proposed remedy "prohibits truthful speech," is "contrary to Mr. Feijo's right to refrain from speaking at all," forces Respondents "to repudiate publicly their faith in God's revealed truth and be forced to embrace and proclaim as their own the FTC's faith in so-called 'science'," and "compels Respondents to conduct government-mandated speech as a condition precedent to continuing their religious ministry." RAB at 12, 57-64; RRB at 58, 64.

Paragraph V of the Order requires Respondents to send to all consumers who have bought the four Challenged Products since the beginning of 2005 an exact copy of the letter appended to the Order as Attachment A. The ALJ modified the proposed letter attached to the Complaint "to make it clear that the information contained in the letter is information that the FTC has required Respondents to transmit to consumers." ID at 121. Neither the letter nor anything else in the Order compels Respondents to do anything "as a condition precedent to continuing their religious ministry," or forces Respondents to "repudiate publicly 'their faith' in God's revealed truth and be forced to endorse and proclaim as their own the FTC's faith in so-called 'science.'" RRB at 58. Neither does the Commission see any evidence that the ALJ punished Respondents for their political or religious beliefs in his proposed order.

However, in the Order the Commission issues here today, in the interest of brevity, the Commission has further modified the first and second paragraphs of the letter required by Paragraph V (appended to the Order as Attachment A).

IV. Conclusion

The Commission, for the reasons stated in this opinion, has determined to deny the appeal of Respondents and to make final the attached Order, which is identical to the order entered by the

ALJ, except as to the modifications made to Attachment A, the letter required to be sent to consumers by Respondents.

FINAL ORDER

The Commission has heard this matter on the appeal of Respondents from the Initial Decision and on briefs and oral argument in support of and in opposition to the appeal. For the reasons stated in the accompanying Opinion of the Commission, the Commission has determined to enter the following order. Accordingly,

I.

IT IS HEREBY ORDERED that for purposes of this Order, the following definitions shall apply:

A. "Competent and reliable scientific evidence" shall mean 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.

B. "Covered Product or Service" shall mean any dietary supplement, food, drug, or other health-related product, service, or program, including, but not limited to, BioShark, 7 Herb Formula, GDU, and BioMixx.

C. "Food" and "drug" shall mean "food" and "drug" as defined in Section 15 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 55.

D. "Advertisement" means any written or verbal statement, illustration, or depiction that is designed to

effect a sale or to create interest in the purchasing of goods or services, whether it appears in a book, brochure, newspaper, magazine, pamphlet, leaflet, circular, mailer, book insert, letter, catalogue, poster, chart, billboard, public transit card, point of purchase display, packaging, package insert, label, film, slide, radio, television or cable television, video news release, audio program transmitted over a telephone system, infomercial, the Internet, e-mail, or in any other medium.

E. Unless otherwise specified, "Respondents" shall mean Daniel Chapter One and its successors and assigns, affiliates, or subsidiaries, and its officer, James Feijo, individually and as an officer of the corporation; and each of the above's agents, representatives, and employees.

F. "Commerce" shall mean "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

G. "Endorsement" shall mean "endorsement" as defined in 16 C.F.R. § 255.0(b).

II.

IT IS HEREBY ORDERED that Respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of BioShark, 7 Herb Formula, GDU, and BioMixx, or any substantially similar health-related program, service, or product, or any other Covered Product or Service, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of product or program names or endorsements, that such health-related program, service, product, or Covered Product or Service prevents, treats, or cures or assists in the prevention, treatment, or cure of any type of tumor or cancer, including but not limited to representations that:

A. BioShark inhibits tumor growth;

B. BioShark 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; or

H. BioMixx heals the destructive effects of radiation or chemotherapy;

unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

IT IS FURTHER ORDERED that Respondents, directly or through any person, corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product or Service, in or affecting commerce, shall not make any representation, in any manner, directly or by implication, including through the use of a product name, endorsement, depiction, or illustration, about the efficacy, performance, or health-related benefits of any Covered Product or Service unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

IV.

IT IS FURTHER ORDERED that:

A. Nothing in this order shall prohibit Respondents from making any representation for any drug that is permitted in labeling for such drug under any tentative or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and

B. Nothing in this order shall prohibit Respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

V.

IT IS FURTHER ORDERED that:

A. Respondents shall, within seven (7) days after the date of service of this order, deliver to the Commission a list, in the form of a sworn affidavit, of all consumers who purchased BioShark, 7 Herb Formula, GDU, and/or BioMixx, on or after January 1, 2005 through the date of service of this order. Such list shall include each consumer's name and address, the product(s) purchased, and, if available, the consumer's telephone number and email address;

B. Within forty-five (45) days after the date of service of this order, Respondents shall send by first class mail, postage prepaid, an exact copy of the notice attached as Attachment A to all persons identified in Part V.A., above. The face of the envelope containing the notice shall be an exact copy of Attachment B. The mailing shall not include any other documents; and

C. Except as provided in this order, Respondents, and their officers, agents, servants, employees, attorneys, and representatives shall not sell, rent, lease, transfer, or otherwise disclose the name, address, telephone number, credit card number, bank account number, e-mail address, or other identifying information of any person who paid any money to any Respondent, at any time prior to the issuance of this order, in connection with the purchase of BioShark, 7 Herb Formula, GDU, and/or BioMixx. *Provided, however,* that Respondents may disclose such identifying information to the FTC pursuant to Part V.A., above, or any law enforcement agency, or as required by any law, regulation, or court order.

VI.

IT IS FURTHER ORDERED that for a period of five (5) years after the last date of dissemination of any representation covered by this order, Respondents shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:

A. All advertisements and promotional materials containing the representation;

B. All materials that were relied upon in disseminating the representation; and

C. All tests, reports, studies, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question such representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

VII.

IT IS FURTHER ORDERED that Respondents shall deliver a copy of this order to all current and future principals, officers,

directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

VIII.

IT IS FURTHER ORDERED that Respondent Feijo, for a period of ten (10) years after the date of issuance of this order, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment. The notice shall include the individual Respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Paragraph shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

IX.

IT IS FURTHER ORDERED that Respondent DCO and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation(s) that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. *Provided, however*, that, with respect to any proposed change in the corporation about which Respondent DCO learns less than thirty (30) days prior to the date such action is to take place, Respondent DCO shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Paragraph shall be sent by certified mail to the Associate

Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

X.

IT IS FURTHER ORDERED that Respondents shall, within sixty (60) days after the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

XI.

IT IS FURTHER ORDERED that this order will terminate on December 18, 2029, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

A. Any paragraph in this order that terminates in less than twenty (20) years;

B. This order's application to any Respondent that is not named as a defendant in such complaint; and

C. This order if such complaint is filed after the order has terminated pursuant to this paragraph.

Provided further, that if such complaint is dismissed or a federal court rules that the Respondents did not violate any provision of this order, and the dismissal is either not appealed or upheld on appeal, then the order will terminate according to this paragraph as though the complaint was never filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

ATTACHMENT A
LETTER TO BE SENT BY FIRST CLASS MAIL
[To be printed on letterhead of Daniel Chapter One]

[Name and address of recipient] [Date]

Dear [Recipient]:

Our records show that you bought **[names of products]** from our website **[name of website]** or through a call center using our toll-free number. We are writing to tell you that the Federal Trade Commission ("FTC") has found our advertising claims for these products to be deceptive because they were not substantiated by competent and reliable scientific evidence, and the FTC has issued an Order prohibiting us from making these claims in the future.

The Order entered against us by the FTC requires that we send you the following information from the FTC about the scientific evidence on these products:

Competent and reliable scientific evidence does not demonstrate that any of the ingredients in BioShark, 7 Herb Formula, GDU or BioMixx, are effective when used for prevention, treatment or cure of cancer.

It is important that you talk to your doctor or health care provider before using any herbal product in order to ensure that all aspects of your medical treatment work together. Some herbal products may interfere or affect your cancer or other medical treatment, may keep your medicines from doing what they are supposed to do, or could be harmful when taken with other medicines, or in high doses. It is also important that you talk to your doctor or health care provider before you decide to take any herbal product instead of taking cancer treatments that have been scientifically proven to be safe and effective in humans.

Sincerely,

Final Order

ATTACHMENT B

Daniel Chapter One
1028 East Main Road
Portsmouth, Rhode Island, 02871

[name and address of purchaser]

GOVERNMENT ORDERED NOTICE

INTERLOCUTORY, MODIFYING, VACATING, AND MISCELLANEOUS ORDERS

DYNA-E INTERNATIONAL, INC.
AND
GEORGE WHEELER

Docket No. 9336, Order, July 2, 2009

Order withdrawing the Matter from adjudication.

ORDER WITHDRAWING MATTER FROM ADJUDICATION FOR THE PURPOSE OF CONSIDERING A PROPOSED CONSENT AGREEMENT

Complaint Counsel and Respondents having jointly moved that this matter be withdrawn from adjudication to enable the Commission to consider a proposed Consent Agreement, and having submitted a proposed Consent Agreement containing a proposed Order, executed by the Respondents and by Complaint Counsel and approved by the Director of the Bureau of Consumer Protection, which, if accepted by the Commission, would resolve this matter in its entirety;

IT IS ORDERED, pursuant to Rule 3.25(c) of the Commission Rules of Practice, 16 C.F.R. § 3.25(c) (2009), that this matter in its entirety be and it hereby is withdrawn from adjudication, and that all proceedings before the Administrative Law Judge be and they hereby are stayed pending a determination by the Commission with respect to the proposed Consent Agreement, pursuant to Rule 3.25(f), 16 C.F.R. § 3.25(f); and

IT IS FURTHER ORDERED, pursuant to Rule 3.25(b) of the Commission Rules of Practice, 16 C.F.R. § 3.25(b), that the proposed Consent Agreement not be placed on the public record unless and until it is accepted by the Commission.

By the Commission.

Interlocutory Orders, Etc.

WHOLE FOODS MARKET, INC.

Docket No. 9324, Order, July 9, 2009

Order granting the Motion by Ahold U.S.A., Inc., New Seasons Market, Inc., Save Mart Supermarkets, Gelson's Markets, Safeway, Inc., Harris Teeter, Inc., and Apollo Management Holding L.P. and ordering Respondent to return any third-party documents that were subject to any outstanding discovery requests in *Kottaras v. Whole Foods Market, Inc.*

ORDER GRANTING THIRD PARTIES' MOTION TO ENFORCE PROTECTIVE ORDER

Ahold U.S.A., Inc., New Seasons Market, Inc., Save Mart Supermarkets, Gelson's Markets, Safeway, Inc., Harris Teeter, Inc., and Apollo Management Holding L.P. ("Moving Third Parties") have filed a motion requesting that the Commission enforce the Protective Order Governing Confidential Information ("Protective Order") issued in this matter. On May 21, 2009, the Commission issued an Order relieving Respondent Whole Foods Market, Inc. ("Whole Foods") of its obligation under Paragraph 12 of the Protective Order to return any third-party documents that were subject to any outstanding discovery requests in related federal court litigation,[1] provided that Whole Foods complied with its obligations under Paragraph 11 of the Protective Order. The Commission did so reluctantly. The Commission's investigations and cases rely heavily on the good faith cooperation of Third Parties. Third Party cooperation in turn is based in no small part on the expectation that their documents and testimony will be used only in the Commission action at issue. The purpose of the Commission's May 21, 2009 Order was to allow the United States District Court to rule on the appropriateness of the discovery requests pending before it. Absent such an order from the Commission, the documents could have been returned immediately, thus mooting the issue and depriving the District Court of the opportunity to rule.

[1] The discovery requests covered included but were not limited to outstanding discovery requests in *Kottaras v. Whole Foods Market, Inc*., No. 1:08-cv-01832 (D.D.C.) (*Kottaras*).

The Commission issued its final Decision and Order in this matter on May 28, 2009. The Moving Third Parties filed the present motion on July 2, 2009. The Moving Third Parties request an order instructing Whole Foods to return immediately to the Moving Third Parties all documents upon entry of an order permitting as much by the District Court in *Kottaras*. That request reflects the intent of the Commission's May 21, 2009 Order. Moreover, Whole Foods has advised the Moving Third Parties that it does not oppose returning the documents, consistent with its obligations in the District Court. Accordingly,

IT IS ORDERED THAT Whole Foods shall return immediately to the Moving Third Parties all documents produced by the Moving Third Parties in this matter, when so directed by the United States District Court in *Kottaras v. Whole Foods Market, Inc*., Case No. 1:08CV-01832 (D.D.C.).

By the Commission.

Interlocutory Orders, Etc.

WHOLE FOODS MARKET, INC.

Docket No. 9324, Order, July 20, 2009

Order granting Kroger's request for joinder with Ahold U.S.A., Inc., New Seasons Market, Inc., Save Mart Supermarkets, Gelson's Markets, Safeway, Inc., Harris Teeter, Inc., and Apollo Management Holding L.P.

ORDER GRANTING KROGER CO. REQUEST

The Kroger Co. ("Kroger") has effected a filing joining and incorporating by reference the Motion to Enforce Protective Order ("Third Parties' Motion") which Ahold U.S.A., Inc., New Seasons Market, Inc., Save Mart Supermarkets, Gelson's Markets, Safeway, Inc., Harris Teeter, Inc., and Apollo Management Holding L.P. filed on July 2, 2009. The Commission issued an Order granting that Motion on July 9, 2009 (copy attached) and Kroger filed its joinder on July 13, 2009. The Kroger filing therefore will be treated as a request for the same relief granted by the July 9 Order.

For the reasons detailed in the July 9 Order, the Commission has determined to grant the Kroger request. Accordingly,

IT IS ORDERED THAT Whole Foods shall return immediately to Kroger all documents produced by Kroger in this matter, when so directed by the United States District Court in *Kottaras v. Whole Foods Market, Inc*., Case No. 1:08CV-01832 (D.D.C.).

By the Commission.

CARILION CLINIC

Docket No. 9338, Order, August 11, 2009

Order withdrawing the Matter from adjudication.

ORDER

Complaint Counsel and Respondent Carilion Clinic, Inc., have jointly moved, pursuant to Rule 3.25(b) of the Commission Rules of Practice, to withdraw this matter from adjudication for the purpose of considering a proposed consent agreement. The ALJ has certified the motion to the Commission, pursuant to Rule 3.25(d).

Upon consideration of the motion, the Commission has determined to withdraw this matter from adjudication for thirty (30) days. Absent another order by the Commission, this matter will revert to Part 3 adjudicative status at 12:01 a.m. on Friday, September 11th.

IT IS ORDERED THAT Complaint Counsel and Respondent's request to withdraw this matter from adjudication is **granted**. This matter is withdrawn from adjudication until 12:01 a.m. on Friday, September 11, 2009, at which time it will return to adjudicative status under Part 3 of the Commission Rules of Practice.

By the Commission.

Interlocutory Orders, Etc.

THORATEC CORPORATION
AND
HEARTWARE INTERNATIONAL, INC.

Docket No. 9339, Order, August 11, 2009

Order dismissing the Complaint.

ORDER DISMISSING COMPLAINT

On July 28, 2009, the Federal Trade Commission issued the Administrative Complaint in this matter, having reason to believe that Respondents Thoratec Corporation ("Thoratec") and HeartWare International, Inc. ("HeartWare") had entered into a merger agreement in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and which, if consummated, would violate Section 5 of the FTC Act, and Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18. Complaint Counsel and the Respondents have now filed a Joint Motion to Dismiss Complaint, which states that the Respondents have decided not to proceed with the proposed merger and that Thoratec has withdrawn its Hart-Scott-Rodino Notification and Report Form filed for the proposed transaction.[1]

The Commission has determined to dismiss the Administrative Complaint without prejudice as the most important elements of the relief set out in the Notice of Contemplated Relief in the Administrative Complaint have been accomplished without the need for further administrative litigation.[2] In particular, the Respondents have announced that

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[1] *See* Joint Motion to Dismiss Complaint (Aug. 5, 2009), *available at* http://www.ftc.gov/os/adjpro/d9339/090805jointmodismisscmplt.pdf.

[2] *Cf.* Order Dismissing Complaint, In the Matter of CSL Limited and Cerberus-Plasma Holdings, LLC (June 22, 2009), *available at* http://www.ftc.gov/os/adjpro/d9337/090622commorderdismisscomplaint.pdf; Order Dismissing Complaint, In the Matter of Inova Health System Foundation and Prince William Health System, Inc., Docket No. 9326 (June 17, 2008), *available at* http://www.ftc.gov/os/adjpro/d9326/080617orderdismisscmpt.pdf; Order Dismissing Complaint, In the Matter of Red Sky Holdings LP and Newpark Resources, Inc., Docket No. 9333 (Dec. 10, 2008), *available at* http://www.ftc.gov/os/adjpro/d9333/081210redskycmpt.pdf;

they have decided not to proceed with the proposed acquisition, and Thoratec has withdrawn its Hart-Scott-Rodino Notification and Report Form filed for the proposed transaction. As a consequence, the Respondents would not be able to effect the proposed transaction without filing new Hart-Scott-Rodino Notification and Report Forms.

For the foregoing reasons, the Commission has determined that the public interest warrants dismissal of the Administrative Complaint in this matter. The Commission has determined to do so without prejudice, however, because it is not reaching a decision on the merits. Accordingly,

IT IS ORDERED THAT the Administrative Complaint in this matter be, and it hereby is, dismissed without prejudice.

By the Commission.

Order Dismissing Complaint, In the Matter of Equitable Resources, Inc., Dominion Resources, Inc., Consolidated Natural Gas Company, and The Peoples Natural Gas Company, Docket No. 9322 (Jan. 31, 2008), *available at* http://www.ftc.gov/os/adjpro/d9322/080204complaint.pdf.

Interlocutory Orders, Etc.

ASPEN TECHNOLOGY, INC.

Docket No. 9310, Order, August 20, 2009

Order modifying the Order issued on December 20, 2004 by adding provisions intended to remediate its inability to achieve fully its stated purpose as a result of actions by AspenTech.

ORDER TO SHOW CAUSE AND ORDER MODIFYING ORDER

On December 20, 2004, the Federal Trade Commission ("Commission") issued a Decision and Order ("Order") in Docket No. 9310 resolving claims contained in the Commission's Complaint issued on August 7, 2003. The Complaint alleged that the acquisition of Hyprotech Limited ("Hyprotech") by Respondent Aspen Technology, Inc. ("AspenTech"), lessened competition in several relevant markets, including the licensing of process engineering simulation software, in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C.§ 45, and Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18. Respondent denied these allegations but agreed to settle the matter through entry of the Order, which became final on December 27, 2004, before the administrative trial had begun.

The Order requires AspenTech, among other things, to divest Hyprotech's process engineering simulation software, known as HYSYS, and certain related products specified in the Order that were marketed together with HYSYS (collectively, "Hyprotech assets"). The Order requires AspenTech to divest the Hyprotech assets it owns and to sublicense rights to the Hyprotech assets it licenses from third parties if the relevant license agreements permit it to do so. The Order also requires that AspenTech divest or license the Hyprotech assets to an acquirer approved by the Commission and in a manner approved by the Commission and incorporates into the Order the terms of any Commission-approved divestiture agreement between AspenTech and a Commission-approved acquirer. On December 20, 2004, the Commission approved divestiture of the Hyprotech assets to Honeywell International Inc. ("Honeywell') pursuant to a purchase and sale agreement previously submitted to the Commission. The Order requires AspenTech to have divested the Hyprotech assets to Honeywell on or before March 28, 2005. The

purpose of the divestiture of these assets, as stated in the Order, is "to allow the Commission-approved Acquirer [Honeywell] to engage in the continued development and licensing of Hyprotech Process Engineering Simulation Software and to remedy the lessening of competition as alleged in the Commission's complaint . . ." in the markets for process engineering simulation software. Order ¶ II.K.

Following entry of the Order in 2004, issues arose concerning the scope and timeliness of AspenTech's delivery and licensing of some of the assets required to be divested and licensed. After a full investigation, the Commission found reason to believe that AspenTech did not transfer certain of the Hyprotech assets to Honeywell by the deadline contained in the Order and did not assist Honeywell in obtaining license rights to certain assets believed to be owned by a third party but licensed to AspenTech; the Commission notified the Department of Justice of its intention to file an enforcement action. Although AspenTech denies these allegations, it has agreed to settle the matter by consenting to the entry of the attached Order Modifying Order ("Modifying Order").

The assets that the Commission believes AspenTech did not timely transfer to Honeywell consist of software contained in certain of the heat exchange simulation software products collectively referred to by AspenTech as the HTFS suite of products and identified in the Order as ACOL, APLE, FRAN, FIHR, MUSE, PIPE, TASC-Chemical and TASC-Mechanical ("HTFS products"). The Order requires AspenTech to divest all software that it owns in these products and to sublicense all third-party owned software embedded in these products for which it has the right to sublicense. The HTFS products contain software that AspenTech owns and software that AspenTech licenses from third parties. Certain of that third-party software was licensed under an agreement the Commission believes contains explicit language giving AspenTech the right to sublicense all its licensed rights in the software, including its rights to source code, to another party, and the Commission believes this language controls AspenTech's rights to this software. At the time of the original asset transfer, AspenTech removed the third party source code from the HTFS products before delivering them to Honeywell. Without the

relevant licensed source code, the HTFS products were unworkable.

Honeywell sought to obtain from AspenTech the source code that AspenTech had removed from the HTFS products, asserting that this source code was part of the Hyprotech assets the Order required AspenTech to divest or sublicense. AspenTech did not inform the Commission of this controversy or seek Commission guidance regarding its obligations under the Order, and instead directed Honeywell to the third party to obtain rights to the relevant source code. After Honeywell was unable to resolve the issue with AspenTech, it contacted the Commission staff. The Commission staff concluded that the third party agreement gave AspenTech the right to sublicense its rights to the source code, and that, in the opinion of the staff, AspenTech had improperly removed the third party source code from the HTFS products.

AspenTech states that it originally sublicensed to Honeywell the rights that it believes it was permitted to sublicense under the agreement with the third party, which AspenTech believes do not include rights to source code. AspenTech further states that, based on this understanding, it informed Honeywell that, pursuant to Honeywell's demand that AspenTech remove third party code for which it did not have sublicense rights from the Hyprotech assets before transferring them to Honeywell, AspenTech was removing the relevant third party source code from the HTFS products.

The Commission considered AspenTech's assertions, but nonetheless found reason to believe that AspenTech had violated its obligations under the Order.

The full HTFS software, including third-party software, was finally transferred to Honeywell in January 2006, some ten months after the Order's deadline of March 28, 2005. In the intervening period, AspenTech released new next-generation heat exchange products intended ultimately to replace ACOL and TASC, two of the most widely licensed HTFS products. These new products were known as ACOL+ and TASC+ and were not subject to divestiture under the Order. The Commission believes that AspenTech's delay in fully transferring the HTFS software prevented the Order from operating fully as intended and thereby

frustrated its purpose. The Commission believes that, by delaying divestiture of the software, AspenTech impaired Honeywell's ability to compete for customers who use heat exchange products in connection with process engineering simulation software.

The Commission also believes that AspenTech's actions lessened the effect of the Order's requirement that AspenTech provide Honeywell with releases for all Hyprotech assets for a period of two years. Had AspenTech fully complied with the Order, this provision would have provided Honeywell with a two-year entry window during which Honeywell could provide customers the full complement of divested software at least equivalent to that offered by AspenTech, and could seamlessly migrate customers from the AspenTech products to the Honeywell products. Because AspenTech did not provide Honeywell with all of the divested assets in a timely manner, however, Honeywell was denied the full benefit of this Order requirement. Honeywell initially lacked some of the needed products and then lacked the ability to offer seamless migration, although the Commission notes that AspenTech continued to provide updates to the HTFS products to Honeywell for an additional twelve months. The Commission believes these additional updates were required by the Order but AspenTech disagrees.

In view of the foregoing, the Commission has determined in its discretion that it is in the public interest to reopen the proceeding in Docket No. 9310, pursuant to Section 3.72(b) of the Commission's Rules of Practice, 16 CFR §3.72(b), and to modify the Order by adding provisions intended to remediate the inability of the Order to achieve fully its stated purpose as a result of actions by AspenTech. These provisions, set forth as (new) Paragraph XIII, among other things, require AspenTech, to maintain the "Portable Format Export/Import Feature" defined in the Modifying Order to mean "a provision for the export into and import from Portable Format of the Input Variables." Aspen Tech is also required to provide Honeywell the information needed to permit Honeywell to develop the capability to provide customers

with seamless transfer of data and files from AspenTech products to Honeywell's competing products for at least six years.[1]

Respondent AspenTech denies that it has violated the terms of the Order and does not agree with the facts and conclusions as stated herein. In settlement of the Commission's claims regarding violation of the terms of the Order as described, however, AspenTech has consented to the changes contained in this Modifying Order, and waives any further rights it may have under Section 3.72(b) of the Commission's Rules of Practice, 16 C.F.R § 3.72(b).

Respondent, its attorney, and counsel for the Commission therefore executed an Agreement Containing Order To Show Cause and Order Modifying Order ("Agreement"); the Commission thereafter accepted the executed Agreement and placed it on the public record for a period of thirty (30) days for the receipt and consideration of public comments; and the Commission has now determined to accord final approval to the Order To Show Cause and Order Modifying Order. Accordingly,

IT IS ORDERED that this matter be, and it hereby is, reopened; and

IT IS FURTHER ORDERED that the Order in Docket No. 9310 be, and it hereby is, modified to add a new thirteenth (13th) paragraph, which shall read as follows:

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[1] Issues also arose with respect to the software product Flarenet. Hyprotech marketed Flarenet as a product that was part of the Hyprotech family of products, although Hyprotech licensed it from a third party. After acquiring Hyprotech, AspenTech obtained full rights to Flarenet from the third party. However, while the Order and purchase and sale agreement were being negotiated, AspenTech represented that Flarenet was still owned by the third party. Like other products owned by third parties, Flarenet was excluded from the divestiture under the Order. AspenTech asserts that Flarenet was excluded from divestiture for other reasons. Although AspenTech asserts that it has no obligation to provide Honeywell with access to Flarenet, in connection with the settlement of a private cause of action, it has agreed to license Flarenet to Honeywell under an agreement between the parties. Accordingly, there is no need for the Commission to pursue a modification of the Order with respect to Flarenet.

XIII.

IT IS FURTHER ORDERED that:

A. As used in this Paragraph XIII., the following definitions shall apply:

1. "Commercial Version Release" means a new version of any HYSYS Product or Heat Exchange Simulation Software Product, in each case that contains new Input Variables or changes the Portable Format of the relevant software, that is made generally available to customers. For the avoidance of doubt, "Commercial Version Release" shall not include localized versions, patches to a release, or beta or other test versions of a software product.

2. "Consent Agreement" means the Agreement Containing Show Cause Order and Order Modifying Order Pursuant to Rule 3.72, executed by Respondent.

3. "Honeywell" means Honeywell International Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its offices and principal place of business located at 101 Columbia Road, Morris Township, NJ 07962.

4. "Heat Exchange Simulation Software Product" means Respondent's software products known by and licensed by Respondent as of the date the Modifying Order became final as, or previously known and licensed as, ACOL, APLE, FIHR, FRAN, MUSE, PIPE, TASC, Aspen Air Cooled Exchanger (previously known as Acol+), Aspen Fired Heater, Aspen Plate Exchanger (previously known as Plate+), Aspen Plate Fin Exchanger and Aspen Shell & Tube Exchanger (previously known as Tasc+) (each a "Product"). "Heat Exchange

Simulation Software Product" also includes any successor versions of these software programs, but, for the avoidance of doubt, shall not include (i) separate software programs usable in connection with such Product (such as through a "call" to the separate program), (ii) software code from separate software programs incorporated in whole or in part in such Product, except to the extent such code contains enhancements to the heat exchange design and rating capability of the Product or (iii) another software program into which all or a portion of the Product is incorporated, integrated, embedded or attached, provided that this exclusion shall not apply to the Product itself and future enhancements to the heat exchange design and rating capability of the Product as incorporated, integrated, embedded or attached to such other program.

5. "HTFS+ Portability Test Suite" means a suite of test cases that fully tests the validity of a data export from HTFS+ as demonstrated to the satisfaction of the Monitor.

6. "HTFS+ Technical Documentation" means the Technical Documentation of the HTFS+ Portable Format.

7. "HYSYS 2006.0 Update" means the versions of Aspen HYSYS and Aspen HYSYS Dynamics that contain the Portable Format Export/Import Feature as to all Input Variables in Aspen HYSYS version 2006.0 and Aspen HYSYS Dynamics version 2006.0, respectively.

8. "HYSYS Portability Test Suite" means a suite of test cases that, as verified by the Monitor, fully tests the validity of the Portable Format Export/Import Feature in HYSYS 2006.0 Update.

9. "HYSYS Product" means Respondent's software products known by and licensed by Respondent as

of the date this Modifying Order became final as Aspen HYSYS and Aspen HYSYS Dynamics. "HYSYS Product" also includes any successor versions of the Aspen HYSYS and Aspen HYSYS Dynamics software programs, but, for the avoidance of doubt, shall not include (i) separate software programs usable in connection with Aspen HYSYS or Aspen HYSYS Dynamics (such as through a "call" to the separate program), (ii) software code from separate software programs incorporated in whole or in part in Aspen HYSYS or Aspen HYSYS Dynamics, except to the extent such code contains enhancements to the steady-state process simulation or dynamic process simulation capabilities of Aspen HYSYS or Aspen HYSYS Dynamics, respectively, or (iii) another software program into which all or a portion of Aspen HYSYS or Aspen HYSYS Dynamics is incorporated, integrated, embedded or attached, provided that this exclusion shall not apply to Aspen HYSYS itself, Aspen HYSYS Dynamics itself, and future enhancements to the steady-state process simulation or dynamic process simulation capabilities of Aspen HYSYS or Aspen HYSYS Dynamics, respectively, as incorporated, integrated, embedded or attached to such other program.

10. "HYSYS 7.1 Technical Documentation" means Technical Documentation of the XML tags for new Input Variables or changes to the Portable Format in the commercial releases of Aspen HYSYS version 7.1 and Aspen HYSYS Dynamics version 7.1 current as of April 30, 2009 that are not included in Aspen HYSYS version 2006.0 and Aspen HYSYS Dynamics version 2006.0, respectively.

11. "Input Variable" means (i) input data provided as input by the user to define the calculations to be run in a case file in a HYSYS Product or a Heat

Exchange Simulation Software Product, and (ii) input data provided as input by the user to define the flowsheet block and stream graphical layout of a case in a HYSYS Product, but only as to flowsheet block and stream graphical layout input data that can be exported into Portable Format in HYSYS 2006.0 Update.

12. "Modifying Order" means the Order Modifying Order issued by the Commission in this matter.

13. "Monitor" means the person appointed by the Commission to monitor Respondent's compliance with its obligations under this Modifying Order and any related agreements, including the Monitor Agreement.

14. "Monitor Agreement" means the agreement executed by Respondent and the Monitor.

15. "Project Plan" means the plan submitted to and approved by the Monitor that contains a plan and schedule according to which Respondent plans to complete the HYSYS 2006.0 Update, HYSYS 7.1 Technical Documentation, HYSYS Portability Test Suite, HTFS+ Portability Test Suite, and HTFS+ Technical Documentation.

16. "Portable Format" shall mean a structured file format, such as XML or ASCII, that is both human-readable and machine-readable.

17. "Portable Format Export/Import Feature" means a provision for the export into and import from Portable Format of the Input Variables.

18. "Technical Documentation" means the tag itself, the data type of the tag (e.g., integer, real, Boolean, text, choice), valid choices for choice data types, and a definition of the meaning of the tag.

19. "Validate" means:

a. with respect to HYSYS 2006.0 Update, (i) the Monitor has verified that as to Input Variables common to Aspen HYSYS and Aspen HYSYS Dynamics versions 7.1 and HYSYS 2006.0 Update, the Monitor has verified that the native input report (.dmp) text files for each case in the HYSYS Portability Test Suite are shown to be substantially the same as the input report (.dmp) files that are produced when the Portable Format file is exported from Aspen HYSYS version 7.1 and Aspen HYSYS Dynamics version 7.1, and then imported as a new case in HYSYS 2006.0 Update, and (ii) the Monitor has verified, running HYSYS 2006.0 Update in calculation mode, that each case in the HYSYS Portability Test Suite demonstrates that the calculation results from the original case file and the calculation results from the exported/imported case file are substantially the same, using the same quality assurance criteria that Respondent uses for validating its commercial product release on these same test cases; and

b. with respect to a Commercial Version Release of a HYSYS Product, (i) the Monitor has verified that the Commercial Version Release native input report (.dmp) text files are shown to be substantially the same as the input report (.dmp) files that are produced when the Portable Format file is exported and then imported as a new case in the Commercial Version Release, and (ii) as to Input Variables common to the Commercial Version Release and HYSYS 2006.0 Update, the Monitor has verified that the native input report (.dmp) text files for each case in the HYSYS Portability Test Suite are shown to be substantially the same as the input report (.dmp) files that are

produced when the Portable Format file is exported from the Commercial Version Release and then imported as a new case in HYSYS 2006.0 Update, and (iii) the Monitor has verified that the Portable Format Export/Import Feature is used in a substantially similar manner as such feature is used in HYSYS 2006.0 Update.

B. The Monitor's duties and responsibilities shall include, and Respondent shall facilitate, comply with, and take no action inconsistent with or that hinders, the following:

1. the Monitor shall act in a fiduciary capacity for the benefit of the Commission;

2. the Monitor shall monitor Respondent's compliance with the requirements of subparagraphs XIII.F. – XIII.M. of this Modifying Order in consultation with the Commission staff;

3. the Monitor shall, in the Monitor's sole discretion, consult with third parties in the exercise of the Monitor's duties under this Paragraph XIII and the Monitor Agreement;

4. the Monitor shall Validate that the suite of test cases continues to operate properly with HYSYS 2006.0 Update using the same procedures and criteria provided hereunder in subparagraph XIII.G and XIII.L.4.; and

5. the Monitor shall report on a regular basis to the Commission; accordingly, the Monitor Agreement shall require the Monitor to report in writing to the Commission concerning Respondent's compliance with its obligations under subparagraphs XIII.F. – XIII.M. of this Modifying Order:

a. thirty (30) days after the date this Modifying Order becomes final;

b. every sixty (60) days until the first anniversary of the date this Modifying Order becomes final;

c. every six (6) months thereafter through the end of the Monitor's term; and

d. more frequently, as requested by the Commission or its staff; and

6. the Monitor shall, in consultation with Commission staff, attempt to resolve disputes regarding Respondent's compliance with its obligations under subparagraphs XIII.F. – XIII.M.; *provided*, *however*, that nothing in this paragraph shall limit the Commission's ability to assert that actions by AspenTech constitute a violation of the Modifying Order.

C. Respondent shall grant and transfer to the Monitor, and the Monitor shall have, all rights, powers, and authority necessary to carry out the Monitor's duties and responsibilities, including but not limited to the following:

1. subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondent's personnel, books, documents, records kept in the normal course of business, facilities and technical information, and such other information as the Monitor may request, related to Respondent's compliance with its obligations under subparagraphs XIII.F. – XIII.M. of this Modifying Order;

2. the Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions to

which the Monitor and Respondent agree and that the Commission approves;

3. the Monitor shall have authority to employ, at the expense of Respondent, such experts, consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties;

4. Respondent shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor;

5. Respondent may require the Monitor and each of the Monitor's experts, consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Monitor from providing any information to the Commission, and a copy of such agreement shall be provided to the Commission staff; and

6. the Commission may, among other things, require the Monitor and each of the Monitor's experts, consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.

D. The Commission appoints Dr. Thomas L. Teague as Monitor and approves the Monitor Agreement executed by Respondent and Dr. Teague.

E. The Monitor shall serve until Respondent has complied with its obligations under subparagraphs XIII.F. – XIII.M.; if the Commission determines that the Monitor can no longer act, has ceased to act, or has failed to act diligently as Monitor, or if Dr. Teague can no longer act as Monitor, the Commission may appoint a substitute Monitor:

1. the Commission shall select the substitute Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld;

2. if Respondent has not opposed, in writing, including the reasons for opposing, the selection of a proposed substitute Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed substitute Monitor, Respondent shall be deemed to have consented to the selection of the proposed substitute Monitor;

3. Respondent shall enter into Monitor Agreement with the substitute Monitor within a reasonable time thereafter, which shall satisfy the requirements of subparagraphs XIII.B. – XIII.C. and which shall be subject to the approval of the Commission; and

F. For each Commercial Version Release of HYSYS Products or Heat Exchange Simulation Software Products released by Respondent prior to December 31, 2014 (or December 31, 2016, if extended pursuant to subparagraph XIII.N), Respondent shall maintain the Portable Format Export/Import Feature.

G. By no later than July 22, 2009, Respondent shall provide to the Monitor and to Honeywell:

1. The HYSYS 2006.0 Update, including the object code and full source code for HYSYS 2006.0 Update to Honeywell and, unless otherwise requested by the Monitor, in object code form only to the Monitor, with a report of which source code files have been changed.

    a. Upon receipt of the HYSYS 2006.0 Update, the Monitor shall review and Validate the HYSYS 2006.0 Update and determine whether any revisions are necessary.

    b. If the Monitor determines that any revisions are necessary, Respondent shall furnish a final and complete update, incorporating such revisions, to the Monitor and Honeywell as soon as possible, but no later than four (4) weeks after the Monitor notifies Respondent of any requested revisions.

    c. When the Monitor Validates the HYSYS 2006.0 Update, he will notify Respondent and the Commission staff.

2. The HYSYS Portability Test Suite, including the exported XML files from the commercial release of Aspen HYSYS version 7.1 and Aspen HYSYS Dynamics version 7.1 current as of April 30, 2009, and the native format Aspen HYSYS version 2006.0 and Aspen HYSYS Dynamics version 2006.0 input report (.dmp) files that were produced from the importation of these XML files generated from the commercial release of Aspen HYSYS version 7.1 and Aspen HYSYS Dynamics version 7.1 current as of April 30, 2009, respectively.

    a. Upon receipt of the HYSYS Portability Test Suite, the Monitor shall review the HYSYS Portability Test Suite and determine whether the HYSYS Portability Test Suite allows the Monitor to test the Portable Format

Export/Import Feature as to all Input Variables common to the commercial release of Aspen HYSYS version 7.1 and Aspen HYSYS Dynamics version 7.1 current as of April 30, 2009 and HYSYS 2006.0 Update.

b. If the Monitor determines that any revisions to the HYSYS Portability Test Suite are necessary, Respondent shall furnish a final and complete update, incorporating such revisions, to the Monitor and Honeywell as soon as possible, but no later than four (4) weeks after the Monitor notifies Respondent of any requested revisions.

c. When the Monitor determines that the HYSYS Portability Test Suite is complete, he will notify Respondent and the Commission staff.

3. The HYSYS 7.1 Technical Documentation:

a. Upon receipt of the HYSYS 7.1 Technical Documentation, the Monitor shall review the HYSYS 7.1 Technical Documentation to ensure that it is complete.

b. If the Monitor determines that any revisions to the HYSYS 7.1 Technical Documentation are necessary, Respondent shall furnish a final and complete update, incorporating such revisions, to the Monitor and to Honeywell as soon as possible, but no later than four (4) weeks after the Monitor notifies Respondent of any requested revisions.

c. When the Monitor determines that the HYSYS 7.1 Technical Documentation is complete, he will notify Respondent and the Commission staff.

H. By no later than July 22, 2009, Respondent shall complete and provide to the Monitor and to Honeywell the HTFS+ Technical Documentation:

1. Upon receipt of the HTFS+ Technical Documentation, the Monitor shall review the HTFS+ Technical Documentation to ensure its completeness.

2. If the Monitor determines that any revisions are necessary, Respondent shall furnish a final and complete update, incorporating such revisions, to the Monitor and Honeywell as soon as possible, but no later than four (4) weeks after the Monitor notifies Respondent of any requested revisions.

3. When the Monitor determines that the HTFS+ Technical Documentation is complete, he will notify Respondent and the Commission staff.

I. Respondent shall generate and provide to the Monitor and to Honeywell the HTFS+ Portability Test Suite as follows:

1. As part of the HTFS+ Portability Test Suite, Respondent shall generate three (3) sets of test cases:

a. the standard example cases for ACOL, APLE, FIHR, MUSE, and TASC will be run through the import function of HTFS+ and saved in HTFS+ input files;

b. the supplemental set of test input files that are designed by Respondent to map Input Variables that are not already covered by the existing example input cases; and

c. any additional supplemental set of test input files to the extent that additional Input Variables for ACOL, APLE, FIHR, MUSE, or

TASC not covered by the test cases above are identified by the Monitor prior to or on March 1, 2009, Respondent shall generate such additional supplemental test cases in the respective product and run those cases through the import function of HTFS+ and save as HTFS+ input files.

2. Respondent shall complete and provide to the Monitor and Honeywell the HTFS+ Portability Test Suite by no later than July 22, 2009. The HTFS+ Portability Test Suite shall include two (2) formats of the same test cases: the first format as inputs to ACOL, APLE, FIHR, MUSE or TASC, and the second format as run through the import function of HTFS+ and saved as HTFS+ input files.

3. The Monitor shall review the HTFS+ Portability Test Suite.

4. If the Monitor determines that any revisions are necessary, Respondent shall furnish final and complete updates, incorporating such revisions, to the Monitor and Honeywell as soon as possible, but no later than four (4) weeks after the Monitor notifies Respondent of any requested revisions.

5. When the Monitor determines that the HTFS+ Portability Test Suite is complete, he will notify Respondent and the Commission staff.

J. From the date Respondent executes the Consent Agreement until the last of the dates that the Monitor notifies Respondent and the Commission staff that Respondent has completed the HYSYS 2006.0 Update, the HYSYS 7.1 Technical Documentation, the HYSYS Portability Test Suite, the HTFS+ Portability Test Suite, and the HTFS+ Technical Documentation, Respondent shall report weekly to the Monitor on the

status of the Project Plan, or more frequently and in such manner as the Monitor requests.

K. If the Monitor determines that, despite Respondent's good faith efforts to satisfy the requirements of subparagraphs XIII.G. – XIII.J. and to comply with the Project Plan, Respondent is unable to satisfy specific time requirements, the Monitor may extend any of the deadlines in subparagraphs XIII.G. – XIII.J. by up to forty-five (45) days. If the Monitor determines that a longer extension is appropriate, Respondent may include that determination in any request for an extension of time under Rule 4.3(b) of the Commission's Rules of Practice, 16 C.F.R. § 4.3(b), and the Commission will give great weight to that determination in considering whether to grant the extension of time.

L. With respect to any Commercial Version Release of a HYSYS Product or any Heat Exchange Simulation Software Product that (i) Respondent releases after the date Respondent executes the Consent Agreement and prior to December 31, 2014 (or December 31, 2016, if extended pursuant to subparagraph XIII.N.), and (ii) contains new Input Variables, or changes the Portable Format of the relevant software:

1. Respondent shall provide to the Monitor the Technical Documentation of the Portable Format tags for all new Input Variables and changes to the Portable Format in such Commercial Version Release.

2. The Monitor shall review the Technical Documentation to ensure its completeness, and will report to Respondent any necessary revisions.

    a. If the Monitor communicates such revisions to Respondent within two (2) weeks of the Monitor's receipt of the Technical Documentation, Respondent shall provide a

final and complete update incorporating such revisions to the Monitor and to Honeywell no later than two (2) weeks prior to shipping the Commercial Version Release to customers.

b. If the Monitor does not communicate revisions within two (2) weeks from the Monitor's receipt of the Technical Documentation, Respondent shall provide the Technical Documentation to Honeywell no later than two (2) weeks prior to shipping the Commercial Version Release to Customers.

c. For any revisions communicated to Respondent by the Monitor later than two (2) weeks from the Monitor's receipt of the Technical Documentation, Respondent shall provide a final and complete update of the Technical Documentation incorporating such revisions to the Monitor and to Honeywell within four (4) weeks of notification of such revisions from the Monitor.

3. Respondent shall provide to the Monitor a beta version of the Commercial Version Release software.

4. The Monitor shall review and Validate the beta version of the Commercial Version Release, and will report to Respondent any necessary revisions.

a. If the Monitor communicates such revisions to Respondent within two (2) weeks of the Monitor's receipt of the beta version of the Commercial Version Release, Respondent shall provide a final and complete update of the Commercial Version Release incorporating such revisions to the Monitor no later than when the Commercial Version Release is shipped to customers.

b. For any revisions communicated to Respondent by the Monitor later than two (2) weeks from the Monitor's receipt of the beta version of the Commercial Version Release, Respondent shall provide an update of the Commercial Version Release incorporating such revisions to the Monitor and to customers in the next patch shipped to customers for the Commercial Version Release.

5. If, in the Commercial Version Release, Respondent replaces XML with a different Portable Format, the Monitor shall determine an appropriate procedure for the Monitor to Validate such Commercial Version Release and for the provision of Technical Documentation to the Monitor and to Honeywell. Pursuant to such procedure, Respondent shall not ship the Commercial Version Release to customers until at least two (2) weeks after providing the Technical Documentation for such Commercial Version Release to Honeywell.

M. With respect to any software patch for a HYSYS Product or Heat Exchange Simulation Software Product that (i) contains new Input Variable or changes the Portable Format, and (ii) is furnished to customers by Respondent at any time after the date Respondent executes the Consent Agreement and prior to December 31, 2014 (or December 31, 2016, if extended pursuant to subparagraph XIII.N.):

1. Respondent shall provide to the Monitor and to Honeywell the Technical Documentation of the Portable Format tags for the affected Input Variables no later than the date that Respondent makes the software patch generally available to customers.

2. If, after review of the Technical Documentation, the Monitor reports to Respondent necessary revisions, Respondent shall provide an update to

the Technical Documentation incorporating such revisions to the Monitor and to Honeywell within four (4) weeks of notification of such revisions from the Monitor.

N. The duration of Respondent's obligations under subparagraphs XIII.L. and XIII.M. may be extended to December 31, 2016, at the sole option of Honeywell, provided that Honeywell delivers written notice to the general counsel of Respondent, to the Commission staff, and to the Monitor, between April 1, 2014, and June 30, 2014.

O. Respondent shall:

1. Within thirty (30) days after it executes the Consent Agreement, file a verified written report with the Commission setting forth in detail the manner and form in which it has complied, is complying, and will comply with this Paragraph XIII; and

2. On January 1, 2010, and on January 1 for each of the next five (5) years (or seven (7) years if Honeywell chooses to extend the duration of Respondent's commitment under subparagraph XIII.N.), and at such other times as the Commission may require, file a verified written report with the Commission setting forth in detail the manner and form in which it has complied, is complying, and will comply with this Paragraph.

P. The purpose of this Paragraph XIII is to remedy the possible effects of the alleged delays in Respondent's complying with its obligations in the Commission's Order as issued on December 20, 2004, and as discussed in the Commission's Order To Show Cause.

By the Commission, Commissioner Rosch recused.

Concurring Statement of Commissioner Pamela Jones Harbour

In the Matter of Aspen Technology, Inc., Docket No. 9310

Final Approval of Order To Show Cause
and Order Modifying Order

I concur in granting final approval to this Order to Show Cause and Order Modifying Order because I believe these changes to our Order of December 20, 2004 ("Original Order") are likely to remedy the harm created in the marketplace by Aspen's failure to divest assets in the manner required by the Original Order.

I believe, however, that civil penalties would have been the appropriate remedy for Aspen's deliberate failure to comply with either the letter or spirit of the Original Order. Aspen's conduct regarding the Original Order was part of an attempt to gain competitive advantage, which included both untruthful and disingenuous representations. Such threats to the integrity of the Commission's procedures and remedies deserve their own independent sanctions – civil penalties.

POLYPORE INTERNATIONAL, INC.

Docket No. 9327, Order, September 8, 2009

Order granting the Administrative Law Judge's request for a 60-day extension of time to file the Initial Decision.

ORDER

Chief Administrative Law Judge Chappell has moved, pursuant to former Rule 3.51(a) of the Commission Rules of Practice, for a 60-day extension within which to file the Initial Decision in this case, which would give him until November 20, 2009, to file the Initial Decision.[1] Upon consideration of the motion, the Commission has determined that, in light of the other matters on the Administrative Law Judge's docket and the voluminous record in the above-captioned matter, his request should be granted. Accordingly,

IT IS ORDERED THAT the Administrative Law Judge's request for a 60-day extension of time be and it hereby is **granted**. The Administrative Law Judge shall have until November 20, 2009, to file the Initial Decision in this case.

By the Commission.

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[1] Until January 13, 2009, former Commission Rule 3.51(a) provided that an Initial Decision shall be filed "within ninety (90) days after closing the hearing record pursuant to § 3.44(c) . . . or within such further time as the Commission may by order allow upon written request from the Administrative Law Judge." The Complaint in this matter was issued last year, and former Commission Rule 3.51(a) consequently applies to this proceeding. Federal Trade Commission, *Interim Final Rules With Request for Comment*, 74 Fed. Reg. 1804 (January 13, 2009); *see also* Federal Trade Commission, *Final Rule*, 74 Fed. Reg. 20205 (May 1, 2009). Pursuant to former Commission Rule 3.44(c), the hearing record was closed on June 22, 2009, and the ninety-day period will consequently end on September 21, 2009. A sixty-day extension will therefore extend the Administrative Law Judge's time to file an Initial Decision until November 20, 2009.

Interlocutory Orders, Etc.

CARILION CLINIC

Docket No. 9338, Order, September 9, 2009

Order extending the withdrawal from adjudication.

ORDER

On August 11, 2009, the Commission withdrew this matter from adjudication until 12:01 a.m. on Friday, September 11, 2009, in response to a joint motion filed by Complaint Counsel and Respondent pursuant to Rule 3.25(b) of the Commission Rules of Practice. To facilitate further consideration of a proposed consent agreement, the Commission has determined to further extend the withdrawal of this matter from adjudication. Accordingly,

IT IS ORDERED THAT this matter will remain withdrawn from adjudication – and the deadline for Respondent to file its Answer to the Complaint is hereby extended – until 12:01 a.m. on Wednesday, October 14, 2009, at which time this matter will return to adjudicative status under Part 3 of the Commission Rules of Practice.

By the Commission.

THE M GROUP, INC., D/B/A BAMBOOSA
AND
MINDY JOHNSON, MICHAEL MOORE, AND MORRIS SAINTSING

Docket No. 9340, Order, September 17, 2009

Order withdrawing the Matter from adjudication.

ORDER WITHDRAWING MATTER FROM ADJUDICATION FOR THE PURPOSE OF CONSIDERING A PROPOSED CONSENT AGREEMENT

Complaint Counsel and Respondents having jointly moved that this matter be withdrawn from adjudication to enable the Commission to consider a proposed Consent Agreement, and having submitted a proposed Consent Agreement containing a proposed Order, executed by the Respondents and by Complaint Counsel and approved by the Director of the Bureau of Consumer Protection, which, if accepted by the Commission, would resolve this matter in its entirety;

IT IS ORDERED, pursuant to Rule 3.25(c) of the Commission Rules of Practice, 16 C.F.R. § 3.25(c) (2009), that this matter in its entirety be and it hereby is withdrawn from adjudication, and that all proceedings before the Administrative Law Judge be and they hereby are stayed pending a determination by the Commission with respect to the proposed Consent Agreement, pursuant to Rule 3.25(f), 16 C.F.R. § 3.25(f); and

IT IS FURTHER ORDERED, pursuant to Rule 3.25(b) of the Commission Rules of Practice, 16 C.F.R. § 3.25(b), that the proposed Consent Agreement not be placed on the public record unless and until it is accepted by the Commission.

By the Commission.

Interlocutory Orders, Etc.

DANIEL CHAPTER ONE
AND
JAMES FEIJO

Docket No. 9329, Order September 21, 2009

Order granting joint motion.

ORDER

On September 18, 2009, Complaint Counsel and Counsel for the Respondents filed a Joint Motion requesting that the Commission (1) accept the corrected version of Respondents' Appeal Brief attached to the Joint Motion, as a substitute for the Appeal Brief filed on September 14, 2009; and (2) begin the 30-day period within which Complaint Counsel must file their Answering Brief on September 21, 2009. The Commission has determined to grant the Joint Motion. Accordingly,

IT IS ORDERED that the corrected version of Respondents' Appeal Brief filed on September 18, 2009 be and it hereby is accepted as Respondents' Appeal Brief; and

IT IS FURTHER ORDERED that Complaint Counsel shall file their Answering Brief on or before October 20, 2009.

By the Commission.

DANIEL CHAPTER ONE
AND
JAMES FEIJO

Docket No. 9329, Order, October 2, 2009

Order granting Respondents' motion for an extension of time to file their Answering Brief.

ORDER

On September 21, 2009, the Commission issued an Order accepting a corrected version of Respondents' Appeal Brief and granting Complaint Counsel a corollary extension until October 20, 2009 by which to file their Answering Brief in this proceeding. Under Commission Rule 3.52, if Respondents' counsel are served with Complaint Counsel's Answering Brief on October 20, 2009, Respondents' Reply Brief will be due on October 29, 2009. On October 1, 2009, Respondents filed a Motion for leave to file their Reply Brief no later than November 4, 2009, because two of their counsel, including their lead counsel, several months ago "committed to participating in out-of-town, professional meetings on October 26-29, 2009," and therefore "would effectively lose four of the seven business days provided by Rule 3.52 to reply to Complaint Counsel's Answering Brief."

Respondents state in their Motion that Complaint Counsel do not object to the proposed extension. The Commission has determined to grant the Motion. Accordingly,

IT IS ORDERED that Respondents shall file their Reply Brief on or before November 4, 2009.

By the Commission.

Interlocutory Orders, Etc.

CARILION CLINIC

Docket No. 9338, Order, October 14, 2009

Order withdrawing the Matter from adjudication.

ORDER

On August 11, 2009, the Commission issued an Order granting a joint motion filed by Complaint Counsel and the Respondent to withdraw this matter from adjudication for the purpose of considering a proposed consent agreement. On September 9, 2009, the Commission issued an Order extending both the withdrawal from adjudication and the deadline for Respondent to file its Answer to the Complaint until October 14, 2009. On October 6, 2009, the Commission accepted for public comment an Agreement Containing Consent Orders ("Consent Agreement") and issued an Order To Maintain Assets. At that point, Commission Rule 3.25(f), 16 C.F.R. § 3.25(f), became applicable to this proceeding. Accordingly,

IT IS ORDERED THAT this matter will remain withdrawn from adjudication as provided by Commission Rule 3.25(f) – and Respondent's obligation to file an Answer to the Complaint will remain stayed – pending a determination by the Commission with respect to the proposed Consent Agreement, pursuant to Commission Rule 3.25(f).

By the Commission.

Interlocutory Orders, Etc.

DANIEL CHAPTER ONE
AND
JAMES FEIJO

Docket No. 9329, Order, October 16, 2009

Order denying motion to reschedule the Oral Argument.

ORDER DENYING MOTION TO RESCHEDULE ORAL ARGUMENT

On October 13, 2009, the Commission issued a Notice scheduling the Oral Argument in this matter for Thursday, December 3, 2009, at 1 p.m. Complaint Counsel have now filed a Motion requesting that the Commission reschedule the Oral Argument to December 10, 2009 or a later date. Complaint Counsel advised in the Motion that Leonard L. Gordon, the Director of the Commission's Northeast Regional Office, and Lead Complaint Counsel in this proceeding, will be out of the country for the ten days immediately preceding December 3, 2009. Complaint Counsel further advise that Respondents do not object to the Motion.

The Commission understands and is sympathetic to the timing concerns that Complaint Counsel cite in their Motion. However, the Motion does not indicate that Director Gordon's absence from the United States for the ten days preceding December 3 will either prevent him from participating in the Oral Argument or prevent Complaint Counsel from adequately preparing for the Oral Argument. Moreover, Respondents' Reply Brief must be filed by November 4, 2009, and, as a consequence of January 2009 revisions to in a number of the Commission Rules governing adjudicative proceedings in January of this year, Commission Rule 3.52(b)(2) now provides that the Commission "will schedule oral argument within 15 days after the deadline for the filing of any reply briefs." 16 C.F.R. § 3.52(b)(2). While the revised Rules technically do not apply to this proceeding -- because the Administrative Complaint was issued last year[1] -- the

[1] *See generally* Federal Trade Commission, *Interim Final Rules With Request for Comment*, 74 Fed. Reg. 1804 (January 13, 2009); *see also* Federal Trade Commission, *Final Rule*, 74 Fed. Reg. 20205 (May 1, 2009).

Commission has nevertheless determined to adhere as closely as possible to the post-briefing appellate timetables prescribed by the revised Rules. The Commission's determination to designate December 3rd as the date for the Oral Argument derives from that objective and related considerations. Accordingly,

IT IS ORDERED that Complaint Counsel's Unopposed Motion To Reschedule Oral Argument be, and it hereby is, denied.

By the Commission.

Interlocutory Orders, Etc.

DANIEL CHAPTER ONE
AND
JAMES FEIJO

Docket No. 9329, Order, November 16, 2009

Order giving Complaint Counsel and Respondent each 30 minutes to present their oral arguments.

ORDER REGARDING ORAL ARGUMENT

The Oral Argument on the Appeal which the Respondents have filed from the Initial Decision in this matter has been scheduled for Thursday, December 3, 2009, at 1:00 p.m., in Hearing Room 532-H of the Headquarters Building of the Federal Trade Commission, located at 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. The Respondents and Complaint Counsel have now completed their briefing of the matter, and the Commission has determined that sixty minutes should be sufficient to satisfy the purpose of the Oral Argument; that is, "to emphasize and clarify the written argument appearing in the briefs and to answer questions." Commission Rule 3.52(h), 16 C.F.R. § 3.52(h). Accordingly,

IT IS ORDERED that Respondents and Complaint Counsel will each be allotted thirty minutes to present their respective arguments. As the appellants in this matter, Respondents will have the opportunity to open the argument, and to reserve up to five minutes of their time for rebuttal.

By the Commission.

Interlocutory Orders, Etc.

BASF SE

Docket No. C-4253, Order, December 4, 2009

Order approving respondent's application for Commission approval ofproposed divestiture of BASF's Ciba BV Business and the Ciba IB Business to Dominion Colour Corporation.

LETTER APPROVING APPLICATION FOR DIVESTITURE OF ASSETS

Dear Mr. Schlossberg:

This letter responds to the October 16, 2009, Petition of BASF For Approval of Proposed Divestiture ("Petition") requesting that the Commission approve BASF's divestiture of the Ciba BV Business and the Ciba IB Business to Dominion Colour Corporation ("DCC") pursuant to the order in this matter. The Petition was placed on the public record for comments for thirty days, until November 17, 2009, and no comments were received.

After consideration of the proposed transaction as set forth in the Petition and supplemental documents, as well as other available information, the Commission has determined to approve the divestiture of the Ciba BV Business and the Ciba IB Business to DCC. In according its approval, the Commission has relied upon the information submitted and representations made in connection with BASF's Petition, and has assumed them to be accurate and complete.

By direction of the Commission.

RESPONSES TO PETITIONS TO QUASH OR LIMIT COMPULSORY PROCESS

THORATEC CORPORATION,
AND
HEARTWARE INTERNATIONAL, INC.

FTC File No. 091-0064, Decision, July 21, 2009

RESPONSE TO HEARTWARE INTERNATIONAL, INC.'S PETITION TO LIMIT OR QUASH SUBPOENAS *AD TESTIFICANDUM*

Dear Mr. Buffier:

On June 26, 2009, HeartWare International, Inc. ("HW") filed its Petition to Limit or Quash Subpoenas *Ad Testificandum* Dated April, 24, 2009 ("Petition").[1] The challenged subpoenas were issued in the Commission's investigation to determine whether there is reason to believe that Thoratec Corp.'s acquisition of HW would violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, or Section 7 of the Clayton Act, 15 U.S.C. § 18. This letter advises you of the Commission's disposition of the Petition seeking to limit or quash subpoenas issued to Messrs. Douglas Godshall and James Schuermann for oral testimony at investigational hearings conducted (and to be continued) in accordance with the provisions of Commission Rules 2.8, 2.8A and 2.9, 16 C.F.R. §§ 2.8, 2.8A, 2.9.[2] The Petition was referred to

[1] Commission Rule 2.7(d)(1), 16 C.F.R. § 2.7(d)(1), requires that a petition to limit or quash a subpoena be filed prior to the subpoena's return date or within twenty days after service, whichever first occurs. Even though this Petition may be untimely under a technical reading of the rule, the Commission will entertain it because the events giving rise to HW's claims for relief did not occur until after the expiration of the filing deadline, and HW's Petition was filed promptly after receipt of staff's June 24 letter announcing the reconvening of the investigational hearings.

[2] In ruling on the Petition, the Commission does not reach the issue of whether HW has standing to file the Petition without joining Messrs. Godshall and Schuermann as parties to the Petition. While the Commission understands that counsel for Petitioner also represents Messrs. Godshall and Schuermann, no statement to that effect appears in the Petition. The Commission assumes that the individuals subpoenaed are aware of the instant

the full Commission for determination by Commissioner Pamela Jones Harbour, acting in her sole discretion as the Commission's delegate pursuant to the provisions of Rule 2.7(d)(4), 16 C.F.R. § 2.7(d)(4).

I. Background and Summary

The Federal Trade Commission issued subpoenas *ad testificandum* on April 24, 2009 ("subpoenas"), to Douglas Godshall and James Schuermann for oral testimony at investigational hearings. Mr. Godshall is HW's President and Chief Executive Officer. Mr. Schuermann is the Vice President for Sales and Marketing for HW. Investigational hearings were held on June 5th (Godshall) and June 11th (Schuermann). During the course of these investigational hearings, testimony was withheld by the witnesses upon advice of counsel because the admission of an exhibit, or the testimony being sought, would have elicited information that might be subject to claims of attorney-client privilege and/or the work-product doctrine. Counsel objected to the use of Godshall Exhibit No. 10 (two emails and an attached revenue model spreadsheet) on the ground that the documents had been inadvertently produced, and were subject to both attorney-client privilege and the work-product doctrine.[3] HW's counsel requested the return of the inadvertently produced documents. Commission counsel briefly questioned the witness regarding the factual bases for the privilege claim, and obtained information indicating this exhibit was produced at the "explicit" request of Mr. Buffier,[4] and that it had been requested as part of the "joint defense" of the proposed merger.[5]

Petition and have elected not to raise any additional objections particular to themselves regarding further compliance with the subpoenas.

[3] Godshall IH 245:12-249:20, Jun. 5, 2009. The exhibit was described by Commission counsel as consisting of two emails and a spreadsheet "entitled HeartWare revenue model." *Id*. at 245:20. The top email was from Godshall to Schuermann dated April 15, 2009, "subject re e-mailing HVAD financials JFApril09.XLS." *Id*. at 245:21-23. The transcript provides no further information regarding either the identity of the second email or the contents of either email or the attachment.

[4] *Id*. at 246:4

[5] *Id*. at 248:7-12.

Commission counsel then stated that the privilege and work-product issues would be submitted to the Commission's General Counsel for an evaluation of the protections claimed and instructions regarding the proper disposition of the documents. At the same time, staff reserved the right to recall Mr. Godshall for further testimony, depending on the determination of the General Counsel regarding the documents.[6] HW's counsel also reserved its right to object.[7]

Later during the Godshall investigational hearing, counsel instructed the witness not to respond to questions regarding the substance of his conversations with customers regarding their reaction to the proposed merger transaction on the grounds that communications at the request of counsel were protected by the work-product doctrine.[8] HW's counsel made a clear distinction between (1) the substance of the conversations between the witness and customers undertaken at the behest and under the supervision of counsel, and (2) the identity of the third parties with whom the conversations were held.[9] Mr. Godshall identified ten customers with whom he spoke on behalf of HW's counsel, and one further person with whom he might have had such a conversation. He was not, however, permitted to testify as to the

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[6] *Id*. at 249:10-18. Staff subsequently advised HW's counsel that the staff would delete these documents from their files, and advised that such deletion did not constitute the Commission's agreement as to the validity of the protections being asserted. Petition, Exhibit E at 1 (Letter from James Southworth to Beau Buffier, dated June 12, 2009). Staff also requested "a written description of the process used to review HeartWare's submission for privileged materials." *Id*. The Commission understands that HW has not provided either the requested information regarding HW's privilege review processes or an updated privilege log that includes the deleted documents.

[7] *Id*. at 249:19-20.

[8] *Id*. at 287:7-12, and 20-21.

[9] The conversation between the witness and third parties was subject to work-product protection, but the identities of the third parties were not subject to such protections, according to HW's counsel. *Compare id*. at 288:17-20 (Mr. Buffier: "I'm going to instruct Mr. Godshall not to answer if any of [the substance of] those communications were held at the direction of legal counsel.") *with id*. at 287:20-21 (Mr. Buffier: "You can answer if you remember which doctors [you spoke with].").

substance of those conversations, regarding either the questions asked or the answers given.

In similar manner, Mr. Schuermann was permitted to testify regarding conversations he had with customers regarding their reactions to the transaction when those conversations were not pursuant to counsel's request and direction.[10] The witness did provide some limited information regarding conversations with third parties about the transaction when those discussions had not been undertaken at the direction of counsel. Counsel for HW advised

Mr. Schuermann not to answer any questions about the substance of any conversations that he had with third parties at the direction of counsel.[11]

Subsequent conversations between Bureau of Competition staff and HW's counsel were not successful in resolving the dispute regarding the witnesses' right to withhold answers regarding the substance of conversations undertaken at the request of counsel, and the revenue model and associated documents. On June 24, staff sent a letter to HW's counsel directing the reappearance of the witnesses "to provide testimony regarding communications they had with customers about the proposed acquisition," stating staff's belief that HW had not "established the necessary factual predicate to show that this information is protected work product."[12] The letter further directed the witnesses to reappear to answer questions about "sales and market shares with respect to any relevant product being developed by HeartWare," citing HW's privilege claims respecting the revenue model as the reason for not having examined Mr. Schuermann

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[10] Schuermann IH 235:12-15, Jun. 11, 2009 (Ms. Delbaum: "At this point, Mr. Schuermann, I'll just caution you not to reveal any communications that you had at our request. If you have knowledge of customer reaction outside of that, feel free to answer.").

[11] *Id*. at 250:18-25.

[12] Petition, Exhibit C (Letter from James Southworth to Beau Buffier, dated Jun. 24, 2009) at 1.

about sales and market shares during his investigational hearing on June 11.[13]

The Petition, dated June 26, 2009, was filed on June 29. The Petition seeks to limit or quash the reappearance of the witnesses for further investigational hearing examination. Petition at 19. In addition to reiterating HW's claims of attorney-client privilege and work-product protections, the Petition claims that it would be unduly burdensome to require Mr. Schuermann "to return to Washington, D.C. for further hearings," Petition at 18, because staff already had an extended opportunity in which these issues could have been raised with Mr. Schuermann.

II. Third-Party Interviews by HeartWare's Managers at the Direction of Counsel in Anticipation of Litigation Are Entitled to Protection as Trial Preparation Materials.

Commission Rule 2.9(b)(2), 16 C.F.R. § 2.9(b)(2), permits a witness at an investigational hearing to refuse to answer questions the answers to which are privileged. That rule, however, does not provide any guidance regarding the perimeters of the privileges that may be asserted. The Commission will read Rule 2.9(b)(2) *in pari materia* with Rule 3.31(c)(3)(Hearing preparations: Materials.), 16 C.F.R. § 3.31(c)(3). The latter rule protects trial preparation materials from discovery if they were "prepared in anticipation of litigation or for hearing by or for another party or by or for that other party's representative (including the party's attorney, consultant, or agent)." *Id*. The protections afforded by this rule are not absolute; they may be overcome upon a showing that the party seeking discovery has substantial need of the materials in preparation of its case and that the party is unable without undue hardship to obtain substantially equivalent materials by other means. In ordering discovery of such materials when the required showing has been made, the Administrative Law Judge *shall* protect against disclosure of the mental impressions, conclusions, opinions, or legal theories of an attorney or other representative of a party.

[13] *Id*. at 1-2.

Id. (emphasis added). The protections afforded to trial preparation materials under Rule 3.31(c)(3) are substantially similar to the work-product doctrine. *See* 8 CHARLES ALAN WRIGHT, ARTHUR R. MILLER & RICHARD L. MARCUS, FEDERAL PRACTICE AND PROCEDURE 2D §§ 2021 - 2028 at 313-415 (1994); *Hickman v. Taylor*, 329 U.S. 495 (1947). Our rule should be construed accordingly.

Commission staff do not appear to question that some third-party interviews undertaken by these two witnesses were done in anticipation of litigation for HW or its attorneys, and at the direction of counsel. Mr. Godshall's testimony on the latter point stands unrebutted in this record:

Q: Have you talked to any customers about this transaction?

A: I've spoken with many customers and have been advised by – have been requested by counsel to speak to customers, to help educate counsel as well as to collect customer opinion. So since the transaction, my customer discussions on the subject of this deal have been at the direction of counsel.

Godshall IH at 286:18-25. On the current record, HW has provided an adequate factual basis to support its assertion that customer interviews conducted by HW managers at the direction of counsel in anticipation of litigation are entitled to trial preparation materials protections within the meaning of Rules 2.9(b)(2) and 3.31(c)(3).

Commission staff could only overcome the qualified protections of Rule 3.31(c)(3) by showing that there was a "substantial need [for the customer interview materials] . . . and that [staff are] unable without undue hardship to obtain substantial equivalent materials by other means." Customer reactions to prospective mergers are important to the merger review process; however, that importance, standing alone, is not sufficient to overcome the protections of our rule under the circumstances. The Commission understands that staff have had a reasonable opportunity to interview each of HW's customers identified in the investigational hearing testimony of Messrs. Godshall and Schuermann. The record does not support a finding that staff are

"unable without undue hardship to obtain the substantial equivalent of the [customer interviews identified by the testimony of Messrs. Godshall and Schuermann] by other means." *Id*. The Commission also believes that staff can obtain comparable information from other third-party interviewees, at least to the extent that the identity of those third parties has been provided by HW.[14] Accordingly, the Petition shall be granted in part.[15]

III. Additional Investigative Hearing Time Is Not Unduly Burdensome.

HW has not demonstrated that resumption of the investigational hearings is unwarranted. Directing the witnesses to reappear for further examination regarding sales and market shares does not necessarily raise any claim of privilege.[16] HW's does not dispute staff's right to question Mr. Schuermann regarding sales and market share information.[17] Rather, it objects to the resumption of Mr. Schuermann's investigational hearing on the grounds that staff had, and failed to avail themselves of, the

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[14] HW does not contest its obligation to identify the customers whose interviews were conducted by its managers at the request of counsel in anticipation of litigation. Godshall IH at 287:20-21. *See also Upjohn Co. v. United States*, 449 U.S. 383, 396 (1981) ("Upjohn has provided the IRS with a list of such employees, and the IRS has already interviewed some 25 of them.").

[15] Granting the Petition in part recognizes the validity of the privilege claim, but is not a limitation upon staff's right to ask questions regarding customer interviews, including without limitation issues related to: (1) the unprivileged details of otherwise privileged conversations, (2) issues related to the scope of privilege being claimed with respect to otherwise privileged conversations, or (3) the further examination of the factual bases for such claims of privilege. In any subsequent questioning, HW may assert further privilege claims, and staff may seek resolution of such claims through a district court enforcement action commenced by the FTC's General Counsel in accordance with the provisions of Rule 2.13, 16 C.F.R. § 2.13.

[16] Staff's request to resume the investigational hearings of the witnesses may be based in part on HW's assertion that Godshall Exhibit 10 is protected by claims of privilege and the work-product doctrine, but that does not provide a ground for prohibiting the resumed examination of these witnesses. It is not necessary to resolve whether that exhibit is privileged to dispose of the Petition.

[17] Petition at 17-18.

opportunity to examine Mr. Schuermann regarding those subjects during the first 9½ hours (including breaks) of his investigational hearing on June 11. Petition at 18. HW claims that staff should not have a "second bite of the apple" because doing so would constitute an "abuse of process" and would be "presumptively unreasonable" in light of the 7-hour limitation on civil litigation depositions conducted pursuant to Fed. R. Civ. P. 30(d)(1). Petition at 18-19.

The mistake lies in HW's assumption that Commission investigational hearings should be governed, by analogy, by the limitations included within the Federal Rules of Civil Procedure. To the extent that the scope of the Commission's Rules of Practice regarding its conduct of investigations should be construed by analogy to some other legal activities, the Supreme Court has observed that the appropriate analogy is to the grand jury, not to civil litigation.[18] Commission rules applicable to the conduct of investigational hearings do not include time limitations comparable to those cited by HW's Petition.[19] Rule 2.9(b)(6) vests the person conducting an investigational hearing with broad discretion to "take all necessary action[s] to regulate the course of the hearing;" that, of necessity, includes the discretion to adjourn and reconvene a hearing at a later date, especially when, as here, doing so will permit all parties to the hearing to become better informed regarding the scope and validity of any claimed rights to withhold particular evidence or testimony.

HW claims that the Commission should prohibit reconvening these adjourned investigational hearings because reconvening them will impose a "substantial burden and expense" for these

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[18] *Fed. Trade Comm'n v. Morton Salt Co*., 338 U.S. 632, 642-43 (1950) ("[The FTC] has a power of inquisition, if one chooses to call it that, which is not derived from the judicial function. It is more analogous to the Grand Jury, which does not depend on a case or controversy for power to get evidence but can investigate merely on suspicion that the law is being violated, or even just because it wants assurances that it is not. When investigatory and accusatory duties are delegated to an administrative body, it, too, may take steps to inform itself as to whether there is probable violation of the law.").

[19] *See* Rules 2.8 (Investigational Hearings), 2.8A (Withholding Requested Materials), and 2.9 (Rights of Witnesses in Investigations), 16 C.F.R. §§ 2.8, 2.8A, 2.9.

witnesses. Petition at 3 and 18. HW cites no legal authority for its burdensomeness claim.[20] Accordingly, the Commission finds that the burdens claimed are not of a magnitude sufficient to justify the discretionary quashing of these subpoenas by the Commission.[21] That said, the Commission is aware that reconvening investigational hearings will impose some burden. The Commission encourages staff to consider reconvening these investigational hearings at a location that will mitigate some of the travel burden for the witnesses.[22]

IV. CONCLUSION AND ORDER

For all the foregoing reasons, **IT IS ORDERED THAT** the Petition be, and it hereby is, **GRANTED** in part and **DENIED** in part.

IT IS FURTHER ORDERED THAT Commission staff may, subject to Petitioner's right to withhold information in accordance with the terms of the Commission's Rules of Practice and this Letter Ruling, reconvene the adjourned investigational hearings of

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[20] Furthermore, HW does not contest the relevance of the subject area to be covered in the resumed investigational hearing. Petition at 17-18 ("[HW] has never disputed or objected to Mr. Schuermann being questioned as to his views on 'sales and market shares with respect to any relevant product being developed by HeartWare.' [HW's] sole objection has been with respect to questions about the substance of the document (and communications surrounding the document) to the extent that such questions would divulge information protected by the work-product doctrine or the attorney-client privilege.").

[21] *See Fed. Trade Comm'n v. Texaco, Inc.*, 555 F.2d 862, 882 (D.C. Cir. 1977) (*en banc*) ("Some burden on subpoenaed parties is to be expected and is necessary in furtherance of the agency's legitimate inquiry and the public interest. . . . Thus, courts have refused to modify investigative subpoenas unless compliance threatens to unduly disrupt or seriously hinder normal operations of a business."). HW has provided the Commission with no cognizable justification for why it should afford HW greater relief than it could obtain from a district court in a subpoena enforcement action initiated by the Commission.

[22] The Commission does not know whether staff will need to recall both witnesses in light of this ruling, or whether they ever intended to re-examine Mr. Godshall concerning sales and market shares; the latter point was unclear from the June 24 letter to HW's counsel.

Messrs. Godshall and/or Schuermann at such dates and times as they may direct in writing, in accordance with the powers delegated to them by 16 C.F.R. § 2.9(b)(6).

By direction of the Commission.

Responses to Petitions to Quash

CEPHALON, INC.

FTC File No. 061-0182, Decision, November 13, 2009

RESPONSE TO WATSON PHARMACEUTICALS, INC.'S PETITION TO LIMIT OR QUASH SUBPOENAS *AD TESTIFICANDUM*

Dear Mr. Sunshine:

On July 30, 2009, Paul M. Bisaro (Petitioner), the President and Chief Executive Officer of Watson Pharmaceuticals, Inc. ("Watson"), filed a Petition to Quash Subpoena *Ad Testificandum* Dated July, 22, 2009 ("Petition"). The challenged subpoena was issued in the Commission's ongoing investigation to determine whether Watson, or others, are depriving consumers of access to lower-cost, generic modafinil drug products through any unfair method of competition in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

In the course of the investigation, a subpoena was issued for Petitioner's testimony at an investigational hearing ("IH") to be held on July 31, 2009 at the Commission's offices at 601 New Jersey Ave., N.W. in Washington, DC.[1] Petitioner did not provide the requested testimony. Instead, he filed a Petition asking the Commission to quash the subpoena on the grounds that (a) the Commission already has all the information that it might obtain from his responses to any questions propounded in such an investigational hearing; [2] (b) the subpoena is unreasonable in that it seeks the testimony of a high-level corporate executive;[3] and (c) the subpoena purportedly was issued for an improper purpose.[4]

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[1] Petition, Exhibit A at 1 (Subpoena *Ad Testificandum* issued to Paul Bisaro on July 27, 2009).

[2] *Id*. at 15-17.

[3] *Id. at 17-19.*

[4] *Id*. at 19-20. Watson also suggests (without supporting authority) that the investigatory resolution cited by staff as authority for issuing the instant subpoena expired when the Commission instituted a civil action against Cephalon in February 2008. *Id*. at 15 note 73. This claim is without merit. This is a continuing resolution that contains no time or other limitations. The

The record does not support these claims. Therefore, the relief requested by the Petition is denied.

This letter advises you of the Commission's disposition of the Petition.[5] This ruling was made by Commissioner Pamela Jones Harbour, acting as the Commission's delegate. *See* 16 C.F.R. § 2.7(d)(4). Pursuant to 16 C.F.R. § 2.7(f), Petitioner has the right to request review of this matter by the full Commission. Such a request must be filed with the Secretary of the Commission within three days after service of this letter.[6]

Background and Summary

Watson develops, manufactures, and markets generic versions of brand-name drugs. In December 2004, Watson and its development partner (Carlsbad Technology, Inc.), filed an abbreviated new drug application ("ANDA") for a modafinil product with the United States Food and Drug Administration ("FDA"). Modafinil is the active ingredient in a wakefulness-enhancing drug that at present is distributed in the United States exclusively by Cephalon, Inc. under the brand name Provigil®. Provigil is covered by two Cephalon patents that are relevant to the Petition: U.S. Reissued Patent No. 37,516 ("the '516 Patent"); and U.S. Patent No. **[REDACTED]** Patent"). Petition at 3, 6.

Commission's litigation against Cephalon has no effect on the Commission's ability to continue the investigation of other parties for potential acts of wrongdoing covered by the resolution. Watson also claims the subpoena is unreasonably burdensome because it is returnable in Washington, DC rather than New Jersey, Mr. Bisaro's place of residence. *Id*. at 14 note 72, 19. Petitioner, however, provides no factual basis for this claim of burden.

[5] The request for confidential treatment in the Petition is under review by the Commission Office of General Counsel. Pending the completion of that review, the bracketed material in boldface print in this letter ruling will be redacted from the public record version of this letter ruling. The public record version of this letter ruling will be placed on the public record, including the public Commission Website, at or after 9 a.m. on November 30, 2009.

[6] This letter ruling is being delivered by facsimile and express mail. The facsimile copy is provided as a courtesy. Computation of the time for appeal, therefore, should be calculated from the date you received the original by express mail. In accordance with the provisions of 16 C.F.R. § 2.7(f), the timely filing of a request for review of this matter by the full Commission shall not stay the return date established pursuant to this decision.

On December 22, 2002, four manufacturers of generic drugs (the so-called four "first filers" for the '516 Patent) filed Paragraph IV ANDAs for modafinil – the first step in opening the U.S. market for modafinil to generic competition. Under the Hatch-Waxman Act (the Drug Price Competition and Patent Restoration Act of 1984, Pub. L. 98-417, as amended), the first firm(s) to file a Paragraph IV ANDA for a generic version of a branded drug are eligible for a 180-day period of marketing exclusivity before the FDA can approve later filed ANDAs. Petition at 3. The first-filers' ANDAs certified that their generic versions of modafinil products either did not infringe Cephalon's patents listed in the FDA's Orange Book, or that those patents were invalid. *Id* .[7] Watson and Carlsbad filed their ANDA for modafinil on August 2, 2006, and were not first filers on the '516 patent; however, they were sued by Cephalon for patent infringement and did obtain a license to market generic modafinil as part of the settlement agreement for that suit. Sunshine Decl. at ¶ 7. Under that license, Watson may commence modafinil marketing on April 6, 2012. Petition at 4 n.6.

[REDACTED
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REDACTED .] Sunshine Decl. at ¶¶ 13-14.[8]

On February 13, 2008, the FTC filed an action against Cephalon, alleging that its settlements of the ensuing patent infringement litigation with the four first filers for the '516 Patent prevented generic competition to Provigil® in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. "None of the four first filers for the '516 Patent – at least some of whom

[7] At that time, Cephalon's listing in the FDA's "Orange Book" included the '516 Patent, but did not **[REDACTED .]** *Id*. at 3, Sunshine Decl. at ¶ 13.

[8] **[REDACTED REDACTED REDACTED]**.

had maintained their Hatch-Waxman exclusivity – were named in the FTC's complaint." Petition at 5-6.

I. The Subpoena is Within the Commission's Authority To Seek Relevant Information in a Law Enforcement Investigation

The Congress provided the Commission with the power to issue subpoenas because law enforcement investigations, like this one, frequently require the FTC "to get information from those who best can give it and who are most interested in not doing so." *United States v. Morton Salt Co.*, 338 U.S. 632, 643 (1950). The scope of information that may be required in response to a subpoena is broad. As a general matter, "it is sufficient if the inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably necessary," *id*. at 652, and the information sought can be produced without being "unduly burdensome" or disruptive. *Fed. Trade Comm'n v. Texaco, Inc.*, 555 F.2d 862, 882 (D.C. Cir. 1977). Further, the party who moves to quash an FTC administrative subpoena bears the burden of demonstrating that the subpoena is unreasonable. "[T]he burden of showing that an agency subpoena is unreasonable remains with the respondent, . . . and where, as here, the agency inquiry is authorized by law and the materials sought are relevant to the inquiry, that burden is not easily met. [citations omitted]." *Fed. Trade Comm'n v. Rockefeller*, 591 F.2d 182, 190 (2nd Cir. 1979), *quoting Sec. and Exchange Comm'n v. Brigadoon Scotch Distributing Co.*, 480 F.2d 1047, 1056 (2nd Cir. 1973), *cert. denied*, 415 U.S. 915 (1974). As shown below, Petitioner has not demonstrated that the subpoena issued to Mr. Bisaro fails to meet these criteria. Nothing in *United States v. Powell*, 379 U.S.48 (1964), is to the contrary.

Specifically, an earlier civil investigative demand (CID) asked whether Watson's settlement agreement with Cephalon **[REDACTED REDACTED REDACTED REDACTED REDACTED REDACTED REDACTED]**.[9] The Petition effectively acknowledges

[9] Petition at 15.

that Watson's prior responses regarding these issues have been incomplete. Watson's CID response stated unequivocally, "**[REDACTED REDACTED REDACTED.]**"[10] But at the same time, the Petition confirms that Watson's CID response regarding the absence of a potentially illegal agreement was qualified such that its completeness, and accuracy, was questionable. See Petition at 16 n.75.[11]

On June 11, 2009, FTC staff advised Watson that its responses to the Commission's CID were deficient in that the responses failed, among other things, to indicate "the portion(s) of [each] agreement that **[REDACTED REDACTED REDACTED]**[12] Watson declined to supplement its CID responses, stating that the FTC has a copy of the Settlement Agreement, and "The Agreement speaks for itself."[13] Citing attorney-client privilege, Watson declined to state the reasons **[REDACTED REDACTED]** because "the decision whether to **[REDACTED REDACTED]** is inextricably intertwined with legal matters; Watson's internal deliberations regarding this matter implicate legal advice and are protected from disclosure by the attorney-client privilege."[14]

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[10] *Id*. at 16.

[11] *Id*. at 16 note 75.

[12] Letter from Saralisa Brau to Maria Raptis (June 11, 2009) at 1-2.

[13] Letter from Maria Raptis to Saralisa Brau (June 17, 2009) at 2.

[14] *Id*. Mr. Buchen's **[REDACTED REDACTED REDACTED]** appear to have been conducted in the ordinary course of business. Likewise, his reports on the progress **[REDACTED]** to his corporate superior, Mr. Bisaro, also appear to be ordinary course of business discussions. Petitioner has cited no authority to support a claim that a corporation can shield its day-to-day business activities from scrutiny merely by having those activities discharged by lawyers. *See Fine v. Facet Aerospace Products Co.*, 133 F.R.D. 439, 444 (S.D. NY 1990) (The attorney-client "privilege covers communications made

Likewise, when FTC counsel asked Mr. Buchen at his investigational hearing on June 25, 2009, whether the patent settlement agreement with Cephalon **[REDACTED REDACTED]**, counsel instructed Mr. Buchen not to answer because the Commission was asking "**[REDACTED REDACTED]**."[15] FTC counsel attempted to elicit additional information regarding particular provisions of the patent settlement agreement between Watson and Cephalon that related to **[REDACTED]**, but Mr. Buchen's counsel again instructed him not to answer because, "**[REDACTED REDACTED]**."[16]

It is not necessary to address the validity of Watson's privilege claims to rule on this Petition. *See Petition of Hoechst Marion Roussel, Inc.*, 128 F.T.C. 798, 804 (Nov. 1, 1999) ("The issue here is simply whether Spears must appear for a hearing, not the validity of any privileges Hoechst might claim in response to questions asked during the hearing. Indeed, no assessment of privilege claims is even possible because as yet, no questions have been posed and no proper assertions of privilege have been lodged."). In the event Mr. Bisaro appears and testifies at an investigational hearing, any unresolved dispute between the FTC and Mr. Bisaro concerning the validity of any privilege asserted will be resolved by the district court, if the Commission elects to challenge particular claims of privilege. See 16 C.F.R. § 2.13.

To summarize, the record clearly shows that fully responsive answers to the Commission's questions regarding **[REDACTED]** have not been provided either by Watson or Mr. Buchen. The Commission understands that Mr. Bisaro is the only other Watson employee who possesses any knowledge regarding these issues.[17]

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in connection with the rendering of legal advice, it does not extend to the provision of business and management advice.").

[15] Buchen IH 44:22-24, Jun. 25, 2009.

[16] Buchen IH 48:9-12. This privilege claim, however, fails to account for the Commission's right to obtain information regarding Watson's understanding of the duties and limitations that Watson, or its managers believe were imposed upon the firm by reason of this contract.

[17] Petition at 17; Buchen IH 39:1.

Thus, Mr. Bisaro's testimony is necessary in order for the Commission to satisfy itself that the law is not being violated.[18] Furthermore, Watson's claim that its settlement with Cephalon "speaks for itself,"[19] lacks all merit. Mr. Bisaro's knowledge of the document and its meaning has independent evidentiary value. Thus, contrary to Petitioner's claims, the instant subpoena does not seek information that is already in the Commission's possession. Furthermore, whether the materials and testimony that have been made available to the Commission thus far satisfy its investigative needs is a matter for the Commission to determine, not Petitioner. *See Sec. and Exchange Comm'n v. Arthur Young & Co.*, 584 F.2d 1018, 1031 (D.C. Cir. 1978) ("The breadth of an investigation is for the investigators to determine."). There is therefore no apparent justification for Mr. Bisaro to refuse to answer questions regarding his understanding of Watson's settlement agreement with Cephalon.

II. Exhaustion of Other Investigational Avenues Is Not Required

There is no support for Petitioner's claim that the FTC may only take testimony from Watson's CEO when it can show that he has personal information that is not obtainable through other means.[20] The initial mistake lies in Petitioner's assumption that the Commission's investigational hearings should be governed, by

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[18] *Morton Salt Co.*, 338 U.S. at 642-43.

[19] Letter from Maria Raptis to Saralisa Brau (June 17, 2009) at 2.

[20] Petitioner's reliance on cases holding that a district court judge has discretion to defer discovery depositions of a company's CEO until after other discovery means have been exhausted is not relevant to resolving the Petition. Petition at 17-20. Many of the cases relied upon by Petitioner appear to involve claims asserted by lower level employees in remote company offices about which the CEO was unlikely to have been either involved or informed. For instance, in *Thomas v. Internat'l Bus. Mach.*, 48 F.3d 478 (10th Cir. 1995), a wrongful termination suit, the court affirmed the district court's grant of a protective order where a former clerical employee in IBM's Oklahoma City marketing office sought to compel the CEO, located in New York, to appear in Oklahoma City for a deposition on five days notice. The record in that case indicated that the CEO did not have any knowledge of the employee, the quality of her prior work, or the reasons for her termination.

analogy, by discretionary limitations that may be placed on depositions conducted pursuant to the Federal Rules of Civil Procedure. Counsel has not provided appropriate authority to support its claim that the Commission can only take testimony from Mr. Bisaro regarding relinquishment as a last resort, and then only if the Commission can show that he has personal knowledge of the subjects that will be examined during the investigational hearing.[21]

More importantly, only Mr. Buchen and Mr. Bisaro possess relevant knowledge regarding the **[REDACTED]** issues being investigated by the Commission.[22] Counsel has instructed Mr. Buchen not to tell the FTC which provisions of the Cephalon settlement agreement related to **[REDACTED]** other than a provision regarding Cephalon's obligation to **[REDACTED REDACTED]**.[23]

Unlike Mr. Buchen, Mr. Bisaro is not the General Counsel of Watson; rather, he is Watson's CEO. Mr. Bisaro is an attorney with significant prior business experience as both the general counsel and chief operating officer of another generic drug company.[24] Mr. Bisaro appears to be competent to answer questions regarding the Cephalon settlement agreement without having to disclose any privileged communications that he might have had with Mr. Buchen.

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[21] Petition at 17-18.

[22] Buchen IH at 39:1.

[23] *Id*. at 47:10-11. The relationship between Cephalon's **[REDACTED]** obligations to Watson and **[REDACTED]** are not obvious. This is especially true in light of other provisions in that agreement that appear more likely to be related to **[REDACTED]**; provisions about which Mr. Buchen was instructed by counsel not to testify. *Id*. at 51:6.

[24] Press Release, Watson, Watson Announces CEO Succession Plan (Aug. 2, 2007), available at: http://ir.watson.com/phoenix.zhtml?c=65778&p=irol-newsArticle&ID=1035647&highlight= (Last Visited Oct. 2, 2009).

III. The Subpoena Was Issued for A Proper Purpose.

Petitioner claims that the subpoena should be quashed because it was issued by the FTC for an improper purpose – namely, "**[REDACTED
REDACTED
REDACTED]**."[25]

The analysis of the purpose for the issuance of this subpoena must begin by an examination of the resolution authorizing staff to use compulsory process in conducting this investigation.[26] The Commission's resolution of August 30, 2006 authorized FTC staff to use compulsory process to "determine whether Cephalon, Inc., . . . Watson . . ., or others have engaged in any unfair methods of competition" in violation of the FTC Act "by entering into agreements regarding any modafinil product."[27] Watson does not claim that an agreement not to **[REDACTED
]** regarding modafinil products is beyond the scope of the resolution, nor does it claim that its patent settlement and license with Cephanol would be beyond the scope of the resolution. Further, Watson does not claim that the Bisaro investigational hearing is beyond the scope of the resolution. Thus, the subpoena to Mr. Bisaro is authorized by the resolution, and Petitioner has the burden of establishing the existence of "extraordinary circumstances" before a further inquiry into the *bona fides* of this subpoena would be appropriate. *Carter*, 636 F.2d at 789.[28]

Petitioner speculates that the "**[REDACTED
REDACTED
REDACTED**

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[25] Petition at 19.

[26] *Fed. Trade Comm'n v. Invention Submission Corp.*, 965 F.2d 1086, 1092 (D.C. Cir. 1992), citing *Fed. Trade Comm'n v. Carter*, 636 F.2d 781, 789 (D.C. Cir. 1980).

[27] Petition, Exhibit B.

[28] The full scope of Petitioner's burden is demonstrated by the D.C. Circuit's reliance on *Donaldson v. United States*, 400 U.S. 517, 534-35 (1971), for the proposition that an administrative subpoena must be enforced whenever a valid purpose appears, even if an otherwise improper purpose also appeared.

REDACTED]."[29] Rather than cooperate in the investigation, Watson has chosen to rely instead on incomplete and contradictory answers, and on dubious claims of privilege.[30] These stratagems deprive Petitioner's speculations of probative value. Petitioner acknowledges that FTC staff have expressed concerns that certain provisions of the settlement agreement with Cephalon might delay consumer access to lower-cost generic drugs and violate the FTC Act.[31] Those concerns, even without considering Watson's incomplete and contradictory responses to CIDs and subpoenas, provide ample grounds for asking Mr. Bisaro to sit for an investigational hearing as part of the Commission's continuing investigation.

CONCLUSION AND ORDER

For all the foregoing reasons, **IT IS ORDERED THAT** the Petition be, and it hereby is, **DENIED**.

IT IS FURTHER ORDERED THAT Commission staff may reschedule the investigational hearing of Mr. Bisaro at such date and time as they may direct in writing, in accordance with the powers delegated to them by 16 C.F.R. § 2.9(b)(6).

By direction of the Commission.

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[29] Petition at 19-20.

[30] This record lends a hollow ring to any claim that Watson has "cooperated fully" throughout this investigation. Petition at 5, Sunshine Decl. at ¶ 12.

[31] Petition, Exhibit N at 2 (Letter from Maria Raptis to Saralisa Brau, dated July 21, 2009).

Responses to Petitions to Quash

LIQUIFIED PETROLEUM GAS INVESTIGATION

FTC File No. 091-0115, Decision, December 3, 2009

RESPONSE TO RAMÓN GONZÁLEZ CORDERO'S AND RAMÓN GONZÁLEZ SIMONET'S PETITION TO QUASH OR MODIFY CIVIL INVESTIGATIVE DEMAND AND SUBPOENA *AD TESTIFICANDUM*

Dear Mr. Méndez-Gómez:

The Commission is investigating whether Empire Gas, Inc. and Liquilux Gas Corp, or others, are engaged in violations of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, or violations of federal antitrust laws, including without limitation price fixing, customer allocation, exclusive dealing, unlawful acquisitions, or other conduct regarding liquified petroleum gas ("LPG") or related products in Puerto Rico. Petition at 2. On November 19, 2009, Petitioners, Ramón González Cordero and Ramón González Simonet, officers of Empire and Liquilux, timely filed a petition to quash or modify civil investigative demands ("CID") and subpoenas *ad testificandum* on the grounds that: (1) the FTC does not have jurisdiction to investigate the conduct of Empire and Liquilux because their conduct is not covered by the FTC Act or the federal antitrust laws by reason of the state action doctrine, Petition at 3-5; and (2) the returns on the subpoenas, if required, should be held in Puerto Rico, not Washington, DC, Petition at 13. These claims are wholly without merit, and the Petition must, therefore, be denied.

This letter advises you of the Commission's disposition of the Petition. This ruling was made by Commissioner Pamela Jones Harbour, acting as the Commission's delegate. *See* 16 C.F.R. § 2.7(d)(4). Pursuant to 16 C.F.R. § 2.7(f), Petitioner has the right to request review of this matter by the full Commission. Such a request must be filed with the Secretary of the Commission within three days after service of this letter.[1]

[1] This letter ruling is being delivered by e-mail and express mail. The e-mailed copy is provided as a courtesy. Computation of the time for appeal, therefore, should be calculated from the date you received the original by express mail. In accordance with the provisions of 16 C.F.R. § 2.7(f), the

Responses to Petitions to Quash

This Challenge to the FTC's Jurisdiction Is Premature.

"With rare exceptions . . . , a subpoena enforcement action is not the proper forum in which to litigate disagreements over an agency's authority to pursue an investigation. Unless it is patently clear that an agency lacks the jurisdiction that it seeks to assert, an investigative subpoena will be enforced." *Fed. Trade Comm'n v. Ken Roberts Co.*, 276 F. 3d 583, 584 (D.C. Cir. 2001). "[A]t the subpoena enforcement stage, courts need not determine whether the subpoenaed party is within the agency's jurisdiction or covered by the statute it administers; rather the coverage determination should wait until an enforcement action is brought against the subpoenaed party." *United States v. Construction Prods. Research, Inc.* 73 F.3d 464, 470 (2d Cir. 1996). Investigations should not be bogged down prematurely with jurisdictional challenges. *Fed. Trade Comm'n v. Monahan*, 832 F. 2d 688, 690 (1st Cir. 1987) (Breyer).[2] Petitioners do not claim that the FTC Act excludes their companies or their activities on behalf of those companies from its coverage; rather, they erroneously claim that the so-called state action doctrine is an immunity that excludes them from the Commission's investigatory reach. Petition at 3-4. Petitioners misapprehend the nature and effect of the state action doctrine.

The State Action Doctrine Is Only An Affirmative Defense Assertable In Litigation.

The Petition correctly notes that the Supreme Court determined in *Parker v. Brown*, 317 U.S. 341 (1943), that Congress did not intend by its adoption of the Sherman Act, 15 U.S.C. § 1, to permit the antitrust laws to regulate the sovereign activities of state governments. This so called "state action

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timely filing of a request for review of this matter by the full Commission shall not stay the return date established pursuant to this decision.

[2] *Monahan* relied on *Fed. Trade Comm'n v. Swanson*, 560 F.2d 1, 2 (1st Cir. 1977) ("An agency's investigations should not be bogged down by premature challenges to its regulatory jurisdiction. These subpoenas do not fit within the narrow exception proscribing agency investigations that wander unconscionably far afield; the Commission's regulatory jurisdiction over appellants may be clouded but it is not plainly spurious."). The parties in *Swanson* were tour operators who claimed to be subject only to regulation by the Civil Aeronautics Board.

doctrine" creates a potential affirmative defense to be asserted in litigation – it does not create an immunity from law enforcement proceedings. *South Carolina Bd. of Dentistry v. Fed. Trade Comm'n*, 455 F.3d 436, 444 (4th Cir. 2006).

Assuming, *arguendo*, that Empire Gas, Inc., Liquilux Gas Corp. or others may have some basis for asserting a state action doctrine defense in the event of a Commission law enforcement action against them, that still does not excuse them from responding to valid FTC investigatory compulsory process. To do so would improperly limit the Commission's ability to evaluate the facts that might form the basis for such a defense and whether the Commission has a basis for pursuing a law enforcement action. *Monahan*, 832 F.2d at 689-90 ("We, like the FTC, must wait to see the results of the investigation before we know whether, or the extent to which, the activity falls within the scope of a 'clearly articulated and affirmatively expressed' state policy. . . . Again, we cannot now say, without knowing more facts, whether or not this additional 'state supervision' condition will apply.").[3] Unlike Petitioners' employers, the party seeking state action protection from an FTC investigation in *Monahan* was an agency of the Commonwealth of Massachusetts itself. Petitioners have offered no plausible justification for why the Commission should accord a private party's claims for protection under the state action doctrine from an FTC investigation any greater weight than was accorded to the Massachusetts Board of Registration in Pharmacy by the First Circuit Court of Appeals in *Monahan*. Petitioners are not entitled to have their CIDs or subpoenas quashed or modified by reason of the state action doctrine.[4]

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[3] *Fed. Trade Comm'n v. Ernstthal*, 607 F.2d 488, 490 (D.C. Cir. 1979) ("But where, as here, the FTC does not plainly lack jurisdiction, and the jurisdictional question turns on issues of fact, the agency is not obliged to prove its jurisdiction in a subpoena enforcement proceeding prior to the conclusion of the agency's adjudication.); *South Carolina Bd. of Dentistry*, 455 F.3d at 444 (holding that the Board's state action defense did not qualify for interlocutory appeal because the state action issue would not be "effectively unreviewable" on appeal from the FTC's final decision).

[4] Petitioners' claim that the subpoenas should be made returnable in Puerto Rico is without merit. Petitioner's citation to provisions regarding the taking of testimony pursuant to a CID issued under 15 U.S.C. § 57b-1,

CONCLUSION AND ORDER

For all the foregoing reasons, **IT IS ORDERED THAT** the Petition be, and it hereby is, **DENIED**.

IT IS FURTHER ORDERED THAT Petitioners shall comply with the CIDs on December 11, 2009. Commission staff may reschedule the investigational hearings for Petitioners pursuant to the subpoenas at such dates and times as they may direct in writing, in accordance with the powers delegated to them by 16 C.F.R. § 2.9(b)(6).

By direction of the Commission.

Petition at 13, is unavailing in this case. The subpoenas at issue in this matter were issued under 15 U.S.C. § 49; this latter provision of the FTC Act permits the taking of testimony "at any designated place of hearing."

Responses to Petitions to Quash

CHURCH & DWIGHT CO., INC.

FTC File No. 091-0037, Decision, December 23, 2009

RESPONSE TO PETITION TO QUASH OR LIMIT SUBPOENA *DUCES TECUM* AND CIVIL INVESTIGATIVE DEMAND ISSUED TO CHURCH & DWIGHT, INC.

Dear Mr. Hittinger:

The Commission is investigating whether Church & Dwight ("C&D") has used exclusionary practices to monopolize or attempt to monopolize the domestic distribution and sales of condoms or other C&D products in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.[1] On November 13, 2009, C&D filed, out of time, its Petition to Quash or Limit Subpoena Duces Tecum and Civil Investigative Demand Issued to Church & Dwight, Inc. on June 29, 2009 ("Petition") on the grounds that the subpoena and CID seek irrelevant Canadian marketing documents,[2] and that it would be unduly burdensome for it to produce Canadian marketing documents that are located in Canada. *Id.*[3] By letter dated October 30, 2009, C&D's counsel for the first time sought an "extension" in time to file a petition to quash or modify the subpoena and CID. Staff responded to this request on November 4, 2009, and indicated that they were "willing to grant a short extension of time to file a petition to quash on that issue alone . . . until c.o.b. Friday, November 13."

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[1] The Petition at 1.

[2] The Petition's suggestion on page 1 that the investigation is further limited to C&D's marketing practices through retail chains is incorrect. The scope of the investigation is defined by the resolution authorizing the use of compulsory process. *Fed. Trade Comm'n v. Invention Submission Corp.*, 965 F.2d 1086, 1092 (D.C. Cir. 1992) (". . . we have previously made clear that 'the validity of Commission subpoenas is to be measured against the purposes stated in the resolution, and not by reference to extraneous evidence.' [*Fed. Trade Comm'n v. Carter*, 636 F.2d 781, 789 (D.C. Cir. 1980)]."). The Petition's reliance on particular specifications of the subpoena or CID for this claimed limitation is, therefore, unavailing.

[3] The subpoena and CID were served on C&D on July 2, 2009, and were returnable on July 30, 2009.

Petition, Exhibit C at 1 (Letter from Assistant Regional Director Graybill to Lesli Esposito and Carl Hittinger dated Nov. 4, 2009).

On December 7, 2009, C&D filed a Request for Leave to File Out of Time ("Request") a further petition to quash or modify the subpoena because staff refused to accede to C&D's request to be allowed to redact "irrelevant" information from responsive documents that relate to C&D's non-condom products. C&D claims it should be allowed to redact such information because: (1) non-condom information is irrelevant to the investigation; and (2) press reports about the investigation (based on non-FTC sources) indicate that there may be a potential FTC data security problem that entitles C&D to redact such information, Request, Exhibit 1 at 9.

The FTC cannot prevent private party-witnesses or complainants from providing the media with information about an FTC investigation. In any event, there is nothing in the media reports cited by C&D, Request, Exhibits 1 (F & G), that shows the existence of a data security problem at the FTC. Further, C&D has provided no evidence that its legitimate concerns with the security of its confidential business information in the hands of the FTC will not be adequately protected by the provisions of 15 U.S.C. §§ 46(f) and 57b-2.

The Petition and Request are both time barred and otherwise wholly without merit; and must, therefore, be denied. C&D shall comply with the subpoena and CID on January 26, 2010.

This letter advises you of the Commission's disposition of the Petition and Request. This ruling was made by Commissioner Pamela Jones Harbour, acting as the Commission's delegate. *See* 16 C.F.R. § 2.7(d)(4). Pursuant to 16 C.F.R. § 2.7(f), Petitioner has the right to request review of this matter by the full Commission. Such a request must be filed with the Secretary of the Commission within three days after service of this letter.[4]

[4] This letter ruling is being delivered by e-mail and express mail. The e-mail copy is provided as a courtesy. Computation of the time for appeal, therefore, should be calculated from the date you receive the original by express mail. In accordance with the provisions of 16 C.F.R. § 2.7(f), the

I. The Petition and Request Are Time Barred.

A. The Petition Is Time Barred.

The Commission's rules of practice have separate provisions regarding extensions of time to comply with a subpoena or CID, Rule 2.7(c), 16 C.F.R. § 2.7(c), and extensions of time within which a petition to quash or limit a subpoena or CID may be filed. Rule 2.7(d)(3). Petitions to quash or limit a subpoena or CID must be filed by the earlier of the return date of the subpoena or CID or twenty (20) days after service of the subpoena or CID. In the absence of a timely extension of time within which to file a petition to quash or limit, the Petition and Request in this matter should have been filed no later than July 22, 2009. After the expiration of the time within which to file a petition to quash or limit, the recipient of a subpoena or CID can only file such a challenge if the Commission grants it leave to file a petition out of time based on a showing of extraordinary or unforeseeable circumstances. Rule 2.7(d)(3) grants certain staff managers the authority to "rule upon requests for extensions of time within which to file" a petition to quash or limit; however, the grant of such authority does not extend to requests to revive already expired periods of limitation.

The rules prescribe a reasonably short period within which petitions to quash or limit must be filed in order to insure that such petitions are resolved as early in the investigation as is practicable. The issues raised by the Petition and Request in this matter illustrate why these issues should be resolved as soon as possible. Objections should have been filed by July 22nd, so that these issues could have been resolved in July or August of this year. Because these issues were not presented in a timely manner, the Commission's ability to finish its investigation and assess whether an enforcement action against C&D would be in the public interest has been impaired, without any countervailing benefit to the public. In short, reading the provisions of Rule 2.7(d)(3) so it would permit staff to revive elapsed periods of

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timely filing of a request for review of this matter by the full Commission shall not stay the return date established pursuant to this decision.

limitation would eviscerate the rule's salutary purpose (expediting the resolution of petitions to quash or limit process).

There appears to have been some confusion on the part of both staff and C&D with regards to staff's authority to grant an extension of time to file a petition to quash or limit after the expiration of the limitations period for such filing. Accordingly, the Petition will be treated as if it had been filed as a motion for leave to file the Petition out of time.

B. C&D Waived the Right to Raise the Issues Set Forth In the Request.

C&D's justification for not filing the Request raising the redaction issues along with the Petition was "because appropriate grounds for filing [such] a petition to quash or limit the subpoena did not arise before at least October 30, 2009." Request at 2. C&D's Exhibits, however, do not support its claim. Instruction R to the subpoena (Petition, Exhibit A) expressly prohibited redactions on any basis other than a claim of privilege. Additionally, on July 28, 2009, staff advised C&D in writing that it had no right to redact information unless the redaction was based on a claim of privilege. Request, Exhibit (1)(C) (Letter from Sylvia Kundig to Carl Hittinger and Lesli Esposito dated Jul. 28, 2009). That letter directed C&D to "please produce unredacted versions of all non-privileged, responsive documents." *Id*. at 1. The clear directive contained in the letter of July 28 cannot reasonably be construed to apply only to some subset of documents, instead of the entirety of the documents to be produced. In short, C&D knew, or should have known, that it had no right to redact non-privileged information from responsive documents at least as early as some point shortly after its receipt of the subpoena.

Even if it were assumed, *arguendo*, that there was some lingering ambiguity regarding redaction of non-privileged information until sometime on or about October 30, 2009, it does not explain C&D's filing of a piecemeal petition with the Commission–Part A on November 13th and Part B on December 7th. *Wellness Support Network*, File No. 072-3179 at 2 (FTC Apr. 24, 2008) (Letter Ruling dismissing appeal from denial of petition

to quash CID) ("The rule is clear on its face that all grounds for challenging a CID shall be joined in the initial application, absent some extraordinary circumstances. To construe the rule in any other fashion would serve no purpose other than inviting piecemeal challenges to CIDs and a parade of dilatory motions seeking seriatim deconstruction of each CID."). C&D has offered no evidence to support its decision to file the Petition and Request separately.

As set forth below, the Petition and Request are substantially without merit; therefore, denial of leave to file the Petition and Request out of time leads to the same result that would have been obtained had such leave been granted. Accordingly, leave to file the Petition and Request out of time is denied.

II. The Information Being Sought Is Reasonably Relevant to the Investigation.

A. The Canadian Marketing Documents and Information Are Reasonably Relevant to the Investigation.

The Petition correctly notes that documents are relevant to investigatory process if they are reasonably relevant to the FTC's investigation measured against the scope and purpose set forth in the resolution authorizing the use of compulsory process. Petition at 4 (quoting *Fed. Trade Comm'n v. Texaco, Inc.*, 555 F.2d 862, 874 (D.C. Cir. 1977) ("The relevance of the material sought by the FTC must be measured against the scope and purpose of the FTC's investigation, as set forth in the Commission's resolution."). The Petition further acknowledges that a United States company may be compelled to produce records of its foreign subsidiaries. Petition at 5 (citing *In re Polypore*, 2009 WL 569708 (F.T.C. Feb. 3, 2009) (Chappell, A.L.J.)).[5]

Petitioner argues that its Canadian marketing documents do not meet the requisite relevance standard because differences in law and practices, as well as market conditions, between the United States and Canada would render the Canadian records incapable of any probative value regarding either comparable or

[5] Docket No. 9327.

comparative marketing practices undertaken by C&D in the United States. The Petition claims this is so, because the Commission would be incapable of acquiring data sufficient to support a "natural experiment" that would be admissible in evidence. Petition at 5-8. It is premature to speculate on whether the Canadian marketing documents might be admissible in evidence during an enforcement action to support a natural experiment or for any other purpose.[6] A fuller quotation from the *Texaco* case relied upon by Petitioner will illustrate the point:

> We agree with the FTC that comparative information of this sort is "reasonably relevant" to its investigation. While, in response to the companies' arguments, the FTC has advanced several examples to demonstrate the relevance of bid files, the Commission emphasized that this approach which requires, in effect, the delineation of a particular theory of violation is inappropriate in the pre-complaint stage; and here, too, we agree. While the FTC has not articulated the specific anti-competitive practices which may be present, it could not reasonably do so without access to the relevant documents. Certainly a wide range of investigation is necessary and appropriate where, as here, multifaceted activities are involved, and the precise character of possible violations cannot be known in advance.

Texaco, 555 F.2d at 877 (footnotes omitted). It is early in the Commission's investigation. The Commission is not yet in a

[6] "There is also this question of what counts as evidence. Economists have this thing that it's not evidence unless you can run a regression." Fed. Trade Comm'n Resale Price Maintenance Hearings: Examining Theories of Benefit from Resale Price Maintenance, Tr.100, Feb. 17, 2009 (Dr. Benjamin Klein). It is premature to even speculate either whether the Canadian marketing data will be able to produce reliably predictive regression analyses or whether it might otherwise be admissible for some other purposes at trial. More importantly, however, even if C&D's Canadian marketing records were neither capable of supporting regression analysis nor admissible at trial, those records will still help the Commission decide whether there is reason to believe that an enforcement action against C&D would be in the public interest.

position to "anticipate" potential theories of liability or resolve questions of evidence admissibility; and *Texaco* confirms that the FTC should not be asked to do so at this point in an investigation.

B. Information and Documents About C&D's Non-Condom Products Are Reasonably Relevant to the Investigation.

The Request claims that C&D should be allowed to redact information regarding C&D's non-condom products because such information bears "absolutely no relation to the stated purpose of the Commission's investigation . . . as set forth in the Resolution." Request, Exhibit 1 at 4. This claim is without merit on a variety of levels. This claim misstates the terms of the resolution authorizing the use of process. Petition, Exhibit D at 1 ("Nature and Scope of Investigation: To determine whether [C&D] has attempted to acquire . . . a monopoly in the distribution or sale of condoms in the United States . . . through exclusionary practices [regarding] . . . Trojan brand condoms and other products distributed and sold by [C&D] . . . in violation of Section 5 of the Federal Trade Commission Act. . . ."). The resolution on its face authorizes an investigation regarding the marketing of all of C&D's products. Additionally, the probative value of any given part of a document can be and is affected by its context; that is to say that context can sometimes be as important as text. It is frequently necessary in a law enforcement investigation for witnesses to be able to identify and authenticate documents; those witnesses may need to see the entire document to be able to tell whether they are looking at a final document as opposed to earlier drafts or proposals. Finally, a comparative analysis of C&D's marketing strategies can have significant probative value; for instance, a comparison of marketing strategies for products where C&D may have market power to the marketing practices where it may not have market power could be informative. The request to redact information relating to C&D's non-condom products must be denied because those materials are reasonably relevant to the Commission's investigation.

III. No Evidence Supports C&D's Burden Claim

"Some burden on subpoenaed parties is to be expected and is necessary in furtherance of the agency's legitimate inquiry and the public interest. The burden of showing that the request is unreasonable is on the subpoenaed party," *Texaco*, 555 F.2d at 882, and is not easily met where, as here, the FTC seeks information that is reasonably relevant to its investigation. Petitioner claims that compliance will cost it "hundreds of thousands of dollars" and involve more than 1,000 staff-hours of effort. Petition at 8. C&D has not supported this claim with facts, and has not noted that staff have repeatedly offered to work with it to mitigate production costs wherever possible. "At a minimum, a petitioner alleging burden must (i) identify the particular requests that impose an undue burden; (ii) describe the records that would need to be searched to meet that burden; and (iii) provide evidence in the form of testimony or documents establishing the burden (*e.g.*, the person-hours and cost of meeting the particular specifications at issue)." *Nat'l Claims Service, Inc.*, 125 F.T.C. 1325, 1328-29 (Jun. 2, 1998). C&D made no reasonable attempt to show factually that the production of its Canadian marketing documents would "unduly disrupt or seriously hinder normal operations of [its] business."[7]

IV. CONCLUSION AND ORDER

For all the foregoing reasons, **IT IS ORDERED THAT** C&D be, and it hereby is, **DENIED** leave to file its Petition and Request out of time.

IT IS FURTHER ORDERED THAT Petitioner shall comply with the subpoena and CID on January 26, 2010.

By direction of the Commission.

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[7] *Texaco*, 555 F.2d at 882 ("Thus courts have refused to modify investigative subpoenas unless compliance threatens to unduly disrupt or seriously hinder normal operations of a business."). Further, C&D's relevance and burden claims appear to be contradicted by its own records. It appears that C&D has already produced some documents showing that C&D can and does readily produce Canadian marketing experience records to interested US retailers.

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