UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

DANIEL CHAPTER ONE, a corporate sole, and JAMES FEIJO, individually, and as an officer of Daniel Chapter One, Petitioners, v. FEDERAL TRADE COMMISSION, Respondent.	)	No. 10-1064

PETITIONERS' EMERGENCY MOTION FOR STAY
PENDING REVIEW OF FTC MODIFIED FINAL ORDER

EXHIBIT A

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Jon Leibowitz, Chairman**
Pamela Jones Harbour
William E. Kovacic
J. Thomas Rosch

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

MODIFIED 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:

1. BioShark inhibits tumor growth;
2. BioShark is effective in the treatment of cancer;
3. 7 Herb Formula is effective in the treatment or cure of cancer;
4. 7 Herb Formula inhibits tumor formation;
5. GDU eliminates tumors;
6. GDU is effective in the treatment of cancer;
7. BioMixx is effective in the treatment of cancer; or
8. 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 final and effective date 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 and until the date this order becomes final and effective. 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 final and effective date 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 and until the date this order becomes final and effective, 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 final and effective date 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 final and effective date 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 January 25, 2030, 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.

Donald S. Clark
Secretary

SEAL:
ISSUED: January 25, 2010

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,

ATTACHMENT B

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

[name and address of purchaser]

GOVERNMENT ORDERED NOTICE

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

DANIEL CHAPTER ONE, a corporate sole, and JAMES FEIJO, individually, and as an officer of Daniel Chapter One, Petitioners, v. FEDERAL TRADE COMMISSION, Respondent.	)	No. 10-1064

PETITIONERS' EMERGENCY MOTION FOR STAY
PENDING REVIEW OF FTC MODIFIED FINAL ORDER

EXHIBIT B

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

Commissioners: **Jon Leibowitz, Chairman**
Pamela Jones Harbour
William E. Kovacic
J. Thomas Rosch

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

ORDER DENYING RESPONDENTS' APPLICATION FOR STAY OF MODIFIED FINAL ORDER PENDING PETITION FOR REVIEW

The Commission issued its Opinion on December 18, 2009 ("Opinion") and its Modified Final Order ("Order") on January 25, 2010.[1] The Commission's Order was served on Respondents Daniel Chapter One ("DCO") and James Feijo (collectively "Respondents") and counsel by February 1, 2010. Respondents' compliance is required no later than 60 days after service of the Order; that is, by April 2, 2010. 15 U.S.C. § 45(g)(2).

On February 25, 2010, pursuant to Rule 3.56 of the Commission's Rules of Practice, 16 C.F.R. § 3.56, Respondents moved for a stay of the Order until the later of the following: (1) the expiration of the time for filing a petition for review of the Order in a United States Court of Appeals; (2) the issuance of a final order regarding Respondents' petition for review; (3) the denial of a petition for panel rehearing; (4) the denial of a petition for rehearing *en banc*, or the expiration of the time for filing such petitions for rehearing; or (5) the denial of a petition for certiorari in the United States Supreme Court, or the expiration of time to file such petition.

[1] Citation references to the materials are abbreviated as follows:
"Op." refers to the Opinion of the Commission issued on December 18, 2009;
"Order" refers to the Modified Final Order issued on January 25, 2010; and
"R. Mem." refers to Respondents' Memorandum in Support of Respondents' Application for Stay, filed on February 25, 2010.

Respondents have failed, however, to justify such relief is warranted. All factors for granting a stay weigh against granting the motion. Respondents have shown neither a likelihood of success on the merits on appeal, nor that they will suffer irreparable harm absent the requested relief. Moreover, given that other parties will be harmed if the stay is granted, it is not in the public interest to grant Respondents' motion. Accordingly, the Commission denies the motion.

Background

Respondents, DCO, a corporation sole organized under the laws of the State of Washington, and its overseer and trustee, James Feijo, advertise and sell four DCO products to the public – Bioshark, 7 Herb Formula, GDU, and BioMixx ("Challenged Products").[2] Respondents claim the Challenged Products can prevent, treat, or cure cancer, inhibit tumors, or ameliorate the adverse effects of radiation and chemotherapy. Respondents made these claims during their radio shows, over the internet, and through print media. 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.

The Commission's Opinion considered the record and arguments of counsel. The Commission analyzed whether the FTC has jurisdiction over Respondents; the claims Respondents made within their advertisements; whether Respondents' claims were properly substantiated; and Respondents' defenses and constitutional arguments. After finding the Commission has jurisdiction over Respondents and considering the record evidence presented by both parties, we concluded that Respondents did not have competent or reliable evidence to substantiate their claims that the Challenged Products treat, cure or prevent cancer, inhibit tumors, or ameliorate the adverse effects of radiation and chemotherapy.

Accordingly, the Commission issued a cease-and-desist Order against Respondents. Among other requirements, Respondents may make efficacy claims for products they sell only so long as the representations are true, non-misleading, and, at the time they are made, Respondents possess and rely on competent and reliable scientific evidence to substantiate their claims. The Order limits what they may say relating to the sale of certain products, but it does not otherwise limit their speech or religious practices. The Order also requires Respondents to send to all consumers who have bought the Challenged Products a letter notifying them the FTC found DCO's advertising claims for the Challenged Products to be deceptive because they were not substantiated by competent and reliable scientific evidence, and that the FTC has issued an Order prohibiting Respondents from making the claims in the future.

Before us now is Respondents' Application for Stay of Modified Final Order Pending Judicial Review.

[2] DCO currently sells 150 to 200 products, including the four products challenged in the Complaint.

Applicable Standard

Section 5(g) of the Federal Trade Commission Act provides that Commission cease and desist orders (except divestiture orders) take effect "upon the sixtieth day after such order is served," unless "stayed, in whole or in part and subject to such conditions as may be appropriate, by … the Commission" or "an appropriate court of appeals of the United States." 15 U.S.C. § 45(g)(2); *see also* 16 C.F.R. § 3.56(a). A party seeking a stay must first apply for such relief to the Commission, 15 U.S.C. § 45(g)(2)(A), (B)(ii). Pursuant to Rule 3.56(c) of the Commission's Rules of Practice, an application for a stay must address the following four factors: (1) the likelihood of the applicant's success on appeal; (2) whether the applicant will suffer irreparable harm if a stay is not granted; (3) the degree of injury to other parties if a stay is granted; and (4) why the stay is in the public interest. 16 C.F.R. § 3.56(c); *see, e.g.*, *In the Matter of Toys "R" Us, Inc.*, 126 F.T.C. 695, 696 (1998). We consider these factors below.

Analysis

1. Likelihood of Respondents' Success on Appeal

Respondents correctly note that in assessing the likelihood of their success on the merits on appeal, the Commission need not "harbor doubt about its decision in order to grant the stay." *In the Matter of California Dental Ass'n*, 1996 FTC LEXIS 277, at *10 (May 22, 1996). Respondents also correctly state they may satisfy the "'merits' factor if their argument on at least one claim is 'substantial' – so long as the other three factors weigh in their favor." R. Mem. at 1 (*citations omitted*). Finally, if the equities decidedly tip in favor of the Respondents it is enough that they "raise questions sufficiently serious and substantial to constitute 'fair ground for litigation.'" R. Mem. at 1-2 (*citations omitted*). Respondents' arguments, however, merely disagree with the Opinion of the Commission and raise no serious or substantial questions on the merits; disagreement does not establish a likelihood of success on appeal.

a. Jurisdiction

Respondents argue that the Commission does not have jurisdiction because DCO is a corporation sole operating under the laws of Washington, and as such is dedicated to religious, nonprofit purposes. They assert the Commission misapplied *Community Blood Bank of Kansas City Area, Inc. v. FTC*, 405 F.2d 1011 (8th Cir. 1969) when it found DCO's members derived a profit from DCO's activities. Respondents raised these arguments on appeal to the Commission and the Commission rejected them. *See* Op. at 6-8 (summarizing Respondents' same

jurisdictional arguments).[3] As we stated in *North Texas Specialty Physicians*, Docket No. 9312 (Jan. 20, 2006), merely repeating arguments the Commission rejected before does not provide the Commission with "sufficient reason to question its prior decision or any of the bases for it, and Respondent[s'] renewal of its legal arguments, without more, is insufficient to justify granting a stay." *Id*. at 3 (*citations omitted*).

The Commission does not question the seriousness of Respondents' religious beliefs, but controlling authorities refute their legal arguments. *California Dental Ass'n v. FTC*, 526 U.S. 756, 766-67 (1999) and *Community Blood Bank*, 405 2d at 1022, both hold the Commission's jurisdiction extends to a corporation organized to carry on business for its own profit or that of its members. The record here establishes that DCO carries on a business that inures to the economic benefit of Respondent James Feijo, its sole overseer and trustee of DCO's assets. DCO sells its products through publications, a call center, radio shows, and over the Internet. In addition, a number of retail stores and chiropractic centers in various states sell DCO products. Any consumer may purchase DCO's products. James Feijo's wife, Patricia Feijo, is a signatory to DCO's bank accounts and had check writing authority. DCO's revenue covered all of the Feijos' living expenses including two houses, cars, pool and gardening expenses, tennis and golf club expenses, and expenditures on retail items and restaurant bills. The evidence supports a finding that DCO was engaged in commercial activities and that the beneficiary of DCO's profit was James Feijo. Op. at 7, 8.

b. Substantiation

Respondents also question the propriety of the FTC's substantiation doctrine. They argue that the reasonable basis theory creates presumptions that violate both Sections 5 and 12 of the FTC Act, as well as the First Amendment commercial speech doctrine. Respondents raised these same arguments below and we continue to find them without merit.

Longstanding case law has consistently held that advertising claims can be found deceptive under Sections 5 and 12 of the FTC Act if they are shown either to be false or to lack a reasonable basis substantiating the claims made in the advertisement. *See, e.g.*, *FTC v. National Urological Group*, 645 F. Supp. 2d 1167 (N.D. Ga. 2008), *aff'd*, 2009 U.S. App. LEXIS 27388 (11th Cir. 2009); *FTC v. Pantron I*, 33 F.3d 1088, 1096 n.23 (9th Cir. 1994); *In the Matter of Thompson Med. Co.*, 104 F.T.C. 648, 818-19 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986). Under the reasonable basis standard, claims about a product's attributes, performance or efficacy carry with them the express or implied representation that the advertiser possessed a reasonable basis substantiating the claims at the time they were made. *See Thompson*, 104 F.T.C. 648, at 813; *FTC v. Direct Mktg. Concepts*, 569 F. Supp. 2d 285, 298 (D. Mass. 2008); *In the Matter of Kroger Co.*, Docket No. C-9102, 1978 FTC LEXIS 332, at *15 (May 17, 1978). Although

[3] The Commission's factual findings must be accepted if they are supported by relevant evidence sufficient so that a reasonable mind might agree with the conclusions. *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 454 (1986). *See also* Section 5(c) of the Act, 15 U.S.C. § 45(c), which provides that "(t)he findings of the Commission as to the facts, if supported by evidence, shall be conclusive" upon review in the Court of Appeals.

Respondents may not like the case law, they cannot dispute that courts continue to hold the FTC may show a respondent made deceptive claims if it did not have a reasonable basis for their advertisements. Applying that standard in the matter before us now and after reviewing the evidence, the Administrative Law Judge ("ALJ") and the Commission found Respondents did not possess any adequate substantiation for their health-related efficacy claims.

Respondents assert the ALJ and the Commission misapplied the FTC Guide, *Dietary Supplements: An Advertising Guide for Industry*, ("Guide") contending that the ALJ and the Commission applied the Guide as a fixed rule of law rather than a flexible standard. The standard's flexibility, however, lies in its tailoring the level of substantiation required to the nature of the product claims at issue. Here, Respondents claimed that the Challenged Products could prevent, treat, or cure cancer, inhibit tumors, or ameliorate the adverse effects of radiation and chemotherapy. As the Guide itself notes, such claims about efficacy typically should be supported with competent and reliable scientific evidence. *See* Guide at 9. Further, case law supports holding the Respondents to a competent and reliable scientific standard for the efficacy claims they made. *See 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*, 645 F. Supp. 2d at 1189; *Direct Mktg.*, 569 F. Supp. 2d at 300, 303; *FTC v. QT, Inc*., 448 F. Supp. 2d 908, 961 (N.D. Ill. 2006), *aff'd*, 512 F. 3d 858 (7th Cir. 2008). Finally, the ALJ and the Commission relied on expert testimony to determine what competent and reliable scientific evidence would adequately substantiate Respondents' claims.

c. First Amendment Arguments

Respondents argue the Commission's Opinion and Order unconstitutionally deprives them of free exercise of religion and freedom of speech, denies Respondents' liberty and property without due process, and erroneously dismissed their Religious Freedom Restoration Act Claim. Respondents' arguments are without merit.

The evidence established the primary purpose and effect of the speech at issue here – Respondents' representations relating to the Challenged Products – was to sell those products, not to solicit charitable contributions. Op. at 13. Such commercial speech is accorded less protection than other constitutionally protected forms of speech. *See Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 562-63 (1980). Specifically, misleading or deceptive commercial speech is afforded no protection under the First Amendment. *See, e.g., Cent. Hudson*, 447 U.S. 557; *Edenfield v. Fane*, 507 U.S. 761 (1993); and *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173 (1999). Respondents' claims about the efficacy of the Challenged Products were not substantiated and were, therefore, deceptive. Op. at 11, 14.

Respondents argue their due process rights were violated because two of the sitting Commissioners pre-judged the matter. Respondents point to a speech made by Commissioner

Rosch in 2008[4] and Commissioner Harbour's statements during oral argument. Respondents' reliance on *Cinderella Career & Finishing Schools, Inc. v. FTC*, 425 F.2d 583 (D.C. Cir. 1970) is misplaced. In that case, the court noted that the statements relied on to show prejudgment were made while the appeal was pending before the Commission; here Commissioner Rosch made these general statements about a "bogus cancer cure" sweep as only a small part of a larger speech on self-regulation. Commissioner Rosch delivered this speech almost a full year before Respondents had even filed their appeal in this case, before evidence was entered in the matter, and before the ALJ issued his Initial Decision (August 2009). Further, if Respondents had wanted to disqualify Commissioner Rosch, they should have sought his disqualification before now by the filing "of a timely and sufficient affidavit of personal bias or other disqualification of a presiding or participating employee." 5 U.S.C. § 556(b). They have never made such a filing.

Nor is there any merit to Respondent's arguments based on Commissioner Harbour's comments during the oral argument before the Commission. Like any appellate tribunal, the Commission may properly probe and even challenge the positions being argued to it, as well as the practical ramifications of its ruling. In the present case, for example, there is no impropriety in inquiring into the potential that the continued sale of "cancer cures" whose efficacy is unsubstantiated could harm consumers who might turn to such products in place of other medical treatment. In any event, none of the statements to which Respondents refer could lead "a disinterested observer [to] conclude that (a commissioner) has in some measure adjudged the facts as well as the law of a particular case in advance of hearing it." *Gilligan, Will & Co. v. SEC*, 267 F.2d 461, 469 (2d Cir. 1959) (describing the grounds for disqualification). Moreover, there was ample evidence in the record to support the Commission's decision in this matter.

Respondents' final two arguments supporting their assertion that they are likely to succeed on the merits are that the FTC erroneously dismissed the Respondents' Religious Freedom Restoration Act claim ("RFRA") and that the FTC is forcing the Respondents to send a letter to consumers to which Respondents object for moral, ethical, and religious reasons. Respondents' arguments again misapply the law to the facts in this matter. RFRA applies when the government substantially burdens a person's exercise of religion. The case upon which Respondents rely is *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418 (2006). In that case, the use of a hallucinogenic tea was central to the entity's core beliefs, the tea was not sold or otherwise provided to non-believers, and the tea was only used during the sacramental rite of communion. Nothing in the record before us reveals similar facts. DCO was engaged in commercial activity by selling the Challenged Products and DCO engaged in deception to make those sales. DCO's sales were not dependent upon a consumer's belief system or whether they had any religious affiliation at all. DCO sold their products completely outside of any religious ceremony or sacrament.

The Commission has not burdened Respondents' exercise of religion; it has only limited how DCO can sell its products. The Commission found the Respondents violated Section 5 of

[4] J. Thomas Rosch, *Self-Regulation And Consumer Protection: A Complement To Federal Law Enforcement*, before the 2008 National Advertising Division Annual Conference, at 16-17 (Sept. 23, 2008).

the FTC Act, which provides the Commission with the authority to fashion an order requiring respondents to cease and desist from such acts and practices. *FTC v. Nat'l Lead Co.*, 352 U.S. 419, 428 (1957). The Commission took great care in issuing the Order in this matter and making it clear that the letter informing consumers of the FTC's Opinion and Order plainly state it is the FTC's Order that requires Respondents to transmit the information. The Order does not require that Respondents profess to agree with the FTC or that Respondents modify their religious ministry in any way.

2. Irreparable Injury

Respondents argue that compliance with the Order "would be nearly fatal to the DCO ministry, imposing incalculable losses that can neither be accurately measured nor compensated, and causing serious harm to its 'good will.'" R. Mem. at 23. Respondents base this argument on the provisions of Paragraphs II and III which prohibit Respondents from making any representation about the efficacy of any of their products "unless the representation is true, non-misleading, and, at the time it is made, [DCO] possess[es] and rel[ies] upon competent and reliable scientific evidence that substantiate[s]" their claims. R. Mem. at 25 (*quoting* Paragraph III of the Order). These limitations, Respondents argue, will prevent them from selling any of their products, essentially shut down DCO, and injure the business's goodwill with its steady customers. [5]

Respondents may not recognize it, but the Commission's Order merely requires Respondents to follow the law. Paragraphs II and III of the Order cover both the Challenged Products as well as other products sold by Respondents and permit Respondents to make efficacy claims relating to those products so long as the representations are true, non-misleading, and substantiated. Op. at 24. "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." *Id.* The Commission would be hard pressed to find that irreparable injury results from an Order requiring marketers of health-related programs to make only true, substantiated representations about the products they are selling, especially after finding those marketers engaged in deceptive advertising for untested cancer cures. The Order has been tailored narrowly to apply only to their commercial advertising and only to the type of speech that has been found to be deceptive; the Order does not otherwise reach into Respondents' religious speech or practices.

Paragraph V of the Order requires Respondents to send a letter to their customers notifying them of the Commission's Opinion and Order and the findings therein. Respondents assert they will be irreparably harmed if they are compelled to send this letter on their letterhead to certain customers because such a requirement will violate their First Amendment freedoms of speech and religion. Respondents note, however, that if the government can demonstrate "that its mandate is 'a narrowly tailored means of serving a compelling state interest,'" then a speaker can be required to make disclosures. R. Mem. at 22 (*quoting Pacific Gas & Electric Co. v. Cal.*

[5] We accept Respondents' Declarations submitted for the purposes of supporting their irreparable harm argument, but do not find they are sufficient to meet their burden of showing irreparable injury.

P.U.C., 475 U.S. 1, 19 (1986)). The compelling interest here is protecting cancer patients from deceptive advertising claims. The required letter is carefully limited to address only the issues in this matter. In particular, the letter is to be sent only to Respondents' customers who purchased the four Challenged Products; it is drafted to show that the FTC found DCO's advertising claims for those products to be deceptive and that the information about the scientific evidence relating to the products is from the FTC; and it is not drafted to force Respondents to say they agree with the FTC's findings. The letter does not mention Respondents' religious beliefs or teachings. The letter does not compel Respondents to state they have repudiated their faith or endorsed the FTC's Opinion. The letter is narrowly crafted to inform consumers about the FTC's Opinion and Order.

3. Degree of Injury to Other Parties and the Public Interest

The final remaining questions are whether a stay would harm other parties and whether it is in the public interest. *In the Matter of California Dental Ass'n*, 1996 FTC LEXIS 277, at *7-8. These two factors are stated separately, but the FTC considers them together because Complaint Counsel is responsible for representing the public interest by enforcing the law. *See Id.* at *8.

Respondents argue that a stay would not harm any party because they assert there is no evidence that any consumer was economically harmed or misled by Respondents' representations, and that there is no evidence in the record that the four Challenged Products have actually harmed anyone's medical or cancer treatment.

Respondents' argument ignores all the record evidence showing that Respondents engaged in deceptive advertising. And while Respondents may not believe that deception constitutes a "bona fide injury to any consumer," the Commission does. Consumers are harmed when they purchase products that are marketed to prevent, treat, or cure cancer, inhibit tumors, or ameliorate the adverse effects of radiation and chemotherapy, and there is no substantiation for those claims. As the findings of fact show, this harm arises if consumers forego beneficial and effective therapy for untested therapies like the ones at issue here. This harm comes from consumers risking their health to potential side effects and harmful interactions between Respondents' products and other therapies. These harms are real and they are substantial. Because of the nature of the harm, issuing a stay is not in the public interest.

Conclusion

Taking all of these factors into consideration, the Commission has determined that a stay is inappropriate. Respondents are unlikely to succeed on the merits and in the Commission's judgment the potential harm to consumers from granting a stay substantially outweighs the

potential harm to Respondents from denying the request for a stay. We find that DCO and James Feijo have not met their burden for showing a stay of the Modified Final Order pending judicial review is warranted. Accordingly,

IT IS ORDERED THAT the Respondents' Application for Stay of Modified Final Order Pending Judicial Review is **DENIED**.

By the Commission.

Donald S. Clark
Secretary

ISSUED: March 22, 2010

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

DANIEL CHAPTER ONE, a corporate sole, and JAMES FEIJO, individually, and as an officer of Daniel Chapter One, Petitioners, v. FEDERAL TRADE COMMISSION, Respondent.	)	No. 10-1064

PETITIONERS' EMERGENCY MOTION FOR STAY
PENDING REVIEW OF FTC MODIFIED FINAL ORDER

EXHIBIT C

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Jon Leibowitz, Chairman**
Pamela Jones Harbour
William E. Kovacic
J. Thomas Rosch

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

RESPONDENTS' APPLICATION FOR STAY OF MODIFIED FINAL ORDER PENDING JUDICIAL REVIEW

The Respondents, pursuant to 15 U.S.C. section 45(g)(2)(A) and section 3.56(b) of the Rules of Practice of the Federal Trade Commission ("FTC"), 16 C.F.R. section 3.56(b), respectfully apply to the Commission for a stay of the Modified Final Order ("Order") issued on January 25, 2010 and served on January 29, 2009, in the above-entitled matter, pending judicial review by a United States court of appeals in an appropriate federal judicial circuit.

For reasons therefor, Respondents submit: (i) that their arguments for overturning the Order on appeal are likely to succeed on the merits or, alternatively, are substantially meritorious; (ii) that the injuries to Respondents if enforcement of the Order were not stayed would be irreparable; (iii) that no party or the public would be injured by the granting of the requested stay; and (iv) that a stay of the Order would be in the public interest, all as more fully set forth in the attached Memorandum of Law in support of this Application, together

with the Declarations of James Fieijo, Patricia Feijo, Deane Mink, D.C., Karen S. Orr, D.C., Charles Sizemore, D.D.S., and Jerry Hughes.

WHEREFORE, Respondents pray that their Application be granted, and that the Commission enter an Order staying enforcement of the Modified Final Order herein until the later of the following — the expiration of the time for filing a petition for review of the Modified Final Order in a United States court of appeals, the issuance of a final order regarding Respondents' petition for review, the denial of a petition for panel rehearing, the denial of a petition for rehearing *en banc*, or the expiration of the time for filing such petitions for rehearing, the denial of a petition for certiorari in the United States Supreme Court, or the expiration of time to file such petition.

Respectfully submitted,

/s/
_____

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Attorneys for Respondents

February 25, 2010

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Jon Leibowitz, Chairman**
Pamela Jones Harbour
William E. Kovacic
J. Thomas Rosch

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

MEMORANDUM IN SUPPORT OF RESPONDENTS' APPLICATION FOR STAY OF MODIFIED FINAL ORDER PENDING PETITION FOR REVIEW

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February 25, 2010

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INTRODUCTION

This Memorandum is submitted, pursuant to 16 C.F.R. section 3.56(b) and 15 U.S.C. section 45(g)(2)(A), in support of Respondents' Application for Stay of the Modified Final Order ("Order") of the Federal Trade Commission ("FTC") issued on January 25, 2010.

The Order should be stayed pending judicial review because:

(I) Respondents' legal and constitutional challenges are substantial;

(II) if a stay is not granted, Respondents will suffer irreparable harm;

(III) if the stay is granted, no party will be injured and if the stay is granted, the public interest would be benefitted.

See Washington Metropolitan Area Transit Co. v. Holiday Tours, Inc., 559 F.2d 841, 843 (D.C. Cir. 1977); FTC Rule 3.56(c).

ARGUMENT

I. RESPONDENTS' LEGAL AND CONSTITUTIONAL CHALLENGES TO THE ORDER ARE SUBSTANTIAL.

In assessing the likelihood of Respondents' success on the merits on appeal, the Commission need not "harbor doubt about its decision in order to grant the stay." In re California Dental Ass'n., 1996 FTC LEXIS 277, at *9 (May 22, 1996). Respondents satisfy the "merits" factor if their argument on at least one claim is "substantial" — so long as the other three factors weigh in their favor. *See* Deu Thapa v. Gonzales, 460 F.3d 323, 335-36 (2d Cir. 2006). *See also* WMAT v. Holiday Tours, 559 F.2d at 844-45; Michigan Coalition of Radioactive Material Users, Inc. v. Griepentrog, 945 F.2d 150 (6th Cir. 1991); Rum Creek Coal Sales, Inc. v. Caperton, 926 F.2d 353, 359 (4th Cir. 1991). Because the balance of the equities weighs in favor of Respondents, as shown in Parts II and III below, it is enough that

Respondents raise questions sufficiently serious and substantial to constitute "'fair ground for litigation.'" Safety-Kleen, Inc. v. Wyche, 274 F.3d 846, 859 (4th Cir. 2001). *See also* United States v. Baylor University Medical Center, 711 F.2d 38, 39-40 (5th Cir. 1983).

A. The FTC Failed to Apply the Statutory Requirements Governing FTC Jurisdiction over Respondents' Nonprofit Religious Ministry.

The FTC complaint charged that, beginning in 2005 and continuing to the present, Respondents engaged in the allegedly-deceptive practices specified therein. *See* Complaint, ¶ 5. During this entire period, Daniel Chapter One ("DCO") was operating as a "corporation sole," having been so organized in 2002 under the laws of the State of Washington. Opinion of the Commission ("Op."), p. 4. Under Washington law, only **churches or religious societies** may "become a corporation sole." RCW 24.12.010. A corporation sole is permitted to engage in commerce (RCW 24.12.020), but its "overseer" is required to hold all property gained from such commerce "**in trust** for the use, purpose, benefit, and behoof of his religious … society or church." RCW 24.12.030 (emphasis added).

The FTC stated that DCO's Articles of Incorporation failed to "specifically declare that DCO was organized exclusively for charitable or other clearly nonprofit purposes." Op., p. 4. To the contrary, the Articles clearly state that DCO is a "church" dedicated to "promote the Kingdom of God."[1] *See* DCO Articles of Incorporation. Indeed, by definition, a Washington corporation sole is dedicated to engage in "religious" activities. *See* RCW 24.12.030.

The FTC found fault, however, with DCO's Articles for not expressly stating that, "upon dissolution," none of DCO's assets or earnings may distributed to "any individual or

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[1] Luke 4:43 ("[Jesus] said … I must preach the kingdom of God.").

for-profit corporation." Op., p. 4. But Article 4 of DCO's Articles ensures the same result — having created an express trust whereby all assets, are held in trust for DCO's overarching religious purpose. *See* In re Catholic Bishop of Spokane, 329 Bankr. Rep. 304, 325-26 (E.D. Wash. 2005).

The FTC also incorrectly presumed that, by engaging in money-generating sales of products, DCO must necessarily be engaged in such activities for a commercial, profit-making purpose. *See* Op., pp. 4-8. Under Washington law, however, a corporation sole is authorized to "transact[] business" without negating the corporation's charitable purpose. *See* Catholic Bishop, 329 Bankr. Rep. at 327-28. Indeed, the history and modern use of the corporation sole form strongly establish their essential "ecclesiastical" nature and purpose. *See* J. O'Hara, "The Modern Corporation Sole," 93 *Dickinson L. Rev.* 23 (1988).

The FTC compounded its misunderstanding of state law by its misapplication of the federal law that circumscribes FTC jurisdiction over nonprofit corporations. Purporting to apply the rule in Community Blood Bank of the Kansas City Area, Inc. v. FTC, 504 F.2d 1011, 1015 (8th Cir. 1969), the FTC erroneously ruled that DCO was subject to FTC jurisdiction because "**by engaging in commercial activities**, DCO operates a commercial enterprise and thereby is not … organized or engaged in only charitable purposes." Op., p. 7 (emphasis added). By this statement, the FTC repeated the same error that it made in Community Blood Bank when it claimed jurisdiction over "any corporation engaged in business only for charitable purposes … that receives income in excess of expenses." *See id.*, 405 F.2d at 1016.

However, the court in Community Blood Bank expressly rejected that argument, ruling that "even though a corporation's income exceeds its disbursements its nonprofit character is not necessarily destroyed." *Id.,* 405 F.2d at 1017. Instead, the court adopted the rule that an entity's nonprofit character is lost **only if it can be shown that** either the entity or its members "derived a profit **over and above** the ability to **perpetuate or maintain** [its] existence." *Id.*, 405 F.2d at 1019 (emphasis added).

Applying this rule here, the FTC must prove that the income from DCO's marketed products was **not** being "used exclusively for the purposes authorized by law and their articles of incorporation." *See id.*, 405 F.2d at 1020. As pointed out above, the FTC erroneously presumed that simply "by engaging in commercial activities, DCO operates a commercial enterprise and thereby is not a business organized or engaged in only charitable purposes." Op., p. 7. But DCO is fully authorized by Washington state law governing corporation soles to engage in commercial activities for the benefit of its religious purpose of advancing the Kingdom of God. The mere fact that it "engages in commercial activities" does not transform the organization into a "commercial enterprise." Indeed, if the FTC's reasoning were adopted, it would extend FTC jurisdiction to cover **any** nonprofit organization that engages in **any** commercial activity, no matter what the purpose and use of the income.

In the alternative, the FTC determined that it had jurisdiction over DCO because Mr. Feijo, as overseer, "distributed [DCO] funds to himself and his wife for their benefit." Op., p. 8. In support of this finding, the FTC observed that the Feijos lived in two homes and used two cars, each of which was owned by "DCO or its affiliate," and DCO "was the source of all of [the Feijos'] living expenses." *Id.* But the legal test whether the FTC has jurisdiction over

DCO as a nonprofit organization is not whether the Feijos utilized DCO's assets, or even benefitted from DCO's payment of their expenses. Rather, the question is whether Mr. Feijo "derived a profit" for his personal "pecuniary gain," that is, whether DCO was "merely [a] vehicle through which a pecuniary profit could be realized for [himself and his wife]." *See* Community Blood Bank, 405 F.2d at 1017.

Notably absent from the Commission's ruling was any finding about the specific use to which the two homes and the two cars were put, and the reason for payment of certain expenses reimbursed to the Feijos'. *See* Op., p. 8. Under the rule of Community Blood Bank, it is incumbent upon the FTC to prove that such use and payments were for the Feijos' "personal profit, benefit, or advantage[,]" and not for the purpose of perpetuating and maintaining DCO's religious services and programs. *See id.*, 405 F.2d at 1021. The record shows that the Feijos, as the sole officers of DCO, are engaged full-time in the DCO "house ministry" — including, "spiritual counseling," health education, marketing DCO products, producing its publications, maintaining its website, and hosting its radio program. *See* Op., pp. 2, 4-6. As the court pointed out in Community Blood Bank, the **FTC has the burden** to show that the Feijos' use of DCO properties and receipt of payment for certain expenses were "infected with commercial intent," not with the intent of "promoting [DCO's] program in the public interest." *See id.*, 405 F.2d at 1022. **The FTC never met this burden.**

B. As Applied Here, the FTC's "Reasonable Basis Theory" Is Unauthorized by Statute and Violative of Respondents' First Amendment Rights.

The FTC has characterized its ruling as one in which it "found" DCO's representations with respect to BioShark, 7 Herb Formula, GDU, and BioMixx (hereinafter "the four Challenged Products") to be "deceptive because they were not substantiated by competent and reliable scientific evidence." *See* Order, Attachment A. Throughout the administrative proceedings, the FTC made **no effort** to demonstrate that Respondents' representations were, in fact, **untruthful** or **misleading**. *See* ALJ Initial Decision ("ALJ Dec."), p. 99 n.4; Op., pp. 11-12. Instead, utilizing its "reasonable basis theory," the FTC foisted upon Respondents the burden to "substantiate" their representations by what the FTC deemed to be "competent and reliable scientific evidence." ALJ Dec., pp. 99-100; Op., p. 20. The FTC's "**reasonable basis theory**" **presumes** that, if Respondents' representations are "**unsubstantiated**," they are inherently **deceptive**. *See* Op., pp. 11-12. Such a presumption violates both sections 5 and 12 of the FTC Act, as well as the First Amendment commercial speech doctrine.

1. The FTC's " Reasonable Basis Theory" Is a Not a Rule of Law, but Only a Policy Guide Wholly Inapplicable to this Case.

The FTC claims that its "reasonable basis theory" is established by "Commission and federal case law." *Id.*, p. 11. However, neither of the two cases cited by the FTC demonstrates how the language of either section 5 or 12 of the FTC Act could possibly be construed to require marketing representations to meet an FTC-contrived standard of "reasonableness." Rather, it appears that the courts in the two cited cases simply assumed that the FTC's construct is authorized by law. *See* F.T.C. v. Pantron I, 33 F.3d. 1088 (9th Cir. 1994); Thompson Medical Co., Inc. v. FTC, 791 F.2d 189 (D.C. Cir. 1986). While the parties in these (and other) cases have "concede[d] the validity of the reasonable basis theory,"

along with its "competent-and-reliable-scientific-evidence" offspring,[2] Respondents vigorously contest them both.

The FTC standard of "competent and reliable scientific evidence" is not derived from the statutory language, but from the "reasonable basis theory," itself. *See* FTC v. National Urological Group, Inc., 2008 U.S. Dist. LEXIS 44145, *45-*44 (N.D. Ga. 2008). And the "reasonable basis theory" appears to have been created "because it does not require the FTC to prove that [a] message was false in order to prevail." *See* FTC v. Garvey, 383 F.3d 891, 901 (9th Cir. 2004). If the FTC is **not required** to shoulder its statutory burden of having to prove an advertisement to be, in fact, "false" or "deceptive," as it chose not to do in this case,[3] "it is difficult to imagine **how the Commission could fail to prevail** on a reasonable basis theory." Pantron I, 33 F.3d at 1096 (emphasis added). According to that theory, the advertiser has the burden to substantiate by "competent and reliable scientific evidence" any health-benefit claim, and the FTC is free to set the bar as high or as low as it wants. *See, e.g.,* Thompson Medical, 791 F.2d at 193-96.

The reasonable basis/scientific evidence standard is **not** a rule enacted pursuant to the Administrative Procedure Act's ("APA") rulemaking procedures. Rather, as FTC Commissioner J. Thomas Rosch has explained, the FTC aborted its effort to adopt a regulation

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[2] *See, e.g.* American Home Products Corp. v. FTC, 695 F.2d 681, 693, 710 (9th Cir. 1982).

[3] *See* ALJ Dec., p. 99, n.4.

because "there did not appear to be a way to develop workable rules."[4] Instead, the FTC resorted to the promulgation of an Industry Guide to establish its policy governing health claims about dietary supplements. FTC Guide, *Dietary Supplements: An Advertising Guide for Industry* (hereinafter "DSG") (Apr. 2001).[5] Industry Guides are "administrative interpretations of the law intended to help advertisers comply with the [FTC] Act; [but] they are **not binding law themselves."** *See* "FTC Publishes Final Guides Governing Endorsements, Testimonials," ("Testimony Guide") p. 2 (Oct. 5, 2009) (emphasis added).

As an Industry Guide, the "require[ment] [that] claims about the efficacy or safety of dietary supplements … be supported with 'competent and reliable scientific evidence'" is **not a fixed legal standard**, but is "'**flexible.**'" *See* Op., p. 16 (emphasis added). As the court noted in the American Home Products, "the Commission has chosen not to bind itself in advance to rules as to the interpretation of the phrase 'reasonable basis,'" and therefore any order issued by the FTC is deliberately "imprecise." *Id.*, 695 F.2d at 710. Thus, the Guide states that the standard is only "**typically** require[d] [of] claims about the efficacy and safety of dietary supplements." DSG, p. 9 (emphasis added). Further, the evidentiary standard is "sufficiently flexible" so that it may be raised or lowered depending upon the FTC's assessment of the type of product or claim, the cost/feasibility of developing substantiation of the claim, the risk of harm, and the opinions of experts. *Id.*, pp. 8-9, 25.

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[4] J. T. Rosch, "Self-Regulation and Consumer Protection: A Complement to Federal Law Enforcement," (hereinafter "Rosch") pp. 10-11 (Sep. 23, 2008). This article is provided to the public on the FTC website, http://www.ftc.gov/.

[5] http://www.ftc.gov/bcp/edu/pubs/business/adv/bus09.shtm.

In this case, however, the FTC has presented the reasonable basis theory, with its companion "competent and reliable scientific evidence" standard, as if it were a fixed rule of law governing every FTC enforcement action against allegedly misleading health claims concerning dietary supplements:

> [W]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. [Op., p. 16 (emphasis added).]

The use of such flexible standard in an enforcement case is the rule of man masquerading as the rule of law. Not only does the Guide fail to provide any fixed rule of application, it does not purport to set the "competent and reliable scientific evidence" as the rule governing FTC enforcement actions. Rather, the Guide is "intended to help advertisers comply with the [FTC] Act." DSG, p. 2. As a "help to comply," the Guide serves the practical goal of ensuring an advertiser that — if he affirmatively substantiates "each interpretation" of every express and implied claim by competent and reliable scientific evidence — then the ad would be in "compliance with FTC law." DSG, p. 25. By imposing upon the advertiser this affirmative burden, the Guide is designed to provide a kind of "safe harbor" from a subsequent FTC enforcement action, **not** to impose upon the advertiser in that enforcement action the affirmative — and extra-statutory — burden of substantiating his health-benefit claims by what the FTC deems to be competent and reliable scientific evidence. Yet that is what happened in this case.

2. The Reasonable Basis Theory Erroneously Shifted the Burden of Proof to Respondents.

Both the ALJ and the Commission asserted that "**Respondents have the burden** of establishing what substantiation they relied on for their product claims." *See* ALJ Dec., p. 99; Op., p. 12 (emphasis added). This ruling is not derived from sections 5 and 12 of the FTC Act, but from the DSG, which states that "advertising for … dietary supplements … must be truthful, not misleading, **and substantiated."** DSG, p. 1 (emphasis added). Further, "supplement marketers are cautioned that the FTC will require **both** [i] strong scientific support **and** [ii] careful presentation for [health] claims." *Id.*, p. 2 (emphasis added). These two statements demonstrate why an Industry Guide is ill-suited to provide a legal standard governing an FTC enforcement action. It makes sense to advise an advertiser who is seeking a wide berth from an FTC enforcement action to assume the burden of affirmatively substantiating his product claims **before** he makes them. It does not make sense, however, to impose upon an advertiser **after** he has run an ad to affirmatively substantiate his claims in an enforcement proceeding in which the FTC has the statutory burden of proving that the claims are false or deceptive. But that is exactly what has occurred here.

While the FTC claims that "Complaint Counsel had borne the burden of proving that Respondents' representations were not substantiated" by competent and reliable scientific evidence (Op., p. 22), that is quite different from the burden imposed on the FTC under a fair construction of the language of the FTC Act. Section 5 declares that "false" advertisements are unlawful; section 12 declares "deceptive" ones to be so. It naturally follows from such language that the burden is upon the FTC to prove falsity or deceptiveness. *See* ALJ Dec., p. 99 n.4.

In this case, however, the Commission finds fault with Respondents for "hav[ing] 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." Op., p. 18. If the FTC's theory is that an advertising claim is false or deceptive because there is no "competent and reliable scientific evidence" to support the claim, then the FTC should be required to "produce" such evidence showing that the "overall net impression" of Respondents' claims was demonstrably **false or deceptive**. Instead, the FTC has the burden only to show that the advertiser does **not** have sufficient scientific evidence acceptable to the FTC that his claim is demonstrably **true or nonmisleading**. *See* Op., p. 20. Thus, the Commission has characterized its ruling against Respondents as one in which the FTC "found [DCO's] claims for the [four Challenged Products] to be deceptive because they were **not substantiated** by competent and reliable scientific evidence." *See* Order, Attachment A (emphasis added).

As the court of appeals observed in Pantron I, "it is difficult to imagine how the Commission could fail to prevail … on a reasonable basis theory,"[6] whereby the FTC has complete discretion to impose whatever evidentiary standard of reasonableness that it chooses and then, to require the advertiser to prove affirmatively that his claims meet that standard.

3. The Reasonable Basis Theory Is *Ultra Vires*, an FTC Add-On that Prejudiced Respondents.

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[6] Pantron I, 33 F.3d at 1096 n.23.

The DSG insists not merely that "that advertising for any product — including dietary supplements — must be truthful, not misleading, **and substantiated**." DSG, p. 1 (underlining original; bold added). To be substantiated, an advertisement for a dietary supplement must "typically" rest upon "competent and reliable scientific evidence." *Id.* at 3. But the DSG cites neither statutory provision nor agency regulation that imposes an affirmative duty upon any advertiser that "before disseminating an ad, [he] must have adequate substantiation for all objective product claims." *Id.* at 3. Rather, it is based on **yet another** FTC "policy" statement, purportedly resting upon "the FTC's deception authority." *Id.* n.6. In fact, it is an FTC add-on, a usurpation of authority never conferred by Congress.

Paragraphs II and III of the Order mandate not only that each of Respondents' representations concerning their products be "true" and "nonmisleading," but that "at the time it is made, Respondents **possess and rely** upon competent and reliable scientific evidence that substantiates the representation." (Emphasis added.) Further, the Commission affirmed the ALJ's decision not because it found DCO's claims "false" and "misleading," but because Respondents had failed to substantiate its claims "by 'competent and reliable scientific evidence.'" Op., p. 20.

Although the DSG claims that the FTC's "role" is "to ensure that consumers get **accurate** information about dietary supplements so that they can make an **informed decision** about these products" (DSG, p. 1 (emphasis added)), **the FTC makes the decision** for the consumer under the Guide's "reasonable basis theory." For example, the Guide states that "[i]t is not enough that a testimonial represents the honest opinion of the endorser. Advertisers **must also** have **appropriate scientific evidence** to back up the underlying claim." *Id.,* p. 18

(emphasis added). Thus, no matter how truthful and nonmisleading an advertising representation based upon an individual testimony may be, "**anecdotal evidence** of a product's effect, based solely on the experiences of individual consumers, is **generally insufficient** to substantiate a claim." *Id.*, p. 18 (emphasis added). In like manner, the Guide states that in "**some situations** … **traditional use evidence** alone will be inadequate to substantiate a claim, even if that claim is carefully qualified to convey the limited nature of the support." *Id.*, p. 21 (emphasis added). In both instances, the Guide substitutes its standard of "competent and relevant scientific evidence" (*id.*, pp. 19-21), as the Commission did in this case. *See* Op., pp. 19-22.

In short, the FTC has presumptuously assumed a paternalistic role, selectively usurping the part of American consumers to choose, instead of enforcing the Congressional mandate to police false and deceptive ads so that **consumers can make an informed decision for themselves.** This is not only contrary to statute, but contrary to the First Amendment commercial speech doctrine.

4. The FTC's "Reasonable Basis Theory" Collided with Respondents' Rights under the First Amendment Commercial Speech Doctrine.

Throughout this proceeding, the FTC has rejected Respondents' claim that the FTC action against them violated the Supreme Court's First Amendment commercial speech doctrine. The Commission ruled that because the ALJ found "Respondents' commercial speech deceptive[,] no further analysis is necessary." *See* Op., p. 14. But the ALJ did **not** find that Respondents' representations were **actually** misleading or deceptive; rather, he presumed, and the Commission agreed, that they were misleading **solely** because they were not

supported by "competent and reliable scientific evidence." *See* ALJ Dec., pp. 99-106; Op., pp. 18-22. Such bootstrapping is constitutionally impermissible.

In Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), marketers of dietary supplements made claims that their products would help people in their battle against cancer, similar to DCO's representations here. *Compare* Pearson, 164 F.3d at 652, *with* ALJ Dec., pp. 83-95. In Pearson, as here, the government agency found such claims to be misleading because, as here, they did not meet a pre-determined "scientific" standard. *Compare* Pearson, 164 F.3d at 652-55, *with* ALJ Dec., pp. 99-106. In Pearson, the agency, as here, ruled that the health claims made were "entirely outside the protection of the First Amendment." *Compare* Pearson, 164 F.3d at 655, *with* ALJ Dec., pp. 115-16. In Pearson, the court rejected this ruling as "almost frivolous," based as it was upon a "paternalistic assumption" that "claims lacking 'significant scientific agreement' are inherently misleading." *Id.*, 164 F.3d at 655.

Unquestionably, the FTC case against Respondents is on all fours with Pearson. The FTC's predetermined standard of "competent and reliable scientific evidence" played the same role in this case as did the FDA's "signficant scientific agreement" standard — establishing that DCO's advertising claims were *per se* misleading. In a futile effort to show that "*Pearson* bears no resemblance to this case," the Commission asserted that "[t]his case involves a purely **adjudicatory challenge to specific representations** made in [DCO's] advertisements." Op., p. 21 (emphasis added). But, from beginning to end, the FTC's case has been exclusively based upon the asserted lack of "competent and reliable scientific evidence" for DCO's claims. And the standard by which those claims were measured to be "misleading" was pre-set in an

Industry Guide, which, in turn, was not even subjected to the APA rulemaking procedure, much less to the adversarial process characteristic of an adjudication.

C. Paragraphs II and III of the Final Order Unconstitutionally Deny Respondents Free Exercise of Religion and Freedom of Speech.

The FTC also misapplied Bolger v. Young Drugs Prods. Corp, 463 U.S. 60 (1983), to cut off Respondents' broader First Amendment claim that DCO's product claims must be considered in the context of its active engagement in the national debate on health care. *See* Op., p. 13. While the Bolger Court found that the ads in that case were "properly characterized as commercial speech," it warned that "an **economic motivation** … would clearly be **insufficient** by itself to turn the materials into commercial speech." *See* Bolger, 463 U.S. at 66. (emphasis added). The FTC, however, did not heed that warning, having already erroneously and summarily concluded that "the **primary purpose and effect** of Respondents' representations concerning the four Challenged Products was to **sell** those products." Op., p. 13 (emphasis added).

In remarks delivered just five days after the FTC announced its Cancer Cure Sweep, FTC Commissioner Rosch acknowledged that the First Amendment raised a higher barrier to FTC regulation where an entity was engaged in an activity that "blend[ed] commercial speech [with] noncommercial speech and debate on an issue of public importance." Rosch, p. 5. Citing Nike, Inc. v. Kasky, 539 U.S. 654 (2003), Commissioner Rosch acknowledged that such blending of speech "pose[s] difficult constitutional issues." *Id.* Yet, despite Justice Stevens' strong suggestion in Nike that the New York Times rule of knowing falsity or

reckless disregard of such falsity,[7] would apply when "commercial speech, noncommercial speech and debate on an issue of public importance" converge,[8] Commissioner Rosch found the Supreme Court's New York Times rule totally inapplicable. *See* Op., p. 13. Commissioner Rosch was equally dismissive of the Schaumburg test[9] that requires proof of actual fraud or deception in the regulation of money solicitations by nonprofit organizations. *Id.* In short, the FTC decided that neither New York Times nor Schaumburg applied because Respondents were engaged in a commercial activity.

The First Amendment cannot be divorced from the money that is required to participate fully in the marketplace of ideas, whether it be the ongoing debate over healthcare, or the solicitation of money by nonprofit organizations, or the election of candidates for public office. Just a few weeks ago, the U.S. Supreme Court ruled that the government cannot deprive the people of vital "information, knowledge and opinion" by erecting economic barriers of entry into the electioneering marketplace. *See* Citizens United v. FEC, __ U.S. __, Majority Slip Opinion, p. 38 (Jan. 21, 2010). Nor does the First Amendment permit "[p]rolix laws [that] chill speech," as the Federal Election Commission ("FEC") is wont to do by "amorphous regulatory interpretation." *Id.*, Slip Op., p. 7. Neither can the FTC censor Respondents' overall healthcare speech by its overly complex "scientific" evidentiary standard.

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[7] New York Times v. Sullivan, 376 U.S. 254, 279-80 (1964).

[8] Nike, 539 U.S. at 664 (Stevens, J., concurring).

[9] *See* Illinois *ex rel* Madigan v. Telemarketing Associates, Inc., 538 U.S. 600, 612, 619-20 (2003).

D. The FTC Denied Respondents' Liberty and Property without Due Process of Law.

On September 23, 2008, five days after the FTC had issued its press release announcing its "Bogus Cancer Cures" sweep, Commissioner Rosch made public comments prejudicial to Respondents. *See* Rosch, p. 16. With specific reference to the "sweep," the Commissioner stressed that the FTC was most concerned about "consumer injury [that] goes beyond the consumer's pocketbook." *Id.*, pp. 16-17. Unwittingly, the Commissioner revealed that the FTC was partial to "conventional" medicine, decrying marketing:

> (i) "'natural' cures" to cancer patients who are "afraid of conventional treatment [and] find out too late that the treatment does not work";
>
> (ii) "'natural' remedies [that] cause[] unexpected side effects"; and
>
> (iii) "'natural' remedies [that] made conventional treatment less effective." *[Id.*, pp. 16-17.][10]

The **FTC's press release**, however, stated nothing about misleading claims about medical safety, only about "efficacy."[11] Indeed, the FTC's litigation of this case in no way correlates

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[10] Commissioner Rosch's official biography indicates no health-related qualifications or experience undergirding these opinions. http://www.ftc.gov/commissioners/rosch/index.shtml. Interestingly, "[t]he [sweep] began through an Internet surf conducted by the FTC, the U.S. Food and Drug Administration (FDA), and Competition Bureau Canada in June 2007." http://www.ftc.gov/opa/2008/09/boguscures.shtm.) This raises the question as to whether the FTC's decision to support "conventional" medicine against "natural remedies" originated with the FDA or the government of Canada, creating the appearance that the FTC may be using its statutory enforcement powers against "false" and "deceptive" advertising in pursuit of what may be a political agenda of the FDA or a foreign government.

[11] *See* "FTC Sweep Stops Peddlers of Bogus Cancer Cures" (Sept. 18, 2008) http://www.ftc.gov/opa/2008/09/boguscures.shtm.

with the FTC's stated concerns — as there is **no allegation** in the complaint, and **no record proof**, that the four Challenged Products pose a danger to consumer safety. *See* Op., pp. 1-2.

In Cinderella Career and Finishing Schools, Inc. v. FTC, 425 F.2d 583 (D.C. Cir. 1970), the court of appeals observed:

> There is a marked difference between the issuance of a **press release** which states that the Commission has filed a complaint because it has "reason to believe" that there may have been a violation, and **statements by a Commissioner** … which give the appearance that he has already prejudged the case. [*Id.*, 425 F.2d at 590 (emphasis added).]

Indeed, a Commissioner is duty-bound to take care not to "prejudge cases or **to make speeches which give the appearance that the case has been prejudged.**" *Id.* (emphasis added). In his September 23, 2008 remarks, Commissioner Rosch described the FTC "bogus cancer cure" targets, among which was DCO, as actively engaged in "particularly harmful practice[s]." Rosch, p. 16. Clearly, Commissioner Rosch had already made up his mind that DCO was "marketing … bogus cancer cures," and that such marketing was a "particularly harmful practice." While Commissioner Rosch claims that the views expressed in his 2008 speech are only his own, the speech appears on the official FTC website, accessible from the FTC home page. Additionally, the speech appears on official FTC stationery. Altogether, Commissioner Rosch has created the public perception that he, the author of the FTC 2009 opinion against DCO, had made up his mind as far back as September 23, 2008.

Additionally, at the December 3, 2009 oral argument there is evidence that Commissioner Pamela Harbour shared Commissioner Rosch's personal bias. Twice she expressed concern about the potential impact that the four Challenged Products might have on

"[p]eople who are terminally ill [who] are relying on these medicines to cure them." Tr. Oral Arg., p. 21, ll. 16-21; and p. 24, ll. 8-10. And in a breach of judicial propriety, Commissioner Harbour warned Respondents that they faced what could only be understood as divine judgment:

> You know, ultimately the Commission will render its judgment, but I know that your clients must realize that **there will come a time** when their actions will be judged by a **higher tribunal**.... [*Id.*, Oral Arg. Tr., p. 26, ll. 7- 11 (emphasis added).]

Not only did Commissioner Harbour's words bespeak an attitude of partiality, they rested on a charge that the four Challenged Products threatened consumer health and safety, totally unsupported by the record. *Id.,* p. 26, ll. 12-15. As a matter of due process of law, an FTC Commissioner, sitting in final judgment of an adjudicated case, can neither prejudge the case nor rely on information *dehors* the record, nor give the impression that such information might be relied on. *See* Cinderella, 425 F.2d at 589.

E. The FTC Erroneously Dismissed Respondents' Religious Freedom Restoration Act Claim.

The Commission summarily dismissed Respondents' Religious Freedom Restoration Act ("RFRA") claim on the ground that the "Order imposes no burden on Respondents' exercise of religion; it only applies to their commercial advertising." Op., p. 24. This ruling is clearly erroneous.

The Order is not limited to Respondents' "advertising." Rather, Paragraph V of the Order mandates that Respondents both produce the names of the consumers who purchased one or more of the four Challenged Products, and to write a letter to them, imposing upon them duties that would be violative of their religious convictions and practices. Declaration of

James Feijo ("J. Feijo Decl.") ¶¶ 21, 24-25; Declaration of Patricia Feijo ("P. Feijo Decl.") ¶ 40. Enforcement of such an order against Respondents would substantially burden Respondents' "exercise of religion" which, by definition includes more than mere "belief and profession," but includes … **abstention from** physical acts." *See* Employment Division, Dept. of Human Resources v. Smith, 494 U.S. 872, 877 (1990) (emphasis added).

The Order also is not limited to the "commercial" aspect of Respondents' advertising. Rather, it would require Respondents to embrace the FTC's **secular belief** in **science** as **their own**, thereby "fencing" Respondents out of the dietary supplement market because Respondents rely upon God's revelation and individual testimonials, rather than so-called "science." *See* J. Feijo Decl. ¶¶ 7-11. Indeed, individual testimonies appear to be anathema to the FTC. *See* DSG, pp. 18-19. The Bible, however, states that they set the standard of truth. *See, e.g.,* Deuteronomy 19:15; John 8:17. In McDaniel v. Paty, 435 U.S. 618 (1978), the Supreme Court warned against the civil enforcement of a standard that denied "[r]eligionists … the full measure of protection afforded speech [and] association." *Id.*, 435 U.S. at 641. Indeed, the law should not be used as a sword to "justify repression of religion or its adherents from any aspect of public life,"[12] including participation in healthcare or commerce.

In Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal, 546 U.S. 418 (2006), the Supreme Court ruled that "RFRA expressly adopted the compelling interest test 'as set forth in Sherbert v. Verner … and Wisconsin v. Yoder….' § 2000bb(b)(1)." O Centro, 546

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[12] *Id.*

U.S. 418, 431 (2006). Accordingly, on a petition for review, the court of appeals would decide whether RFRA applies, and if so, whether its compelling interest test has been met. *See id.*, 546 U.S. at 430-31. Thus, the 15 U.S.C. section 45(c) rule of due deference to FTC factual findings would not apply.

F. Paragraph V of the Final Order Violates the Well-Established First Amendment Principle of Speaker Autonomy.

The FTC has treated Respondents' objection to Paragraph V and the Attachment A letter as if it were based solely upon the religious guarantee of the First Amendment. *See* Op., p. 25. But Respondents' moral, ethical, and religious objection to this paragraph and the coerced letter has also been based on the First Amendment guarantees of the freedom of speech and of the press.[13] In Wooley v. Maynard, 430 U.S. 705 (1977), the petitioner filed an affidavit wherein he stated that he "refused to be coerced by the State into advertising a slogan which [he found] morally, ethically, religiously and politically abhorrent." *Id.*, 430 U.S. at 713. The Court ruled that government may not "require" persons to "use their private property … for the State's ideological message — or suffer a penalty" for noncompliance. *Id.*, 430 U.S. at 715.

Respondents have repeatedly voiced their moral, ethical, and religious objections to the FTC-extrapolated secular standard of "competent and reliable scientific evidence," prompting both the ALJ and the Commission to make changes in the Attachment A letter. *See* ALJ Dec., p. 121; Op., p. 25. Nevertheless, the Order would still require that the FTC "scientific" viewpoint be sent at Respondents' expense, on Respondents' stationery, and in an envelope

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[13] *See* Respondents' Appeal Brief, p. 65 and Respondents' Reply Brief, p. 64.

with Respondents' return address — mandating that Respondents use their private property as a vehicle for the FTC's infomercial, or suffer a crushing "civil" sanction of up to $11,000 for each letter unsent. *See* 15 U.S.C. § 45(m).

Neither the ALJ's nor the Commission's modifications are of constitutional avail. In Pacific Gas and Electric Company v. California P.U.C., 475 U.S. 1 (1986), the Supreme Court extended the Wooley rule to a company "billing envelope[] to distribute the message of another." *See id.*, 475 U.S. at 17. Citing Miami Herald Publishing Co. v. Tornillo, 418 U.S. 241 (1974), the Court in Pacific Gas ruled that "[f]or corporations as for individuals, the choice to speak, includes within it the choice of what not to say." *Id.*, 475 U.S. at 16, citing Tornillo, 418 U.S. at 258. Thus, the Court held that the California P.U.C. Commission's order to disseminate a message "in envelopes that [Pacific Gas] owns and that bear [its] return address" would unconstitutionally "forc[e] [Pacific Gas] to speak where it would prefer to remain silent." Pacific Gas, 475 U.S. at 18.

This principle of "speaker autonomy" — the right "to choose the content of his own message" — is a "fundamental rule of protection under the First Amendment." *See* Hurley v. Irish-American Gay, Lesbian and Bisexual Group of Boston, 515 U.S. 557, 573 (1995). To be sure, the Court has acknowledged that even this bedrock principle must yield if the government can demonstrate that its mandate is "a narrowly tailored means of serving a compelling state interest." *See* Pacific Gas, 475 U.S. at 19. But neither the ALJ nor the FTC made any such

attempt. And even if such an attempt were made, it would fail, just as such efforts by the government failed in Wooley,[14] Pacific Gas,[15] Tornillo,[16] Hurley,[17] and Barnette.[18]

II. IF THE STAY IS NOT GRANTED, RESPONDENTS WILL SUFFER IRREPARABLE HARM.

Compliance with the Order would be nearly fatal to the DCO ministry, imposing incalculable losses that can neither be accurately measured nor compensated, and causing serious harm to its "good will." *See* Ross-Simmons of Warwick, Inc. v. Baccarat, Inc., 102 F.3d 12, 18-19 (2d Cir. 1996). Indeed, even if the court of appeals eventually reversed the Order, having to comply would cause such disruption in the Respondents' ability to maintain contact and credibility with their current ministry base that it would threaten the "viability" of the product line currently offered by DCO. *See* Reuters Limited v. United Press International, Inc., 903 F.2d 904, 907-08 (2d Cir. 1990). And it would cause Respondents other irreparable injury as described below.

A. The Cease and Desist Sections of the Order Will Cause Irreparable Harm.

The cease and desist sections (*i.e.*, Paragraphs II and III) of the Order apply to:

> [A]ny efficacy claims [and] embraces not just the four Challenged Products, but other dietary supplements, foods, drugs, or other health and related programs, services, or products. [Op., p. 24.]

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[14] 430 U.S. at 715-17.

[15] 475 U.S. at 19-21.

[16] 418 U.S. at 247-54.

[17] 515 U.S. at 575-81.

[18] West Virginia State Board of Education v. Barnette, 319 U.S. 624 at 633-41 (1943).

Thus, the Order is designed to "fence in" DCO's entire ministry, not just the "cancer and tumor" representations[19] about the four Challenged Products, which were the exclusive subjects of this case.

1. Paragraph III Shuts Down Respondents' Health Ministry.

According to Paragraph III, the Order extends to:

> **[A]ny** representation, in **any manner,** directly or **by implication** … about the **efficacy, performance,** or **health-related benefits** of **any** [dietary supplement, food, drug, or **health-related product, service or program]**. [Emphasis added.]

Thus, Paragraph III applies to each and every:

- **product** (150-200) that DCO currently markets.
- claimed "**efficacy, performance, or other health-related benefit**" — cancer, tumor or otherwise — for such products.
- health-related DCO "**services or programs**" (as defined in Paragraph I.B) whether or not those programs include the marketing or distribution of any health-related product.
- DCO representation made **directly or by implication**, such as through **any person** by means of an "**endorsement**," including any testimonial about the efficacy, performance or health-related benefit of any health-related product, service or program.

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[19] The FTC objected not to DCO's **actual** claims that it made about the four Challenged Products, but alleged claims as drafted by complaint counsel and characterized as "Respondents' Unsubstantiated Representations." *Compare* Complaint ¶¶ 9-13 *with* ¶¶ 14-17. By its "restatement," the FTC not only erroneously placed upon Respondents the burden of proving "the [alleged] representation [to be] true, non-misleading, and at the time it was made, [that] Respondents possess[ed] and rel[ied] upon competent and reliable scientific evidence that substantiates the representation" (*see* Part I.B above), but based its entire case on allegations, not evidence.

- DCO "**promotion**" **or** "**distribution**" of any health-related product, service, or program, whether or not offered for sale by DCO.[20]

- representation of any health-related product, service or program, in **any** manner, whether by 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, informercial, the Internet, e-mail, or in **any other medium.** [Order, Paragraph I.D (emphasis added).[21]]

Paragraph III permits no representation as to the encompassed matters:

> **unless** the representation is **true**, **non-misleading**, and, at the time it is made, [DCO] **possess[es] and rel[ies]** upon **competent and reliable scientific evidence** that **substantiates** the representation.

According to Paragraph I.A of the Order:

> "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. [Emphasis added.]

Thus, under Paragraph III of the Order, Respondents would have the burden:

- **of proving** that a representation is "**true**."

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[20] Although the Order states that it is limited to those activities "**affecting commerce**," that broad term reaches any "purely local activity … not itself, 'commercial'," if there is a "rational basis" for believing that, "when viewed in the aggregate," leaving such noncommercial intrastate activity "outside" the FTC "regulatory scheme" would have a "substantial" effect on the commercial marketing and promotion of health-related products, services, and programs. *See* Gonzales v. Raich, 545 U.S. 1, 18-19 (2005).

[21] No "medium" would be a safe harbor. Not even one-on-one personal conversations, seminar discussions, classroom lectures, nor **church sermons** would be outside the Order's "fence."

- **of proving** that a representation is "**nonmisleading**."
- to "**substantiate**" a representation by competent and reliable scientific evidence."
- **of proving** that, **at the time** that the representation was made DCO, in fact, "**possess[ed]**" the substantiating competent and reliable scientific evidence.
- **of proving** that **at the time** that the representation was made, DCO, in fact, "**relie[d] upon"** the substantiating competent and reliable scientific evidence.
- **of proving** that the "tests, analyses, research, studies, or other evidence" relied upon meets the FTC's standard of "**competency and reliability."**
- **of proving** to the satisfaction of the FTC that the evidence was "**based on the expertise of professionals in the relevant area.**"
- **of proving** that the test or study that produced the evidence "has been **evaluated** in an **objective** manner by persons **qualified** to do so."
- **of proving** that the "**procedures"** were "**generally accepted in the profession** to yield **accurate and reliable results**."

It appears impossible for Respondents to continue any aspect of their healthcare ministry and, at the same time, to comply with Paragraph III of the Order, because:

- DCO **does not currently possess** the kind of "competent and reliable scientific evidence" required by the FTC to **substantiate** any **representation** of the **health-benefits** of any of its 150-200 products. J. Fiejo Decl. ¶¶ 5-9, 19.
- The health-benefit qualities of DCO's products are not ordinarily detectible by the kinds of studies, tests, and analyses, making it almost **impossible** for DCO to obtain the kind of "scientific evidence" required by the FTC to **substantiate** any **representation** of the **health-benefits** of DCO's many products. J. Feijo Decl. ¶¶ 5-10, 19.
- There would be no assurance that the FTC would be satisfied that the evidence presented met its discretionary standards of relevance, objectivity, qualifications, and accuracy or reliability. J. Feijo Decl. ¶¶ 9-10, 19.

- The Order requires not only that Respondents **possess** the requisite "scientific evidence," but that Respondents must **"rely upon"** that evidence to **substantiate** DCO's **representations** when, because of their religious faith, Respondents can **rely** only upon Almighty God, such scientific evidence that it may or may not have serving only to confirm God's revelation and natural reason. J. Feijo Decl. ¶¶ 5-10, 13-14, 18-19.

- Virtually **all** of DCO's current income is generated by the sales of its products, the stoppage of such sales would immediately **deprive DCO of its major source of income**, thereby bringing DCO's healing ministry to a screeching halt, ending its Internet outreach, its daily Monday through Friday radio programs, its e-mail, telephone, and other one-on-one contacts, discontinuing DCO's health-benefit services and programs until funds from other sources were provided. J. Feijo Decl. ¶ 11-17, 19.

2. Paragraph II Shuts Down the DCO Health Ministry.

Although Paragraph II is limited to representations that DCO might make concerning the "prevent[ion], treat[ment] or cure[] of any type of **tumor or cancer,**" enforcement of that paragraph would have the same effect on Respondents as Paragraph III. DCO's cancer-and-tumor-treatment representations are no more amenable to the FTC's so-called scientific standards than any of its other health-related representations. Although, if read apart from Paragraph III, Paragraph II would permit Respondents to make other health-related-benefit-representations as to all of its products, including the four challenged ones, enforcement of that paragraph, alone, would shut down the current DCO health ministry in the following ways:

- DCO's Monday through Friday radio program regularly receives calls from persons who are battling cancer, or are concerned about tumors, or are worried about nutritional problems during or following chemotherapy, or who have other like concerns. Taking such a call would **imply** that DCO was representing that its products, services, or program would treat or assist in the treatment of cancer. Such calls would have to be screened out. J. Feijo Decl. ¶ 15.

- DCO's radio program regularly receives calls from persons who give testimony of how DCO's products or services or program has assisted them in the treatment of cancer, such as "healing the destructive effects of radiation or

chemotherapy." Taking such a call would be an "endorsement" of DCO's product, service, or program. Such calls would have to screened out. J. Feijo Decl. ¶ 15.

- Because of past cancer/tumor representations about some of its products, and past ministry on the radio, by e-mail, by telephone, and other means, DCO would be required to take affirmative steps to establish that it is an anything-but-cancer healing ministry lest it be implied by silence that those products so marketed in the past have not changed. J. Feijo Decl. ¶ 16. *See also* Declaration of Karen Orr, D.C. ("Orr Decl.") ¶ 8.

- God's call on DCO as a healing ministry is governed by the principle against "respect of persons." Paragraph II would require DCO to violate that entrustment, cutting off those suffering from cancer for only one reason: that the FTC requires it. DCO must answer to God, not man. Refusing to reach out to cancer victims would be analogous to being ordered **not** to heal on the Sabbath, reserving to DCO the same condemnation as the Pharisees. J. Feijo Decl. ¶ 16.

3. The Harm Caused by Paragraphs II and III Would Be without Remedy.

Since 2002, James and Patricia Feijo have worked full-time building DCO as a Christian ministry, the marketing of DCO's products being an integral part of that ministry. J. Feijo Decl. ¶¶ 1, 3-7; P. Feijo Decl. ¶¶ 1, 10, 35-39. Unlike an ordinary commercial enterprise, Respondents' ministry cannot be measured by a valuation in dollars and cents. The Order would force upon the Feijos a Hobson's choice, whether to obey God or man. *See* J. Feijo Decl. ¶¶ 5, 10, 13; *Acts* 3:1-10; 4:1-20. They should not be put at loggerheads with the civil governing authorities before being afforded the opportunity to seek judicial relief from an Article III court. *See* Baylor Medical Center, 711 F.2d at 40. Respondents have substantial grounds for their petition for review that, if decided in their favor, could avert a confrontation between church and state. *See Acts* 5:17-40.

Courts generally recognize that an order should be stayed in those cases where the moving party can show injury to a business's goodwill in relation to its steady customers. *See* Reuters v. UPI, 903 F. 2d at 908. Not only is there evidence that DCO's goodwill would jeopardized by the enforcement of Paragraphs II and/or III of the Order (*see* J. Feijo Decl. ¶¶ 12-17), but a cessation of the current ministry under either of those paragraphs would undermine Respondents' goodwill with those depending upon their ministry. *See* P. Feijo Decl. ¶¶ 6-10, 35-38; Declaration of Jerry Hughes ("Hughes Decl.") ¶¶ 4, 6; Orr Decl. ¶¶ 4-5, 8; Declaration of Deane Mink, D.C. ("Mink Decl.") ¶¶ 4-5, 8; Declaration of Charles Sizemore, D.D.S. ("Sizemore Decl") ¶ 4.

B. The Paragraph V Mandate Would Cause Irreparable Harm.

Paragraph V of the Final Order would require Respondents to disclose its list of consumers of one or more of the four Challenged Products, and to send a letter to such consumers that would tell them (a) that the FTC found Respondents' advertising claims with respect to those four products to be "deceptive" for lack of "scientific evidence," and (b) there is "information from the FTC" about how those products and other "herbal products" generally are either ineffective or unsafe, in contrast to other "cancer treatments that have been scientifically proven to be safe and effective." Furthermore, Paragraph V would require that the letter be sent on DCO letterhead in an envelope with DCO's return address, and that the letter be signed by James Feijo as Overseer of DCO.

Brushing aside Respondents' religious and constitutional objections to both the disclosure of the names of DCO's customers and the contents of the coerced letter, the Commission asserted that it "it did not "see[] any evidence that the ALJ **punished** Respondents

for their political or religious beliefs in his proposed order." Op., p. 25 (emphasis added). However, the question is not whether the letter "punishes," but whether Respondents can be faulted for failing to have produced any "evidence" that might satisfy the FTC that Respondents' religious conscience is violated by the disclosure and letter mandates. It is not within the FTC's jurisdiction to put Respondents "to the proof of their religious doctrines or beliefs." *See* United States v. Ballard, 322 U.S. 78, 86 (1944). Indeed, "[m]en may believe what they cannot prove,"[22] and thus, it is not within the FTC's domain to hold Respondents accountable for the truth of falsity of their beliefs. *Id.*, 322 U.S. at 87; *see also* Founding Church of Scientology v. United States, 409 F.2d 1146, 1157 (D.C. Cir. 1969). It is enough that Respondents' religious beliefs are sincerely held. *See* J. Feijo Decl. ¶¶ 21, 24-25; P. Feijo Decl. ¶ 40.

C. Respondents Will Suffer Irreparable Harm from the Entire Order.

This is not an ordinary false advertising/deceptive practice case. From the beginning, Respondents have made it clear — because of their duty to Almighty God — that they can neither ignore Biblical and testimonial evidence, nor conform their advertising practices to meet an undefined government-prescribed secular standard of scientific evidence. Thus, early in these administrative proceedings, Respondents sought dismissal of this case on the grounds that the FTC policy requiring that Respondents justify their health-benefit claims by "competent and reliable scientific evidence" unconstitutionally violates Respondents' freedom

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[22] *Id.*

of religion. *See* Respondents' Motion to Dismiss for Lack of Jurisdiction and Violation of Respondents' Constitutional Rights and Memorandum in Support, pp. 9-12.

Throughout this administrative proceeding, the FTC has turned a deaf ear to Respondents' objections, refusing even to entertain the possibility that rigid adherence to its so-called scientific test is, in reality, an unconstitutional endorsement of "scientism," namely, that materialistic science is the sole source of truth. *See* H. Schlossburg, Idols for Destruction, pp. 142-46 (Thomas Nelson, NY: 1986). Not surprisingly, the entire Order issued by the FTC in this case rests upon its singular devotion to "competent and reliable scientific evidence," a term that is neither defined by regulation, nor authorized by statute. Yet, unrelentingly, the FTC insists upon conformity, including in its cease and desist order that not only must Respondents "possess," but "rely" on "competent and reliable scientific evidence." To meet this standard, the FTC would coerce Respondents to subordinate their religious faith to the state. When "First Amendment freedoms, for even minimal periods of time" are "threatened," there is "irreparable injury." Elrod v. Burns, 427 U.S. 347, 373 (1976) (plurality opinion).

III. GRANTING A STAY WOULD NOT INJURE ANY PARTY AND WOULD PROMOTE THE PUBLIC INTEREST.

The only remaining question is whether, as demonstrated above, the factors supporting a stay are outweighed by a showing that a stay would harm other parties to the case and/or the public interest. *See, e.g.,* WMAT, 559 F.2d at 844-45; In re California Dental Ass'n, 1996 FTC LEXIS 277, at *7-8. While these two factors are stated separately, the FTC considers them together in cases where Complaint Counsel purports to represent the public by enforcing

the law. *See* California Dental, 1996 FTC LEXIS 277 at 8. *See also* Order Granting Partial Stay, In the Matter of Toys "R" Us, Inc., Docket No. 9278 (Dec. 1, 1998).

A. A Stay Would Not Injure Any Party.

The letter mandated by Paragraph V of the Order requires Respondents to send a letter to some DCO customers "information from the FTC," including the statement: "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 high doses." Order, Attachment A (emphasis added). Yet, there is no evidence in the record demonstrating that any one of the four Challenged Products (or any other DCO product) (i) interfered with or adversely affected any cancer or other medical treatment, (ii) kept any medicine from working the way it is supposed to, or (iii) harmed anyone. *See* Op., pp. 1-3; ALJ Dec., pp. 56-58. Nor is there any evidence that the FTC has ever been recognized by Congress as an agency endowed with the expertise to give medical advice, nor for that matter the expertise to establish scientific standards governing dietary supplements.

Nor is there a scintilla of evidence in this record that any consumer was economically harmed, or actually misled by Respondents's representations with respect to the four Challenged Products (or any other product). *See* Op., p. 10. Indeed, Complaint Counsel deliberately elected to try this case on the "reasonable basis" theory, rather than the "falsity theory," and thereby bypassed having to prove that anyone was actually deceived. *See* ALJ Dec., p. 99; Op., p. 12. To bolster its case that it need not adduce proof of actual injury, physical or otherwise, the FTC relied solely on the claim that "[f]ederal courts have long held

that the Commission has the common sense and expertise" to ascertain the "claims, including implied ones [that] are conveyed in a challenged advertisement." Op., pp. 10-11. In fact, Respondents have received no complaints from any person using their products; rather, they have received "hundreds of expressions of thanks for [DCO's] work." P. Feijo Decl. ¶ 9. *See also* Mink Decl. ¶¶ 4-6; Orr Decl. ¶¶ 4, 6; Hughes Decl. ¶ 3.

In short, the record in this case fails to document any bona fide injury to any consumer. Quite simply, the only harm to the FTC/Complaint Counsel and/or consumers resulting from granting a stay of the Order (assuming the FTC prevailed on appeal) would be a period of delay in obtaining compliance with the Order. Respondents submit that the prospect of such delay carries no prejudice or risk of harm to the FTC — or even to the public. Indeed, delay in obtaining compliance simply does not measure up as a significant factor under the traditional federal standards governing stays pending appeal or judicial review. *See* Baylor Medical Center, 711 F.2d at 40. *See also* EEOC v. Quad/Graphics Inc., 875 F. Supp. 558, 560-61 (E.D. Wis. 1995); A & B Steel Shearing and Processing, Inc. v. United States, 174 F.R.D. 65, 69-70 (E.D. Mich. 1997).

B. A Stay Would Be in the Public Interest.

The letter mandated by Paragraph V to be sent to DCO customers includes the statement that "[i]t is important that you talk to your doctor or health care provider before you decide to take any herbal product instead of taking treatments that have been **scientifically proven to be safe and effective."** Order, Attachment A (emphasis added). Not only is there nothing in the record identifying any such "safe and effective" treatments, there was evidence

of significant safety risks of conventional cancer treatment testified to by the FTC's own expert witness. *See* Tr. 1/55-56, 221-22, 227; P. Feijo Decl. ¶¶ 3, 27.

By endorsing without qualification the "safe[ty] and effective[ness]" of conventional cancer treatments, the required letter is highly misleading. In addition to the specific risks identified by the FTC's expert oncologist, there are numerous others, including:

(i) glandular and brain injury (P. Feijo Decl. ¶¶ 23-24, 27);

(ii) secondary cancers from treatment for primary cancers (*Id.* ¶¶ 19-20); and

(iii) serious damage to bodily organs. *Id.* ¶ 27.

There is also evidence that so-called "scientific studies" are oftentimes sullied by:

(i) special interest group financial interests (*Id.* ¶¶ 12-14, 21); and

(ii) human jealousies, rivalries, and other like foibles (*Id.* ¶¶ 16-18).

Not surprisingly, a survey documented that 64 out of 79 oncologists indicated that they would not personally have undergone the same chemotherapy treatment that they had prescribed for their patients. *Id.* ¶ 28.

There are also studies that demonstrate that dietary supplements and nutritional programs, such as those promoted by Respondents, are helpful, as evidenced by:

(i) the growth of alternative health-care in America (*Id.* ¶¶ 19-21);

(ii) officially-recognized studies showing that nutrients and other dietary supplements help prevent diseases, including cancer and tumors. *Id.* ¶¶ 29-34; Orr Decl. ¶ 4.

Indeed, Respondents have received numerous testimonies from people who have benefitted in the past from their nutritional programs and dietary supplements (P. Feijo Decl. ¶¶ 6-9, 36-

37), and who are continuing to benefit today from DCO products,[23] the ingredients of which are "GRAS" — "Generally Recognized as Safe." P. Feijo Decl. ¶ 38.

In sum, the public interest would actually benefit from the grant of a stay. As demonstrated above, enforcement of the Order would threaten the continued existence of Respondents' ministry. Hughes Decl. ¶¶ 4, 6. Even a severe cut-back in DCO's outreach would deprive persons who are continuing to benefit from DCO's nutritional programs, dietary supplements, and herbal products. Orr Decl. ¶¶ 4-8; Mink Decl. ¶¶ 4-6; Hughes Decl. ¶¶ 3-6. This is particularly true for those persons who have been through surgery, chemotherapy, and/or radiation unsuccessfully and been sent home by their doctors to die. *See* P. Feijo Decl. ¶ 6.

While the FTC has faulted Respondents for not being able to substantiate their representations by "competent and reliable scientific evidence," it has done so blindly, assuming that "modern medicine" must be based solely upon "science," and "science" displaces God. But, in recognition of the limits of "science," the practice of modern medicine is based on faith. *See* P. Feijo Decl. ¶¶ 11,14-15. Ours is a nation built on the foundation that matters of faith are for the individual and family to choose for themselves, not for a regulatory commission and the state to choose for them. *See* Ballard, 322 U.S. at 86-87.

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[23] *See* P. Feijo Decl. ¶ 36; Orr Decl. ¶¶ 4-7; Mink Decl. ¶¶ 4-6.

CONCLUSION

For the reasons set out above, the FTC should stay its Order pending review.

Respectfully submitted,

/s/

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February 25, 2010

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

DANIEL CHAPTER ONE, a corporate sole, and JAMES FEIJO, individually, and as an officer of Daniel Chapter One, Petitioners, v. FEDERAL TRADE COMMISSION, Respondent.	)	No. 10-1064

PETITIONERS' EMERGENCY MOTION FOR STAY
PENDING REVIEW OF FTC MODIFIED FINAL ORDER

EXHIBIT D

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Jon Leibowitz, Chairman**
Pamela Jones Harbour
William E. Kovacic
J. Thomas Rosch

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

DECLARATION OF JAMES FEIJO
IN SUPPORT OF APPLICATION FOR STAY
OF MODIFIED FINAL ORDER PENDING PETITION FOR REVIEW

1. My name is James Feijo (hereinafter "Feijo"). Since October 30, 2002, I have served as Overseer of Daniel Chapter One (hereinafter "DCO"), a corporation sole under the laws of the State of Washington, with principal office at 1028 East Main Road, Portsmouth, Rhode Island 02871. As Overseer of DCO, I have been, and continue to be, trustee of all real estate and other property held by DCO under an express trust for the exclusive use and benefit of DCO. DCO and I are Respondents in the above-captioned matter.

2. This Declaration is submitted in support of Respondents' Application for Stay of the Modified Final Order (hereinafter "the Order") issued by the Federal Trade Commission (hereinafter "FTC") on January 25, 2010, and served upon Respondents on January 29, 2010.

3. On September 16, 2008, the FTC issued a Complaint in the above-entitled matter charging that by their representations, both expressed and implied, concerning the

efficacy of BioShark, 7 Herb Formula, GDU and Bio Mixx (hereinafter "the four Challenged Products") in the "treatment of cancer" or "tumor growth," Respondents violated Sections 5(a) and 12 of the Federal Trade Commission Act. The Commission's Order was issued pursuant to that Complaint about those four Challenged Products. As I understand it, the FTC "found" DCO's "advertising claims for [the four Challenged] products to be deceptive because they were not substantiated by competent and reliable scientific evidence." *See* Modified Final Order, Paragraph V, Attachment A, Letter to be Sent by First Class Mail. Importantly, however, Respondents market not just the four Challenged Products, but also 150 to 200 additional dietary supplements, foods, and other health-related products, services and programs, among which are BioMolecular nutritionals, Kalcifate Plus, Alimentz, Amino Acids, Biotropins, Body Care, CoEnzymes, Electrolytes, Enzymes, Ergo and Thermogenics, Essential Fats, Fiber, Herbs, Homeopathy, Hormonal, Immune Boosters, Minerals, Oils, Speciality, Sportsline, Vitamins, Water Kleen, and Weight Loss.

4. Principally through its website, e-mails, radio show, and printed materials, DCO conducts a world-wide apostolic and healing church ministry serving the physical, emotional and spiritual needs of people under the direct authority of Our Savior and Head of the Church, the Lord Jesus Christ.

5. My wife, Patricia Feijo, who serves as Secretary of DCO, and I believe that we have been provided by God with spiritual gifts in the area of healing and apostleship (*see* 1 Corinthians 12:1, 4-7, 9, and 11), and therefore, this has been a large part of our ministry since even before the formation of DCO. We have engaged in outreach to the poor and sick, taking the healing gospel of the Kingdom of God throughout the world, according to the

principles of the Holy Bible, as led by the Holy Spirit, and informed by study of God's natural world. *See* Romans 12. Additionally, we have been continuously engaged in what is known as an apostolic ministry aiding in the formation and support of local bodies of believers, primarily house churches, in the United States and in other countries. *See* 1 Corinthians 4:9-10. DCO ministers, educates and engages in commerce to accomplish its objectives, presenting the life-giving Gospel to nonbelievers, functioning as a local body of believers, assisting other local bodies of believers, and teaching the life-sustaining principles by which believers are to care for and preserve our bodies, as temples of the Holy Spirit, on earth. *See* 1 Corinthians 3:16-17, 6:19-20. As a husband and wife team (*see* Acts 18:1-3), we educate and minister to the public Biblical principles of wellness, and we make available a variety of dietary supplements designed to improve the spiritual and physical well-being of people regardless of their current spiritual condition, or religious affiliation.

6. Since 2005 our healing ministry has utilized several Internet websites (*e.g.,* www.danielchapterone.com, www.dc1pages.com, www.dc1store.com, www.7herbformula.com, and www.gdu2000.com) through which we educate the public and those affiliated with our ministry, and market and promote a wide variety of herbal and other dietary and nutritional supplements. One of the most important educational methods we use to share information involves the publication of the **personal testimonies** of individuals who have been helped by such products in their fight against cancer and other serious illnesses and infirmities. We believe from Scripture that personal testimonies are the most important evidence of the power of God with respect to a person's spiritual condition, and that the same

principle applies to a person's physical condition. *See, e.g.,* John 9:1-34; Acts 3:1-11. God tells us, "You are My witnesses, that I am God." Isaiah 43:12.

7. Offering the highest quality dietary supplements available, together with unique Biomolecular nutritional formulas, Respondents have relied upon God's revelation, God-endowed natural reason, empirical science rightly-understood, God-confirming individual testimonial evidence, and the 6,000-year recorded human history — beginning with God's provision of plants for food, as recorded in Genesis 1:29 — as the foundation for Respondents' health-beneficial product claims. God's Word teaches us that "He causeth the grass to grow for the cattle, and **herb for the service of man**: that he may bring forth food out of the earth." Psalm 104:14. As an example, one of the four Challenged Products, **7 Herb Formula** contains God-given herbs that have been used for thousands of years. Initially a 6-herb formula developed by friends of the DCO ministry, through reliance on divine revelation and human experience, I added a seventh herb, Eleuthero (Siberian ginseng), which was verified in this case for safety and improved effectiveness by a world-renown herbal expert, Jim Dews (J. Dews Deposition (Feb. 11, 2009), pp. 46, l. 7 - 47, l. 24).

8. Respondents believe that permanent truth is found in God's revelation (*see* John 8:31-32), and that falsity is often found in what passes for science in each generation. *See* 1 Timothy 6:20. Over the years, bleeding, purging, administration of toxic mercury, etc. have all passed as state-of-the-art science. Even today, studies conducted by expert panels prove faulty and inadequate protection against medical practices that, instead of healing the body, cause severe side effects, such as strokes and heart attacks. *See* J. Groopman, "Health Care: Who Knows 'Best'?," Vol. 57, No. 2 (Feb. 11, 2010). The Bible teaches that "there is a way

that seemeth right unto man, but the end thereof are the ways of death." Proverbs 14:12. Thus, the Bible warns against adopting a system of knowledge based upon reason alone, commanding instead reliance on God's revelation in the Holy Scriptures and testimony. *See* Matthew 16:1-17. Modern science is often atheistic at its core, ridiculing the God of the Bible and those of the family of God. *See, e.g.,* Richard Dawkins, The God Delusion, Mariner Books (2006).

9. The limitations of the modern "scientific method" and the value of personal testimonials are increasingly obvious, even to physicians. Bhaswati Bhattacharya, M.D., MPH, an Assistant Clinical Professor of Family Medicine at Weill Cornell Medical College in New York stated it this way in a letter to the editor of the Wall Street Journal:

> While most of the **medical orthodoxy is blind** to the fact that its **gold standard of proof is largely ineffective for anything other than drugs**, the public has used its common sense and moved on, to their **solid data of personal experiences**. [Bsaswatt Bhattachapka, M.D., MPH, "Shouldn't Scientific Medicine Be More Open-Minded?" Wall Street Journal (Jan. 12, 2009).]

10. In recognition of the limitations of materialistic science to discover the true health benefit and efficacious qualities of herbs and foods, Respondents have relied upon God's Holy Scriptures as the source of "all the treasures of wisdom and knowledge." *See* Colossians 2:2-3. The very purpose of Respondents' teaching and healing ministry is to empower people with wisdom and knowledge to choose affordable and sustainable health care plans and programs as an alternative to government-regulated and approved programs. The FTC would allow the marketing of dietary supplements only if such marketing meets the FTC's "flexible," but exclusive, requirement that **all** health-efficacy and health beneficial claims of **all** dietary

supplements, drugs, foods, and other health-related products **must be** substantiated by "scientific evidence" that the FTC deems, in its complete discretion, to be "competent and reliable."

11. The income received by DCO from the marketing of health-related products provides almost all of the funds necessary for the operation of the DCO ministry, including the costs of DCO's Monday-through-Friday radio outreach. Without this income, the DCO ministry could not function.

12. As I understand it, the FTC did not find that Respondent had made any "deceptive" representation with respect to any products other than the four Challenged Products. However, the FTC's Order against Respondents is much broader. For example:

- Paragraph II of the FTC's Order prohibits Respondents from making any cancer or tumor treatment representation in the "manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution" of **any** dietary supplement, food, drug, or other health-related product, service or program, and
- Paragraph III of the Order prohibits Respondents from making **any representation** "about the **efficacy,** performance, or **health-related benefits**" of "**any** dietary supplement, food, drug, or other health-related service or program unless Respondents prove to the satisfaction of the FTC that such representation "is true, non-misleading, and, at the time that it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation." (Emphasis added.)

13. Compliance with Paragraph III of the Order would require Respondents to suspend reliance on God's revelation, God-endowed natural reason, and God-confirming individual testimonial evidence as the foundation for their health-efficacy and health-beneficial claims of their products, and would make it impossible for Respondents to continue their current ministry to offer people a choice between health care benefits and efficacies in a marketplace free from government-imposed health-benefit standards.

14. While Paragraph II of the Order would apply only to cancer-or-tumor treatment representations, and not to other health benefit claims, enforcement of Paragraph II would have the same impact as enforcement of Paragraph III because Paragraph II applies to all of Respondents' products, resulting in the complete shut-down of the DCO's current healing ministry.

15. DCO's Monday-through-Friday radio program regularly receives calls from persons who are battling cancer, or are concerned about tumors, or are worried about nutritional problems during or following chemotherapy, or who have other like concerns. DCO's radio program also regularly receives calls from persons who give testimony of how DCO's products or services or program has assisted them in the treatment of cancer, such as healing the destructive effects of radiation or chemotherapy. Paragraph II appears to prevent the taking of such calls because the mere taking of the call would imply that DCO was representing that its products, services, or program would treat or assist in the treatment of cancer or that such a call from a person helped by a DCO product would be an "endorsement" of that product. Screening out calls would be contrary to DCO's long-standing practice of

taking all callers in the order of their call, requiring a profound change in DCO's ministry outreach.

16. Even if physically possible, compliance with Paragraph II of the Order would require Respondents to take affirmative steps to demonstrate that DCO's healing outreach does not include ministry to persons with cancer or tumors, thereby threatening not only Respondents' economic survival, but their credibility and integrity as a healing ministry open to everyone without respect of persons, need, or rank. *See* James 2:1. Indeed, enforcement of Paragraph II of the Order would be comparable to the enforcement of the Pharisaical doctrine against Jesus healing people on the Sabbath Day, preventing Respondents from responding to a person's dire physical need to meet the FTC's legalistic standard. *See* Matthew 12:9-14.

17. Paragraph II of the Order, whether combined with Paragraph III or standing alone, would cause a shut-down of the current ministry of DCO, the products being an integral part of Respondents' overall ministry of bringing God's wisdom and healing power to the people, and the sale of such products being the dominant source of income for the entire DCO ministry.

18. While Paragraph IV of the Order would allow Respondents to make claims about the safety and efficacy of products if they were based on prior drug approvals of the FDA, Respondents could not morally, ethically, or religiously surrender their judgment to a federal bureaucracy that demonstrably has approved dangerous drugs which harm people, and demonstrably withheld approval from potentially helpful drugs which could help heal people. For example, the New York Times just reported that GlaxoSmithKline manipulated research findings for the FDA to minimize damaging reports that its drug Avandia actually increased

cardiovascular risk (being linked to 304 deaths in the third quarter of 2009). *See* G. Harris, "Research Ties Diabetes Drug to Heart Woes," N.Y. Times, Feb. 19, 2010, p. A1.

19. Moreover, the FDA approval procedures are suitable only for patentable drugs where the company making them can recoup the millions of dollars necessary for completing the product testing. Products which are nutritional, and herbal, are more analagous to foods than to highly-toxic commodities like manufactured pharmaceuticals. DCO could never afford to have its herbal products tested according to government standards. If DCO were effectively forced to comply with FDA Investigational New Drug procedures, DCO would be unable to sell any products. Nor would Respondents be able to meet the kind of studies, tests, and analyses that would yield the "competent and reliable scientific evidence" required by the FTC to substantiate any representation of the health benefits of any of its 150-200 products. The FTC requirement, like the FDA one, would be cost-prohibitive. *See* Bhaswati Bhattacharya, M.D., MPH, Letter to the Editor, "Shouldn't Scientific Medicine Be More Open-Minded?" Wall Street Journal (Jan. 12, 2009) ("Financial incentive is lacking for large clinical trials using ancient modalities that are not patentable nor profit-engendering like a new drug.")

20. Paragraph V.A of the Order would unalterably, irretrievably and irremediably disparage Respondents' reputations and integrity by coercing them to furnish the names, addresses, telephone numbers, e-mail addresses, and products purchased by the consumers of one or more of the four Challenged Products. This would breach such consumers' confidence in Respondents to protect their privacy, including their reasonable expectation that such vital information (i) would not be provided by Respondents to any person or entity without their express permission, (ii) would not be used by any person or entity except for the limited

purpose of purchasing one or more of the four Challenged Products, and (iii) would not be shared in such a way as to put them in jeopardy of receiving unwanted mail, e-mail or telephone call at the risk of such intrusion impairing their health and well-being.

21. Additionally, Paragraph V.A of the Order would unalterably, irretrievably, and irremediably violate my religious convictions and professional conscience, in that such disclosure to a third party of vital and personal information would breach the confidence placed by such consumers in me, both individually and as overseer of DCO. It could very well result in communications (like those contained in the Attachment A letter) that would undermine the health and well-being of persons who are suffering from serious, even terminal, illnesses, causing such persons to be traumatized by communications that are adverse and negative about the healing properties not only of one or more of the four Challenged Products, but any other herbal product, without regard to whether such products would put their health at risk in the way intimated by the content of the Attachment A letter or other like communication.

22. Paragraph V.B of the Order would unalterably, irretrievably, and irremediably disparage Respondents' reputations and integrity, by coercing them to send a letter "to be printed on letterhead of DCO" that, together with the first paragraph of the body of the letter, would create the impression that Respondents are voluntarily writing the letter as part of a consent decree, whereas, in truth, the letter has not been consented to by Respondents, but has been entirely composed by the FTC, an "exact copy" of which is required by Paragraph V.B of the Order to be sent to all consumers who purchased one or more of the four Challenged Products.

23. Paragraph V.B of the Order would also unalterably, irretrievably, and irremediably damage Respondents' reputations and integrity because the letter would create the misimpression that Respondents agree with the FTC's"information" about herbal products and conventional cancer treatments, as stated in the letter's second paragraph.

24. Paragraph V.B of the Order would substantially burden Respondents' free exercise of religion by mandating that Respondents associate with viewpoints with which they disagree, and which Respondents find morally, ethically, religiously, and politically abhorrent. Yet, Paragraph V prohibits Respondents from making their contrary viewpoints known, thereby creating the risk that the ordinary reader of the letter would think that Respondents agree with the FTC's views, putting Respondents at risk of violating their duty to God under the Ninth Commandment: "Thou shall not bear false witness."

25. Paragraph V.B would unalterably, irretrievably, and irremediably violate my religious convictions and professional conscience in that the contents of the letter could jeopardize the health and well-being of persons who are suffering from serious, even terminal, illnesses, causing such persons to be traumatized by unspecified, undocumented, and unsubstantiated information that unnamed and unidentified herbal products may pose a serious threat to their health.

Pursuant to 28 U.S.C. Section 1746, I declare, under penalty of perjury, that the foregoing is true and correct.

James Feijo

Executed on 02/23/2010

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Jon Leibowitz, Chairman**
Pamela Jones Harbour
William E. Kovacic
J. Thomas Rosch

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

DECLARATION OF PATRICIA FEIJO
IN SUPPORT OF APPLICATION FOR STAY
OF MODIFIED FINAL ORDER PENDING PETITION FOR REVIEW

A. Introduction

1. My name is Patricia Feijo. I am Corporate Secretary of Daniel Chapter One (hereinafter "DCO"), a corporation sole under the laws of the State of Washington, with its principal office at 1028 East Main Road, Portsmouth, Rhode Island 02871. I work as part of a husband-and-wife ministry team with my husband, James Feijo, who is Overseer of DCO.

2. This Declaration is submitted in support of Respondents' Application for Stay of the Modified Final Order (hereinafter "the Order") issued by the Federal Trade Commission (hereinafter "FTC") on January 25, 2010, and served upon Respondents on January 29, 2010.

3. Since my mother died of cancer in 1992, and even before that, I have had a personal and abiding interest in this illness. I worked in the field of "Experimental Oncology" in the late 1970's conducting cancer research and testing. In my work, I tested various chemotherapeutic

agents to determine which would be the most effective for a particular patient. I have learned that conventional cancer therapies target just the cancer and are, at the very best, uncertain. Radiation and chemotherapy are based on an ancient method of treating tumors by means of escharotics; something that burns. These treatments are known to be highly toxic, as Dr. Dennis Miller acknowledged in his testimony in this case before the Administrative Law Judge, and often cause irreversible organ damage. Tr. 1/221-22. Chemotherapy and radiation severely deplete the immune system -- the opposite of alternative methods. Conventional cancer treatments are themselves carcinogenic, and can lead to secondary cancers, according to ACI Oncology textbooks.

4. I also have spent years studying alternative approaches to cancer treatment. Tr. 2/346-8. Through study and experience, I came to believe that, among the many ways to care for persons with cancer, the most safe and ultimately the most effective, in terms of health and well-being of the patient, were those methods that support and strengthen the immune system. I also believe that God created in our bodies enormous capability to fight off disease, and that if toxins and other assaults on the body are minimized, nutrition is improved, and God-given herbal and natural remedies are employed, people achieve optimal results. Of course, no protocol works always for everyone who is sick. God is sovereign and in control.

5. Additionally, I have studied classical homeopathy since the 1980's. I graduated from the New England School of Homeopathy in 1993, and have done advanced studies thereafter. Tr. 2/334. In 2007, I completed a Fellowship in Advanced Case Management and am presently in a Ph.D. program under Luc De Schepper, M.D. I have practiced homeopathy under the auspices of DCO for the past 17 years. *See* Tr. 2/324. Homeopathy uses dilute forms of

substances found in nature to trigger the body to cure itself. It is based on the work of Samuel Christian Hahnemann M.D. (1755-1843) and is used in many places throughout the world. Homeopathy is recognized as a complete system of medicine and is nontoxic.

B. Why People Come to DCO.

6. The overwhelming percentage of people who have turned to DCO for information and our products in dealing with cancer have already tried conventional cancer approaches, and these approaches have not worked, and they have been sent home by medical and radiation oncologists to die. Tr. 2/364-65. If the DCO order goes into effect, these people will be deprived of DCO's information and products which have been demonstrated to be helpful to many in achieving a better quality of life, and, in many cases, unleashing the healing power that God placed in the human body when we were created. By way of illustration, two of the people who came to testify for DCO at the hearing — Ernie Jensen and Traci Kulikowski — had literally been "sent home to die," but they were healed using God-given herbs and nutrients. They and many others would be kept from such life-saving information and products by the Order, and would be denied the right to make up their own minds about their treatment.

7. Other people have come to DCO because they have been unable to tolerate the toxic effect of chemotherapy and radiation. Some people are so sensitive to chemicals that they cannot even be in the same room with people wearing perfume, and cannot tolerate the current conventional treatment regimes. These people would be deprived by the Order of some of the only alternatives available to support their body to deal with cancer.

8. Finally, some people have come to DCO because they know the problems with the safety and efficacy of chemotherapy and radiation, and/or have been led by the Spirit of God

away from chemotherapy and radiation, and sometimes surgery, to find alternative approaches to heal their cancer that are supportive of good health.

9. In the history of DCO, I have yet to hear of a person we have helped educate about health issues and provided products to, who has told us that our advice led to their harm. DCO has received hundreds of expressions of thanks for its work, but, to my knowledge, no complaints. I know of no complaints that have been filed with the FTC, and understand that there were none that led to its action against DCO. Lastly, I attended the entire hearing before the FTC Administrative Law Judge and heard no testimony from anyone that they were hurt by the work of DCO. According to Scripture, the civil government should commend, not punish, good works. Romans 13:3-4.

10. DCO seeks to educate people so they can make informed healthcare decisions for themselves. DCO never pressures anyone to follow any particular course; rather, we encourage everyone to seek and do God's will. Conventional cancer therapy is often urged upon patients by evoking "fear" to begin treatment immediately, even with slow-growing cancers. But "God hath not given us the spirit of fear; but of power, and of love, and of a sound mind." 2 Timothy 1:7.

C. Modern Medicine Is Not Omniscient and Cannot even be Trusted to Always Seek Objective Scientific Truth.

11. David H. Newman, M.D. writes about the danger of patients yielding to physicians the power to make medical decisions for them, particularly in a world where there are real limits to scientific knowledge.

> The **patient's abdication** to the forces of modern medicine and technology is often undertaken with a **false impression that there is a high potential for cure**, or that his physician possesses a detailed understanding of the pathways of his ailment. The truth is that in many cases, given the **limits of our science**, we don't. This

> reality only highlights **the importance of patient opinions, views, and desires**. Physicians are only, after all, **consultants** to the health of others…. [W]hen a doctor says, "I don't know," it is rarely a sign of weakness or ignorance. More often it's a sign of a physician who knows and appreciates the **limits of our science** and is willing to be **a partner**. [Hippocrates' Shadow, Scribner (2008), p. 17.]

12. Pharmaceutical manufacturers, surgeons, medical oncologists, and radiation oncologists are not neutral scientific observers of modern cancer-treatments. They make their living from ordering and administering expensive treatments. Former National Academy of Sciences epidemiologist Devra Davis gives illustrations of how "many of the leading figures in the war on cancer profited both from producing cancer-causing chemicals and from producing anti-cancer drugs." Devra Davis, The Secret History of the War on Cancer, Basic Books (2007), p. 11. FTC Expert Witness Dr Miller was quite candid when at the hearing he said of the chemotherapy studies he manages: "you set your statistical design so that you power the study **to prove your point**." Tr. 1/76 (emphasis added).

13. In an interview with cancer-survivor and alternative medicine supporter Suzanne Somers, former Sloan-Kettering Cancer Center employee Ralph Moss, Ph.D., explained how remedies which cannot be patented are not approved by the FDA.

> [I]n the thirty-five years that I've been studying the situation, the FDA has never approved any nontoxic drug, herb, vitamin, or anything like that for cancer. The rule seems to be that nothing of a nonpatented, less profitable nature gets through the FDA system. The only things that get through are these synthetic patented agents that are generally very toxic and ineffective. They are so ineffective that the FDA keeps lowering the bar and allowing things to be approved on lower and lower standards of effectiveness and lower and lower standards of safety. [Suzanne Somers, Knockout, Crown Publishers (2009), p. 46.]

14. Generally, modern medicine circles the wagons, and trains physicians how to deny evidence of patient improvement from alternative therapies. In a section entitled "When families

seek 'quack' methods of cancer therapy," The Manual of Clinical Oncology instructs physicians as follows:

> Patients and their families often become desperate, and willing to try anything. They often fear conventional cancer therapies and may become convinced that the "medical establishment" is depriving them of a cure. Patients easily fall prey to **quacks who may even be licensed physicians**.... The physician should ... state in advance that **he or she will not accept that any improvement in the patient's condition results from the unacceptable modes of therapy**....
>
> a. Explain that increased morbidity occurs without competent, comprehensive medical supervision.
>
> b. Point out the excessive costs involved.
>
> c. Explain the reasons positive results occur with ineffective agents.
>
> (1) A small percentage of many tumor types regress spontaneously....
>
> (2) Patients who are "cured" by unproved methods often do not have cancer at all....
>
> (3) The disappearance of reversible, nonmalignant disease can look like a cancer response....
>
> The physician should acknowledge that although the legitimate medical profession does not have all the answers, this does not imply that someone else does." [(Dennis A. Casiato, M.D., and Barry B. Lowitz, M.C. eds., The Manual of Clinical Oncology, Lippincott Williams & Wilkins, 4th ed.), p. 128.]

15. Robert S. Mendelsohn, M.D. exposes the underpinnings of modern medicine.

> [T]he doctor-patient relationship is based on something other than knowledge. *It's based on faith.*
>
> We don't say we know our doctors are good, we say we have *faith* in them. We *trust* them....
>
> Modern Medicine can't survive without our faith, because Modern Medicine is neither an art nor science. It's a religion....
>
> You can easily test modern medical religion on this characteristic by simply asking your doctor *why*? enough times ... and sooner or later you'll reach the Chasm of Faith. Your doctor will retreat into the fact that you have no way of knowing or understanding all the wonders he has at his command. *Just trust me.* [Robert S. Mendelsohn, M.D., Confessions of a Medical Heretic (1979), pp. xii-xiii.]

Similarly, the FTC expert witness Dr. Miller said in his testimony against DCO that as a cancer patient he would opt for what he is told, and "believe and have faith in his physician." Tr. 1/227. According to Scripture, it can be idolatry to put one's trust in man, and not in God. In 2

Chronicles 16:12, King Asa died after he "was diseased in his feet, until his disease was exceeding great: yet in his disease he sought not to the LORD, but to the physicians."

16. In the field of climatology, the American people have been recently treated to an illustration of how science can work.

> Scientists sometimes like to portray what they do as divorced from the everyday jealousies, rivalries and tribalism of human relationships. What makes science special is that data and results that can be replicated are what matters and the scientific truth will come out in the end.
>
> But a close reading of the emails hacked from the University of East Anglia in November **exposes the real process of everyday science** in lurid detail.
>
> Many of the emails reveal strenuous efforts by the mainstream climate scientists to do what outside observers would regard as **censoring their critics**. And the correspondence raises **awkward questions about the effectiveness of peer review** — the supposed gold standard of scientific merit...." [Fred Pearce, "Climate Change Emails Between Scientists Reveal Flaws in Peer Review," The Guardian, February 2, 2010.[1]]

17. Recent revelations in the New York Times about supposed medical science and its reporting in peer-reviewed journals show that physicians demonstrate similar weaknesses.

> Six of the top medical journals published a significant number of articles in 2008 that were written by ghostwriters, according to a study released Thursday by editors of The Journal of the American Medical Association.....
>
> In the scientific literature, ghostwriting usually refers to medical writers, often sponsored by a drug or medical device company, who make major research or writing contributions to articles published under the names of academic authors.
>
> The concern, the researchers said, is that the work of industry-sponsored writers has the **potential to introduce bias, affecting treatment decisions by doctors and, ultimately, patient care.**
>
> According to the study, responding authors reported a 10.9 percent rate of ghostwriting in The New England Journal of Medicine, the highest rate among the journals. ["Ghostwriting Is Called Rife in Medical Journals," New York Times, Sep. 10, 2009 (emphasis added), http://www.nytimes.com/2009/09/11/business/11ghost.html]

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[1] http://www.guardian.co.uk/environment/2010/feb/02/hacked-climate-emails-flaws-peer-review

18. The "peer review" system used to approve these studies, according to one medical historian, is little more than another barrier to keep out of medical journals that which does not conform to the orthodoxy of the day.

> The appeal to "science' in modern Rationalism is an appeal to professional consensus. No objective criteria exist, and the "expert" is merely an expert on his colleagues' opinions. [Harris L. Coulter, 4 Divided Legacy (1994), p. xxix.]

19. Increasingly, Americans are voting with their feet and turning away from certain aspects of conventional medicine.

> Americans spend almost a third as much money out-of pocket on herbal supplements and other alternative medicines as they do on prescription drugs, a new government report shows.
>
> Out-of-pocket spending on herbal supplements, chiropractic visits, meditation, and other forms of complementary and alternative medicines (CAM) was estimated at $34 billion in a single year. [Salynn Boyles, "Americans Spend $34 Billion on Alternative Medicine," WebMD.][2]

20. According to one estimate, Americans "made 628 million visits to alternative health-care practitioners, 243 million more than visits to all primary-care physicians." [Wynne Brown, "Alternative Medicine Goes Mainstream," Discovery Health.][3]

21. This trend toward alternative medicine has not gone unnoticed in conventional medicine. Increasingly unable to compete in the healthcare marketplace, conventional medicine has turned to government to drive its competitors out of business. What conventional medicine cannot achieve by persuasion it seeks to do by raw government power through the Food and Drug Administration -- and even by agencies with no expertise on medical matters, including

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[2] http://www.webmd.com/balance/news/20090730/americans-spend-34-billion-alternative-medicine

[3] http://health.discovery.com/centers/althealth/medtrends/medtrends.html

the Federal Trade Commission -- which would discourage use of the type of medical care preferred by tens of millions of Americans — for their own good, of course. This problem is not new. Beginning in the 19th Century, allopathic medicine began its efforts to destroy homeopathy, not because it was unsuccessful or expensive, but because it was successful and inexpensive. Harris Coulter, 3 Divided Legacy (1982), pp. 140-236. Pharmacy Professor Richard Henry Parrish II explains that health care providers turned to government to do by compulsion what they could not do by reason**:**

> **Government** became the **arbiter of pharmaceutical fact** because the professions of **pharmacy** and **medicine,** as well as the **pharmaceutical industry**, could enforce **their standards** only through **police powers** reserved to government … at the expense of others' rights of association, speech, and property. [Richard Henry Parrish II, Defining Drugs: How Government Became the Arbiter of Pharmaceutical Fact, Transaction Publishers, (2003), p. 132.]

D. Conventional Cancer Treatment Leaves Much to Be Desired

22. Oncologist Guy B. Faguet, M.D., attributes most "improvements in cancer mortality [since 1950] to the introduction of food refrigeration, to improved dietary and sanitary habits, to early detection, and to better supportive medical care, rather than to improved cancer therapy." Guy B. Faguet, The War on Cancer, Springer (2008), p. 14 (footnote omitted).

23. The National Cancer Institute's website candidly identifies serious risks of radiation therapy:

> Radiation may harm the pituitary gland and other areas of the brain. For children, this damage could cause learning problems or slow down growth and development. In addition, radiation increases the risk of secondary tumors later in life. [http://www.cancer.gov/cancertopics/wyntk/brain/page7]

24. Chemotherapy has been demonstrated to create long-lasting cognitive impairments.

> About half of the young people who survive cancer risk developing cognitive problems that can affect their performance in elementary school, middle school, and college and have an impact on relationships and on job performance." Ellen Clegg, Chemobrain: How Cancer Therapies Can Affect Your Mind, Prometheus Books (2009), p. 156.

25. A leading cancer reference textbook, Holland-Frei Cancer Medicine-6, contains a chapter discussing how secondary cancers can be caused by treatment for primary cancers, and begins as follows:

> Second primary cancers have become an increasingly important concern in oncology during the last two decades, as they now comprise the sixth most common group of malignancies after skin, prostate, breast, lung, and colorectal cancers. [Susan R. Rheingold, MC, Slfred I Neugut, MD, PhD, and Anna T. Meadows, MD, "Secondary Cancers: Incidence, Risk Factors, and Management" Holland-Frei Cancer Medicine-6][4]

26. The literature contains much evidence of the dangers of cancer treatments. For example, one study followed over 30,000 men who had received radiation for prostate cancer, showing a significant increase in development of rectal cancer after radiation for prostate cancer. "Increased Risk of Rectal Cancer after Prostate Radiation: a Population-based Study," Gastroenterology, vol.128, Issue 4, pp. 819-824 (April 2005).[5]

27. Even FTC expert Dennis Miller, M.D., acknowledged that chemotherapy can have "negative effects on cognitive and intellectual functioning ... invariably on the bone marrow." (Tr. 1/55-56). This indicates that the deepest, most precious organs of the human body are being harmed. Miller also says "don't deny a patient effective therapy and in its place substitute

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[4] http://www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=cmed6&part=A43437

[5] http://www.gastrojournal.org/article/S0016-5085(04)02333-9/abstract

something less toxic, less devastating to the different organs of the body." Tr. 1/227. This is a disturbing statement, that such a doctor makes the decision for patients that their organs can and must be devastated. Hippocrates said "First do no harm" -- an oath that all doctors used to take. Vitalistic healers still uphold that in the interest of life, health, and healing. (FTC Complaint Counsel Expert Witness Dr. Miller had not practiced oncology for over 10 years, but, rather**, manages chemotherapy drug trials for pharmaceutical companies**. Tr. 1/47-48, 157.)

28. Although oncologists use chemotherapy liberally to treat their patients, they see the problems with their methods more clearly when they consider using it for themselves. In 1986, McGill Cancer Center scientists sent a questionnaire to 118 doctors who treated non-small-cell lung cancer. More than three-quarters of them recruited patients and carried out trials of toxic drugs for lung cancer. They were asked to imagine that they themselves had cancer, and were asked which of six current trials they themselves would choose. **Sixty-four of the 79 respondents would not consent to be in a trial** containing cisplatin, a common chemotherapy drug. Fifty-eight found all the trials unacceptable based on the ineffectiveness of chemotherapy and its unacceptable degree of toxicity. Ralph Moss, Ph.D., Questioning Chemotherapy, Equinox Press (2000), p. 40.

E. Sound Conventional Medicine Does Not Deny the Importance of Nutrition and Herbal Remedies

29. British physician "Alec Forbes, who helped found the Bristol Cancer Help Center, said that he chose cancer as the disease to treat by alternative medicine because it is the condition which is treated particularly badly by conventional medicine and particularly well by unorthodox

means." Stephen Gascoigne, M.B., Ch. B., C.Ac., Dip. C.H.M., The Manual of Conventional Medicine for Alternative Practitioners. Vol. I, p. 81.

30. The need for good nutrition to gain good health is not a fringe concept. In 1997, Congress made an official finding that: "the importance of nutrition and the **benefits of dietary supplements** to health promotion and disease prevention have been documented increasingly in **scientific studies**; there is a **link** between the ingestion of certain **nutrients** or **dietary supplements** and the prevention of chronic diseases such as **cancer**, heart disease, and osteoporosis." Dietary Supplement Health and Education Act of 1994, Public Law 103-417, section 2 (2) and (3A) (emphasis added).

31. In 2004, the Centers for Disease Control published "The Burden of Chronic Diseases and Their Risk Factors." CDC lists poor nutrition as a major risk factor for heart disease and cancer.

> Improving the American diet could extend Americans' productive life span and reduce their risk for chronic diseases, including heart disease, stroke, some types of cancers, diabetes, and osteoporosis.
> [http://www.cdc.gov/nccdphp/burdenbook2004/toc.htm, p. 42.]

32. The February 2010 issue of the International Journal of Oncology reported on a breakthrough study by physicians affiliated with the M.D. Anderson Cancer Center in Houston, Texas. The physicians studied four homeopathic remedies (Carcinosin, Phytolacca, Conium, and Thuja) which demonstrated their ability to induce cell death when tested with two breast cancer cell lines. Moshe Frenkel, M.D., et al. "Cytotoxic Effects of Ultra-Diluted Remedies on Breast Cancer Cells," International Journal of Oncology, February 2010. The abstract of this study is available at http://www.spandidos-publications.com/ijo/36/2/395. "[T]he cell-killing effects of

two of the remedies investigated … appeared similar to the activity of paclitaxel (Taxol) the most commonly used chemotherapeutic drug for breast cancer, when it was tested in the same two adenocarcinoma cell lines investigated in this study." R. Moss, "A Tipping Point for Homeopathy?" (Feb. 21, 2010).

http://www.cancerdecisions.com/content/view/414/2/lang,english/

33 The literature contains many reports of the specific benefits of numerous vitamins and minerals in the treatment of cancer. For example, one study showed that garlic's chemical properties produce numerous effects that inhibit cancer, including activation of lymphocytes, stimulating immune response, with antitumor effects. "Allicin Stimulates Lymphocytes and Elicits an Antitumor Effect," International Immunology, Vol. 16, No. 2, pp. 275-281, February 2004.

34. Dr Sally Lamont, an expert witness for DCO, testified that all of the DCO challenged products' components are supported by scientific literature as to what DCO claims the products can do (*e.g.*, boost the immune system, detoxify the blood, etc.). *See* Tr. 1/572-74.

F. Stopping DCO's Healing Ministry Impedes its Healing Ministry

35. There is much Biblical support for the proposition that God cares much about, and gives much instruction about, our health and well being.

- When God created the world, including food and herbs, he declared it was good. Genesis 1:11-12, 29-31.
- Old Testament dietary laws were, in part, given to His people based on sound health, hygiene and medical advice not understood by man until thousands of years later. *See, e.g.*, Lev. 11:3; Deut. 14:6. "Kashrut: Jewish Dietary Laws." http://www.jewfaq.org/kashrut.htm
- For believers in Christ, our bodies belong to God, and are considered "a temple of the Holy Spirit, who is in you, whom you have received from God? You are not

your own; you were bought at a price. Therefore honor God with your body." 1 Corinthians 6:19-20.

- Jesus (not Caesar) is called the Great Physician. Luke 4:23.
- Christians receive from the Holy Spirit spiritual gifts designed to minister to others, and some receive the gift of healing. *See* I Corinthians 12:9, 28, and 30.

36. In Scripture, God tells us about a woman who "had suffered under the care of many doctors ... yet instead of getting better she grew worse." Mark 5:26. She “had spent all her living upon physicians, neither could be healed of any....” Luke 8:43. She went to Jesus and was healed, "Daughter, your faith has healed you." Mark 5:34. On January 5, 2010, a woman wrote in to Daniel Chapter One that she “went to three different doctors and each one made me more ill.” She went on to say, "Called your program, ordered 7 Herb Formula, GDU, and FGC ... in 10 days I was well. Praise God. Thank you." This is the kind of testimony we hear regularly. If the FTC Order had been in effect, we would not have been able to answer this lady’s plea and to help her.

37. There have been many similar instances where DCO Biomolecular nutrition products have saved lives when nothing else had worked:

- a toddler near-drowning victim,
- a teenager with Cerebral Palsy in Missouri, and recently
- a baby with failure to thrive in N.Y.

In each of these cases patients were on feeding tubes, doctors had done all they could, and the person grew worse. Two boys literally were dying and doctors had given up hope. These children's lives were saved with DCO products, and the parents are now furious that the government has attacked the DCO ministry. The medical doctor of the teenager with CP has since prescribed DCO 1st Kings as a "medical necessity" because it is the only source of nutrition that will stay in the boy's stomach.

38. All DCO products are made with ingredients that are "GRAS" — Generally Recognized As Safe. Ingredients in DCO products are not drugs and simply nourish the body as God intended. It would be inhumane and unconscionable to demand DCO not tell what it knows because it has not conducted studies that DCO could never afford and that would take years to complete, and to meanwhile cut off the information that can and has saved lives. It would make no sense to sell the products if DCO could not explain what bodily functions they were useful in assisting. The products can be of no benefit to people if they have no idea what to use in a given situation, or how to use them.

G. Stopping DCO's Healing Ministry Impedes its Free Exercise of Religion

39. According to Hebrews 9:27, "And as it is appointed unto men once to die, but after this the judgment...." Nevertheless, some people who get cancer have spent a lifetime avoiding the reality that they are eternal beings, and will spend eternity in either Heaven or Hell. They may have heard the claims of Christ (*e.g.,* "Jesus saith unto him, I am the way, the truth, and the life: no man cometh unto the Father, but by me." John 14:6), but have never responded. People who have physical illness often become sensitive to the things of God, asking questions that lead to their acknowledgment that they are sinners, separated from God, and need a Savior. In the weakness of their illness, they focus on the world to come, and many come to accept Christ's substitutionary death on a cross as payment for their sin — entering into a saving relationship with the living God. As new believers, they are freed from the power of sin, and able to spiritually discern truth. (I Corinthians 2:14 "But the natural man receiveth not the things of the Spirit of God: for they are foolishness unto him: neither can he know [them], because they are spiritually discerned.") The role that God gave the Church is both to minister to the body and to

proclaim the Gospel of God. With respect to those whom God directs to us, DCO seeks to carry out that Great Commission. Tr. 2/325; Matthew 28:18-20. Interference with DCO's healing ministry is also interference with DCO's spiritual ministry. God tells us that if a man comes to us hungry, to feed him first, then give him the gospel. James 2:15-18. People come to us with needs, often physical, that we are told by God to meet.

40. For my husband or I, and our ministry, to sign a letter drafted by the FTC that states that "cancer treatments ... have been scientifically proven to be safe and effective" would be like signing a letter stating that Jesus Christ is a liar and Satan is worthy to be praised — an egregious deception. It would be that deeply offensive and totally against the dictates of conscience. It is repugnant to us to be put in a situation by our federal government to choose between obeying the government or obeying God. However, in such situations, Scripture instructs believers how to respond. *See* Acts 5:29.

Pursuant to 28 U.S.C. Section 1746, I declare, under penalty of perjury, that the foregoing is true and correct.

Patricia Feijo

Patricia Feijo

Executed on 2-23-10

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Jon Leibowitz, Chairman**
Pamela Jones Harbour
William E. Kovacic
J. Thomas Rosch

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

DECLARATION OF DEANE MINK, D.C.
IN SUPPORT OF APPLICATION FOR STAY
OF MODIFIED FINAL ORDER PENDING PETITION FOR REVIEW

1. My name is Deane Mink. I am licensed by the State of Georgia to practice Chiropractic, and have been in private practice for 49 years. I own the Mink Chiropractic Center at 409 Northside Drive, Valdosta, GA 31602. Our center has four chiropractors and we treat over 500 patients per week. Mink Chiropractic Center was awarded the Valdosta-Lowndes County Chamber of Commerce Small Business of the Year Award in 1999. http://www.minkchiro.com/

2. I have been a member of the Georgia Chiropractic Association for 49 years, having served as its President in 1973. I was appointed to the Georgia Board of Chiropractic Examiners in 1974 by Governor (later President) Jimmy Carter. I served on that board for 13 years -- seven as its President. I was elected as Georgia's Chiropractor of the Year in 2001.

3. This Declaration is submitted in support of Respondents' Application for Stay of the Modified Final Order (hereinafter "the Order") issued by the Federal Trade Commission (hereinafter "FTC") on January 25, 2010, and served upon Respondents on January 29, 2010.

4. As a Chiropractor, I have been responsible for supplying my patients with vitamins and other nutritional supplements. I started using Daniel Chapter One ("DCO") products approximately eight years ago –- beginning slowly with several products and as my patients began experiencing more and more fantastic results, I expanded to using DCO's full line of products. I have used many different brands but have come to the point where 90 percent of our nutritional sales are for DCO products.

5. I recommend DCO products because they work. My patients tell me that they work and my patients aren't stupid –- they know what works. For example, 7-Herb Formula was designed to detoxify and cleanse the liver and the blood, and to encourage the functioning of the immune system. In my experience, it is the single best such product on the market. For some of my patients with serious health problems and limited resources, I would call Jim Feijo and he would provide me a couple of cases of 7-Herb Formula at deep discount so my patients can afford to take it frequently.

6. Most of these customers are patients in our chiropractic center and most DCO product sales are repeat customers. Why? Because the products work –- they're readily absorbable, they're powerful and they're affordable. Our patients depend on us for chiropractic treatments, exercise and rehab advice, and nutritional advice. Daniel Chapter One products never let us down. I know of no patients of mine, or anyone else, who have ever had any adverse result from a DCO product. I have never seen any type of

advertising by DCO that could be considered false or deceptive. Jim and Tricia Feijo are fine people who are running a Christian ministry of great value to America, and I have no idea why a branch of the U.S. Government would be attacking DCO for telling the truth about their great products. I am outraged that my taxes are being used by the FTC to harm the health of my patients.

7. I felt so strongly about the FTC effort to impair Daniel Chapter One's ministry and products, that I drove to Washington, D.C. at my own expense to attend and testify at the hearing before the FTC Administrative Law Judge, so I am very familiar with the facts of this case. From that experience, it appears to me that the FTC is using enforcement powers that Congress gave it to do the bidding of the FDA, almost acting as its subsidiary.

8. If my patients were unable to purchase Daniel Chapter One products, I have no doubt that the several hundred persons who obtain their DCO products through our practice would see a decline in their health, and an acceleration of their aging process.

Pursuant to 28 U.S.C. Section 1746, I declare, under penalty of perjury, that the foregoing is true and correct.

Deane Mink, D.C.

Deane Mink, D.C.

Executed on 2-19-10

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Jon Leibowitz, Chairman**
Pamela Jones Harbour
William E. Kovacic
J. Thomas Rosch

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

DECLARATION OF KAREN S. ORR, D.C.
IN SUPPORT OF APPLICATION FOR STAY
OF MODIFIED FINAL ORDER PENDING PETITION FOR REVIEW

1. My name is Karen S. Orr. I am licensed by the State of Pennsylvania as a Chiropractor, and have been in private practice since 1993. I currently am the owner of Orr Family Chiropractic, 1200 Washington Road, Washington, PA, 15301.

2. This Declaration is submitted in support of Respondents' Application for Stay of the Modified Final Order (hereinafter "the Order") issued by the Federal Trade Commission (hereinafter "FTC") on January 25, 2010, and served upon Respondents on January 29, 2010.

3. I first became aware of Daniel Chapter One about 12 years ago when I heard their radio show. I was impressed by their understanding of the human body and the wisdom of their approaches to strengthen the body to heal itself. I telephoned DCO to find out more about their ministry, and have been working informally with DCO since

them. I have great respect for Jim Feijo, as a scientist and as a leading spokesman for the application of Biblical principles to wellness. Tricia Feijo is an outstanding homeopath -- indeed, she has counseled me and my family with respect to homeopathic remedies for many years.

4. All members of my family have used DCO products. I personally take, Endo-24 (i.e., a BioMolecular source of easily-assimilated nutrition), GDU, Omega 3, and Micro Cal, regularly, with great success. When I feel like I need a real lift, I bless my body with 7 Herb Formula, (e.g., for its many healing properties). By way of specific illustration, my husband had a well-established tendency to develop lipomas (benign fatty tumors) on his back, but after a course of taking GDU and L-Lysine, they went away and have not returned. Moreover, I have used various DCO products for my children as they have dealt with various health issues. More specifically, when any of us are fighting an infection or virus, we first utilize Genesis Oil (grapefruit seed extract), this combined with rest and fluids allows the body to heal very quickly. Before I knew of the wonderful healing properties of this product, the one and only time I gave my son (who was 4 yrs. old at the time) an antibiotic, he had a severe allergic reaction to it. With the use of Genesis Oil, he has not had, or needed an antibiotic since. This is a real benefit, as we don't worry about a reaction with this product. In my 12 years of experience with DCO, I have come believe in DCO products as being well designed, and of the highest quality. It would be very upsetting to myself, and others, who use these products as an alternative, for them to be unavailable.

5. For a period of four or five years, I carried a range of DCO products in my practice to offer to my patients, and sold them to those who needed them. In fact, when it

became known that we stocked DCO products, a large number of people came to our office to buy DCO products even though they were not our patients. The only reason that I do not stock their product now is based on choice of mine to be more available to my family and, the easy availability of the product on the DCO website. I direct all of my patients, as well as, non patient DCO customers to the website and order center. Being the mother of two boys, who keep me very active, I have scaled back my time at the office. In doing so, my priorities at the office changed; the time I spend there is now only dedicated to chiropractic care for my patients.

6. In the course of my practice of chiropractic, I have often recommended that my patients use nutritional supplements and herbal products sold at the Daniel Chapter One website -- http://www.danielchapterone.com. I have even recommended these products to my colleagues, and continue to do so. None of my patients have ever been harmed by the products sold by DCO. In fact, while selling the product at my office, I never received one complaint from a person who purchased DCO products from me. Many people who have used DCO products have been helped greatly. Just one of many, examples, a forty-five year old woman who has suffered with rheumatoid arthritis for years came in once a month religiously to purchase her GDU, which in her terms “she couldn’t live, or work without.” Pharmaceuticals given to her for the same diagnosis, “just didn’t work as well for her.” This is just one of many customers who purchased DCO products.

7. Over the years, I have examined the statements that DCO has made about the products offered by DCO, and have never found false or deceptive statements. DCO products are described consistent with my understanding of how those products are

manufactured, and how they work.

8. If the FTC's stay were to go into effect, I fear whether the DCO ministry could survive. Certainly, Jim and Tricia Feijo would be unable to share their wealth of experience about healthcare with their radio listeners. It would be difficult to sell products on their website if they could not candidly describe what they should be used for. Although many of the products sold by DCO are available elsewhere, some of their most important products (*e.g.,* ENDO-24, Bio-Mixx, 7-Herb formula) are not manufactured and sold by others. If my family, my patients, and I were unable to obtain these products, it would be harmful to our health, especially my son, who is allergic to most antibiotics. Just because many educated people choose a different path to healing, does not make it false or wrong. In my opinion, any impairment on the ability of DCO and the Feijos to share their wealth of information about how to achieve and maintain good health would harm the health of many persons now using their product, and many more that would otherwise learn of it and be benefited.

Pursuant to 28 U.S.C. Section 1746, I declare, under penalty of perjury, that the foregoing is true and correct.

K. Orr DC

Karen S. Orr, D.C.

Executed on February 16, 2010

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Jon Leibowitz, Chairman**
Pamela Jones Harbour
William E. Kovacic
J. Thomas Rosch

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

DECLARATION OF CHARLES SIZEMORE, D.D.S.
IN SUPPORT OF APPLICATION FOR STAY
OF MODIFIED FINAL ORDER PENDING PETITION FOR REVIEW

1. My name is Charles Sizemore. I am licensed by the State of Texas to practice as a General Dentist, and have been in private practice at 3020 Legacy Drive, Suite 210, Plano, Texas 75023 since 1995. Before that, I practiced for approximately 20 years in Dallas, Texas.

2. This Declaration is submitted in support of Respondents' Application for Stay of the Modified Final Order (hereinafter "the Order") issued by the Federal Trade Commission (hereinafter "FTC") on January 25, 2010, and served upon Respondents on January 29, 2010.

3. In the course of my practice of dentistry over the past 30 years, I have often recommended that my patients use nutritional supplements and herbal products of the sort sold at the Daniel Chapter One website -- http://www.danielchapterone.com In my

experience, none of my patients have ever been harmed by the products sold by DCO, or other products of this type. I have examined the statements on that website about the products offered by DCO, and find that they are consistent with my understanding of how those products work.

4. If the FTC's stay were to go into effect, it would make it much more difficult for my patients to obtain products that are important and necessary to their health. In some cases, it would make it more expensive for my patients to obtain such products.

Pursuant to 28 U.S.C. Section 1746, I declare, under penalty of perjury, that the foregoing is true and correct.

Charles Sizemore, D.D.S.

Executed on 2-23-10

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Jon Leibowitz, Chairman**
Pamela Jones Harbour
William E. Kovacic
J. Thomas Rosch

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

DECLARATION OF JERRY HUGHES
IN SUPPORT OF APPLICATION FOR STAY
OF MODIFIED FINAL ORDER PENDING PETITION FOR REVIEW

1. My name is Jerry Hughes. I am General Manager of radio station WWAB, 1330 AM, P.O. Box 65, Lakeland, FL 33802, a family owned business.

2. This Declaration is submitted in support of Respondents' Application for Stay of the Modified Final Order (hereinafter "the Order") issued by the Federal Trade Commission (hereinafter "FTC") on January 25, 2010, and served upon Respondents on January 29, 2010.

3. For approximately 10 years, our radio station has carried the Daniel Chapter One Health Watch radio show. This is one of the most popular programs that we have ever offered, and I doubt that we have had a program which has done as much good for our listening audience. From reports we receive, the healing ministry of Daniel Chapter One has helped many detoxify their bodies, strengthen their immune system, and improve their general health. I have also heard

of many listeners who have reported that Daniel Chapter One products have helped their bodies deal with diseases that conventional medicine was unable to address.

4. Our radio station has a branch called Eagles Wings Ministry which serves as an outlet for DCO products. Since the news has gotten around that DCO could be enjoined by the FTC from sharing information, and that they could be unable to tell people how to use their products, and that this could undermine the financial basis of their show, I have had many customers with physical problems telling me that they did not know what they would do without DCO products.

5. Over the years, I have become friends with Jim and Tricia Feijo, and believe that they are doing a great job in promoting wellness, and explaining Biblical principles applicable to health, diet, and nutrition. Their products embody those principles.

6. Lastly, the Daniel Chapter One Health Watch radio show generates revenue for WWAB radio. It has a good listening audience, and we are able to sell local availability spots for that show to businesses and advertisers. Moreover, we generate revenue from the sale of their products. America is currently in the worst economic recession since the Great Depression, many media outlets are having difficulty maintaining revenue, and each such revenue source for a small radio station such as ours is important to our success. It is very difficult to replace a good program, and replacing a program with a 10-year success record likely would be impossible. If the Daniel Chapter One Health Watch were off the air or if we were unable to sell its products to customers who knew from the radio show and the DCO website how and when to use the DCO products, it would create a great additional economic pressure on our station.

Pursuant to 28 U.S.C. Section 1746, I declare under penalty of perjury, that the foregoing is true and correct.

Jerry Hughes

Executed on 2-19-2010

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

DANIEL CHAPTER ONE, a corporate sole, and JAMES FEIJO, individually, and as an officer of Daniel Chapter One, Petitioners, v. FEDERAL TRADE COMMISSION, Respondent.	)	No. 10-1064

PETITIONERS' EMERGENCY MOTION FOR STAY
PENDING REVIEW OF FTC MODIFIED FINAL ORDER

EXHIBIT E

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

COMMISSIONERS: **Jon Leibowitz, Chairman**
Pamela Jones Harbour
William E. Kovacic
J. Thomas Rosch

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

COMPLAINT COUNSEL'S OPPOSITION
TO RESPONDENTS' APPLICATION FOR STAY OF MODIFIED FINAL ORDER
PENDING PETITION FOR REVIEW

Pursuant to Commission Rule 3.56, 16 C.F.R. § 3.56, Complaint Counsel submits this Opposition to the Application for Stay Pending Petition for Review filed by Respondents Daniel Chapter One and James Feijo ("Respondents").[1]

[1] The following terms and abbreviations are used herein:
"Opinion" refers to the Opinion of the Commission issued on December 18, 2009;
"IDF" refers to the Findings of Fact accompanying the Initial Decision made by the Administrative Law Judge on August 5, 2009;
"Order" refers to the Modified Final Order issued by the Commission on January 25, 2010; and
"R. Mem." refers to Respondents' Memorandum in Support of Respondents' Application for Stay, filed on February 25, 2010.

I. INTRODUCTION

Respondents advertise that Bio*Shark, 7 Herb Formula, GDU, and BioMixx (the "Challenged Products") treat, cure or prevent cancer, inhibit tumors, or ameliorate the adverse effects of radiation and chemotherapy. But, as the Commission found, no competent or reliable evidence substantiates these claims, and permitting Respondents to continue to make them threatens the public health.

Commission Rule 3.56 provides that the Commission should consider the following factors when determining whether to grant a stay: (1) the likelihood of the applicant's success on appeal; (2) whether the applicant will suffer irreparable harm if a stay is not granted; (3) the degree of injury to other parties if a stay is granted; and (4) why the stay is in the public interest. The Commission considers the third and fourth prongs together because Complaint Counsel represents the public interest in effective law enforcement. *See Cal. Dental Ass'n,* No. 9259, 1996 FTC LEXIS 277, at *8-9 (May 22, 1996). Respondents satisfy none of these factors.

First, Respondents will not prevail on appeal. Applying long-established precedent, the Commission properly rejected Respondents' main merits argument – namely, that the Commission's substantiation doctrine is untethered to the Commission's authority under Section 5 and, in any event, violates the First Amendment. Time and again, courts have endorsed the Commission's rule that a claim of product effectiveness is deceptive under Section 5 unless the claim is substantiated. This is a garden-variety deception case because Respondents make cancer treatment and prevention claims without even a scintilla of competent evidence to back them up.

Second, Respondents will not be injured in the absence of a stay. To be sure, the Commission's Order deprives Respondents of the ability to continue to disseminate their

deceptive cancer cure advertisements. However, Respondents have no legally-cognizable "right" to engage in deception. An order directing Respondents to stop their illegal practices – and to inform customers of the deception so that they may seek medical attention – does not "injure" Respondents any more than any other obligation to obey the law.

Third, the equities overwhelmingly favor the denial of a stay. As the Commission ruled, Respondents' deceptive marketing of "cancer cures" places especially vulnerable consumers – those suffering from cancer – at grave risk of injury. The Commission's concern should be heightened by the Respondents' argument for a stay – namely, that the Commission's Order unfairly and wrongly requires them to have substantiation for cancer prevention and treatment claims. Permitting Respondents to continue to unleash their deceptive cancer cure claims on the public serves no legitimate end, but rather places cancer patients at an undue risk. Thus, the equities counsel strongly in favor of denying Respondents a stay.

II. RESPONDENTS CANNOT DEMONSTRATE A LIKELIHOOD OF SUCCESS ON THE MERITS.

Respondents' assertions regarding their likelihood of success reiterate the same arguments that Respondents presented to the ALJ and the Commission. These reiterations "offer the Commission no sufficient reason to question its prior decision or any of the bases for it, and Respondent[s]' renewal of [their] legal arguments, without more, is insufficient to justify granting a stay." *N. Tex. Specialty Physicians*, No. 9312, at 3 (FTC Jan. 20, 2006) (order granting in part and denying in part respondent's motion for stay of final order).[2]

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[2] Respondents' *ad hominem* attacks on Commissioners Rosch and Harbour do not raise due process issues, but rather show the desperate nature of Respondents' arguments. Complaint Counsel will not dignify those accusations further.

Because Respondents' stay argument adds little that is new, we address the merits only briefly.

A. Respondents' Jurisdictional Arguments Are Meritless.

Respondents attempt, as they have throughout these proceedings, to avoid the merits of this case by claiming that the FTC does not have jurisdiction over them. As the Commission thoroughly discussed, the exercise of jurisdiction is proper here because DCO operates as a commercial enterprise and its profits inure to the benefit of James Feijo. *See Opinion* at 4-8; *IDF* at 22-157.

The ALJ held a day-long evidentiary hearing on the jurisdictional issue and made over ten pages of factual findings, which the Commission adopted, concerning the Respondents' business operations, marketing, and finances.[3] *See IDF* 22-157. Those findings include:

> * DCO was previously a for-profit corporation. *IDF* 23.
>
> * DCO operates a call center and also sells its products over the Internet and through retailers. *IDF* 84, 158.
>
> * DCO offers its customers coupons and volume discounts on their purchases. *IDF* 113 -115.
>
> * DCO sells 150 to 200 products generating approximately $2 million in gross sales, with the acquisition costs for those products being about 30 percent of the sale price. *IDF* 9, 10, 83.
>
> * James Feijo has complete control of DCO's bank accounts, does not maintain his own bank account and instead uses DCO's funds to pay for all of his expenses, including dining out, golf club memberships, homes,

[3] On appeal these factual findings will be given deference by the reviewing court. *See Removatron,* 884 F.2d 1489, 1496 (1st Cir. 1989) ("In reviewing the Commission's determinations, 'the findings of the Commission as to the facts, if supported by the evidence shall be conclusive'") (citing 15 U.S.C. § 45(c) and *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 454 (1986)).

> cars, tennis lessons, and cigars. Neither DCO nor James Feijo keep any records of what DCO spends on Feijo's behalf. *IDF* 55-79.

The facts refute Respondents' jurisdictional challenge, and thus their new arguments about the scope and purpose of DCO's ministry fall flat. Whatever else DCO may do to further its religious objectives, DCO sells cancer cures as part of a commercial enterprise that has none of the hallmarks of a religious endeavor – the products are not used in religious services, the products are not sold only to DCO religious adherents, and DCO's religious exercise does not involve the use of these products. There is no reason to believe that Respondents will prevail on their jurisdictional defenses on appeal.

B. Respondents' Attacks on the Substantiation Doctrine Are Baseless.

Respondents made no effort to produce competent evidence to substantiate their cancer cure claims. Instead, they resort to attacking the FTC's substantiation doctrine, arguing that it has no basis in the FTC Act and is constitutionally unsound. There is no reason for the Commission to revisit this argument.

The substantiation doctrine is rooted in Section 5's hostility to deceptive claims, requiring advertising touting the effectiveness of a product to have competent and reliable evidence that the claim is true. For more than twenty-five years, the Commission has relied on the substantiation doctrine – especially with respect to health claims of the kind at issue here – and there is an unbroken string of judicial decisions approving the doctrine. *See, e.g., FTC v. Nat'l Urological Group*, 645 F. Supp. 2d 1167 (N.D. Ga. 2008), *aff'd*, 2009 U.S. App. LEXIS 27388 (1st Cir. 2009); *FTC v. Bronson Partners, LLC*, 564 F. Supp. 2d 119 (D. Conn. 2008); *FTC v. Direct Mktg. Concepts*, 569 F. Supp. 2d 285 (D. Mass. 2008); *FTC v. QT, Inc.*, 448 F. Supp. 2d 908 (N.D. Ill. 2006), *aff'd*, 512 F.3d 858 (7th Cir. 2008); *FTC v. Natural Solution, Inc.*,

No. CV 06-6112-JFW, 2007 U.S. Dist. LEXIS 60783 (C.D. Cal. Aug. 7, 2007); *FTC v. Sabal*, 32 F. Supp. 2d 1004 (N.D. Ill. 1998); *FTC v. Pantron I Corp.*, 33 F.3d 1088 (9th Cir. 1994); *Removatron Int'l Corp.*, 111 F.T.C. 206 (1988), *aff'd*, 884 F.2d 1489 (1st Cir. 1989); *Thompson Medical Co.*, 104 F.T.C. 648, 839 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987); *Sterling Drug*, 102 F.T.C. 395 (1983), *aff'*d, 741 F.2d 1146 (9th Cir. 1984), *cert. denied*, 470 U.S. 1084 (1985).

Respondents make no real effort to distinguish this precedent or to explain why a court of appeals is likely to disregard it. There is no basis for a stay.

C. Respondents' Other Arguments Are Equally Unpersuasive.

Respondents make two additional arguments – that their cancer cure advertisements are protected by the free speech and free exercise clauses of the First Amendment – that fail for several reasons.

First, Respondents base their arguments on the fiction that their cancer cure advertisements are not textbook examples of commercial speech, but they are. The ads are just like the ads at issue in *Virginia Pharmacy Board* – they tout the products by making explicit performance claims and by offering the products for sale to all comers at a set price. *See Va. State Pharmacy Bd. v. Va. Citizens Consumer Council*, 425 U.S. 748 (1976). As both the ALJ and the Commission found:

* the advertisements contain factual statements regarding the products' efficacy;

* the primary purpose and effect of the advertisements was to promote the sale of Respondents' products;

* the advertisements contain little or no political or religious content; and

* the advertisements are disseminated broadly on the Internet, not just to religious adherents of Daniel Chapter One.

See Opinion at 5, 7, 12, 13; *IDF* at 84, 158, 179-306.

These facts doom Respondents' First Amendment arguments. The law is clear that Respondents' advertisements are entitled only to the limited protection afforded to commercial speech – protection that does not extend to speech that is deceptive. *See Central Hudson Gas & Electric Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980). Respondents' reliance on *Bolger* only underscores the error in their argument. *Bolger* makes clear that commercial speech is not transformed into pure speech merely because a selling message is mixed with political or religious commentary. *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 67-68 (1983).

Second, Respondents' reliance on the First Amendment's free exercise guarantee and the Religious Freedom Restoration Act ("RFRA"), 42 U.S.C. §2000bb-1(b), also rings hollow. As already noted, the facts found by the ALJ and the Commission refute Respondents' claim that their selling messages were acts of religious expression. The advertisements were virtually devoid of any religious content. And once again, the key case Respondents rely on highlights the weakness of Respondents' case.

To make their RFRA and free exercise claims, Respondents rely on *Gonzalez v. O Centro Espirita Beneficente Uniao do Vegetal,* 546 U.S. 418 (2006). There, the Court considered whether a religious organization's use of a hallucinogenic tea during religious rites was protected by the Act. In ruling that it was, the Court took pains to emphasize that the use of the tea was central to the entity's religious practices, the tea was not sold or otherwise provided to non-adherents, and the tea was used only by adherents as an integral part of a religious exercise.

None of those factors is present here. Respondents' advertisements are disseminated broadly on the Internet, their products are sold to consumers regardless of religious affiliation, their products are not used as part of a religious service or ritual, and the advertisements themselves are essentially devoid of religious content. The First Amendment and RFRA provide no basis for a stay of the Commission's Order.

III. RESPONDENTS WILL NOT SUFFER IRREPARABLE INJURY IN THE ABSENCE OF A STAY.

The Commission's Order does not require that Respondents cease selling any products. The Commission's Order does not require that Respondents cease operating a religious ministry or alter any of their religious or political beliefs. Respondents' hyperbolic arguments about the effect of the Order on their ability to preach or discuss issues of public concern (*see R. Mem.* at 23-25) ignore that the Order only applies to the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of products, not to non-promotional discussions. Respondents are free to say what they wish; they just cannot make unsubstantiated claims while trying to sell their products.

Respondents make two principal arguments in support of their claim that they will suffer irreparable injury in the absence of a stay. First, and most broadly, Respondents argue that the Order's requirement that they have substantiation for health claims will force them to stop marketing their products. But Respondents have it backwards: Their argument *supports* the injunctive relief ordered by the Commission because it underscores Respondents' callous indifference to the grave public health risks caused by their deceptive advertising for untested cancer cures. *See Opinion* at 18 (citing *IDF* 356-361); *Opinion* at 20. The ALJ's Findings of Fact regarding the harm Respondents' products pose to consumers, which were adopted by the

Commission, include:

> * The progression of cancer from foregoing beneficial and effective therapy in favor of untested therapies such as those sold by Respondents. *IDF* 356.
>
> * Harmful potential side effects from the products sold by Respondents. *IDF* 357 -359, 361.
>
> * Harmful interactions between Respondents' products and other therapies. *IDF* 360.

Without even acknowledging these risks, Respondents argue that forcing them to have substantiation for their claims will deprive them of their ability to disseminate their advertising. But being forced to comply with the law hardly constitutes irreparable harm. Indeed, the Respondents "can have no vested interest in a business activity found to be illegal." *United States v. Diapulse Corp. of Am.*, 457 F.2d 25, 29 (2d Cir. 1972).

Similarly, Respondents' arguments that the Order will ruin their dietary supplement business are unpersuasive given the fact that there are hundreds of other supplement retailers that manage to thrive without making unsubstantiated disease claims. That Respondents have lost the competitive advantage that their deceptive advertising previously provided them over their competitors does not constitute irreparable harm.

Respondents' arguments regarding the purported harm from sending the letter required by Paragraph V of the Order fares no better. Respondents object to being directed to send letters to their customers alerting the customers that: (1) the Commission has found the Respondents' claims for these products deceptive because there is no competent and reliable scientific evidence supporting those claims; (2) competent and reliable scientific evidence does not demonstrate the efficacy of the Challenged Products in treating, preventing, or curing cancer; and (3) purchasers should consult with a physician before using herbal products. The letter that

Respondents are to send to purchasers (Exhibit A to the Order) discloses to those purchasers the very risks that the Commission identified.

Respondents raise First Amendment objections to Part V of the Commission's Order. But the Order significantly furthers First Amendment values by providing purchasers information they need to safeguard their health. The Supreme Court has long held that, where commercial speech is concerned, mandatory disclosure of important consumer information is a preferred remedy. *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651-52 (1985) (upholding mandatory disclosures regarding client's responsibility for certain costs in attorney advertising); s*ee also Novartis v. FTC*, 223 F.3d 783, 789 (D.C. Cir. 2000) (rejecting First Amendment challenge to FTC disclosure remedy); *see also USA v. Philip Morris USA, Inc.*, 566 F.3d 1095, 1142-43 (D.C. Cir. 2009) (upholding order requiring tobacco companies to publish broad corrective statements).

Even Respondents concede that the government can require a speaker to make disclosures if the government uses "a narrowly tailored means of serving a compelling state interest." *R. Mem.* at 22 (quoting *Pacific Gas & Electric Co. v. Cal. P.U.C.*,. 475 U.S. 1, 19 (1986)). But that is just what the Commission has ordered. There is no question that the interest here – protecting the health of cancer patients – is a government interest of the highest order. Nor is there any question that the remedy devised by the Commission is one that is tailored carefully to serve the interest of patient health.

IV. THE PUBLIC INTEREST IS FURTHERED BY IMMEDIATE ENFORCEMENT OF THE ORDER.

Because Complaint Counsel represents the public interest in this proceeding, the Commission combines the analysis of whether other parties will be injured if a stay is granted

with the inquiry as to whether a stay is in the public interest. Immediate enforcement of the Order, not a stay, is in the public interest.

In asserting that a stay would not injure any party, Respondents assert that "there is no evidence in the record demonstrating that any one of the four Challenged Products (or any DCO product)" has any harmful effects. *See R. Mem.* at 32. Respondents once again ignore the Commission's findings that the Respondents' products pose a significant health risk. As noted above, the Commission found the following harms: the harm from foregoing a proven cancer treatment in favor of an ineffective treatment; harms from potential side effects from Respondents' products; and harmful interactions that may interfere with other cancer treatments. *Opinion* at 18, *IDF* 356-361. The Commission based these findings on the testimony of Denis Miller, M.D., who was the only medical doctor to testify at trial. Respondents may disagree with what Dr. Miller said, but the Commission made a factual finding crediting his testimony in this regard. In moving for a stay, Respondents simply ignore the Commission's finding and Dr. Miller's testimony, perhaps hoping it will go away. It does not. What also does not go away is the risk that Respondents' deceptive advertising of their products poses to the public, and, for that reason, a stay is contrary to the public interest.

Respondents compound their error of ignoring Dr. Miller's testimony regarding the risks posed by the Respondents' products by attempting to introduce new evidence regarding the efficacy and safety of their products. The declarations containing this evidence should be stricken for two reasons.

First, pursuant to Commission Rule 3.44(c), the Hearing Record in this case was closed on May 7, 2009. Despite this, Respondents offer declarations from two chiropractors (Deane Mink and Karen Orr), a dentist (Charles Sizemore), a radio station manager (Jerry Hughes), and

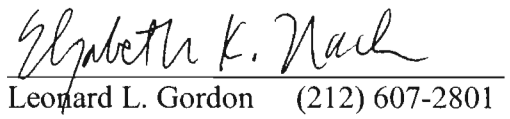
from both Feijos attesting to the efficacy of the Respondents' products. These declarations appear to be a "back door" effort to bolster the Respondents' evidence regarding the efficacy of their products. As the Hearing Record has long since closed, the Mink, Orr, Sizemore, and Hughes declarations, as well as paragraphs 3-38 of Patricia Feijo's declaration and paragraphs 7-10 of James Feijo's declaration should be stricken.

Second, none of these declarants has been qualified to offer expert opinion testimony in this matter. Their declarations are collections of hearsay and anecdotal stories, which do not constitute valid substantiation. As with the evidence the Respondents offered at trial, none of these declarants can testify that there is competent and reliable scientific evidence to substantiate any product claim made by Respondents. As a result, the declarations should be stricken.

V. CONCLUSION

For the reasons set forth herein and in the Commission's Opinion, the Respondents' Application for Stay should be denied.

Respectfully submitted,



Leonard L. Gordon (212) 607-2801
Elizabeth K. Nach (202) 326-2611
Federal Trade Commission
Alexander Hamilton U.S. Custom House
One Bowling Green, Suite 318
New York, NY 10004

Dated: March 4, 2010

CERTIFICATE OF SERVICE

I certify that on March 4, 2010, I served and filed **Complaint Counsel's Opposition to Respondents' Application for Stay of Modified Final Order Pending Petition for Review**, as follows:

The original and twelve paper copies via hand delivery and one electronic copy via email to:

Donald S. Clark
Office of the Secretary
Federal Trade Commission
600 Pennsylvania Avenue, NW, Room H-135
Washington, DC 20580
Email: secretary@ftc.gov

One paper copy via hand delivery and one electronic copy to:

Hon. D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Avenue, NW, Room H-106
Washington, DC 20580
Email: oalj@ftc.gov

One paper copy via Federal Express for delivery the next business day, and one electronic copy to:

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Elizabeth K. Nach

Dated: March 4, 2010

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

DANIEL CHAPTER ONE, a corporate sole, and JAMES FEIJO, individually, and as an officer of Daniel Chapter One, Petitioners, v. FEDERAL TRADE COMMISSION, Respondent.	)	No. 10-1064

PETITIONERS' EMERGENCY MOTION FOR STAY
PENDING REVIEW OF FTC MODIFIED FINAL ORDER

EXHIBIT F

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Jon Liebowitz, Chairman**
Pamela Jones Harbour
William E. Kovacic
J. Thomas Rosch

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

RESPONDENTS' REPLY TO COMPLAINT COUNSEL'S OPPOSITION TO RESPONDENTS' APPLICATION FOR STAY OF MODIFIED FINAL ORDER PENDING PETITION FOR REVIEW

INTRODUCTION

In his zeal to defeat Respondents' Application for a Stay of the Modified Final Order herein ("Opp."), Complaint Counsel makes assertions apparently based on personal predilection that are supported neither by case law, nor by the record, nor by sworn declaration. However, Complaint Counsel's unsupported opinions about the Daniel Chapter One ("DCO") ministry do not constitute record evidence, and his dismissive tone cannot change the fact that Respondents' legal claims on appeal are substantial, and that Respondents would suffer irreparable harm if their requested stay is not granted. Moreover, Complaint Counsel has not overcome Respondents' showing that, if the stay were granted, there would be no significant danger to the public health.

ARGUMENT

1. The Record Does Not Support Complaint Counsel's Claim That the Grant of a Stay "Threatens Public Health."

Without providing any page citation to the Commission's Opinion ("Opinion"), Complaint Counsel claims the Commission has already determined that granting a stay would endanger the public because:

- "the Commission found [that] permitting Respondents to continue to make [cancer treatment] claims **threatens the public health**" (Opp., p. 2 (emphasis added)); and
- "the Commission ruled [that] Respondents' deceptive marketing … places especially vulnerable consumers — those suffering from cancer — at **grave risk of injury**" (Opp., p. 3 (emphasis added)).

These free-floating claims by Complaint Counsel are unfounded. Later, purportedly relying on pages 18 and 20 of the Commission Opinion, Complaint Counsel claims that "the injunctive relief ordered by the Commission … underscores Respondents' **callous indifference** to the **grave public health risks** caused by their deceptive advertising for untested cancer cures." Opp., p. 8 (emphasis added). This is a gross exaggeration of what the Commission stated, and is wholly unsupported by the Administrative Law Judge's ("ALJ") findings of fact 356-61 upon which Complaint Counsel's statement allegedly rests. In fact, in the course of its review of the expert testimony before the ALJ, the Commission observed that the FTC's expert "testified that harm **potentially may** occur from **remedies** that are alternatives to those that have undergone clinical studies on humans." Opinion, p. 18 (emphasis added). Two pages later, the Commission observed that the ALJ's conclusion that "Respondents' representations needed to be substantiated by 'competent and reliable scientific evidence,'" in part, because

"their products **could be** harmful if used with the other products or therapies." *See* Opinion, p. 20 (emphasis added).

The Commission's cautious statements of possible or theoretical harm are a far cry from Complaint Counsel's assertion that the Commission's cease and desist order was based on "Respondents' callous indifference to … **grave public health risks.**" Opp., p. 8 (emphasis added). To the contrary, the Commission has expressly stated that its Order is based on the **sole** ground that "(c)ompetent 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." *See* Modified Final Order ("Order") (emphasis added).

Indeed, the Government's expert testimony (upon which the Commission, and the ALJ before it, relied), viewed in a light most favorable to the Government, demonstrates only that certain ingredients in one or more of Respondents' four Challenged Products — not even the products themselves — could only potentially cause harm. *See* Opinion, pp. 18, 20 and ALJ, Findings of Fact 356-61. Yet, Complaint Counsel takes that evidence of "potential harm," and magnifies it into a finding by the Commission that "the Respondents' **products** pose a **significant health risk."** *See* Opp., p. 11 (emphasis added). But there is no such finding in the Commission Opinion.

Complaint Counsel claims that he "**represents** the public interest in effective law enforcement" (*see* Opp., p. 2 (emphasis added)) which makes it sound like he embodies the public interest — but he misquotes the FTC which only said that he "**is responsible for representing** the public interest…." *See* In the Matter of California Dental Association, 1996

FTC LEXIS 277 AT *8 (May 22, 1996) (emphasis added). Indeed, Complaint Counsel is a lawyer working for a government agency, who not only must prove his case and argue from the record, but should perform his duties dedicated "to the spirit of fair play and decency…."[1] Complaint Counsel has no inherent competence to know what medical therapies are superior, except for himself.[2] Even the Commission is careful not to claim special expertise to represent the public interest in health and well-being, asserting only to have "the common sense and expertise to determine," without any direct evidence from consumers, "'what claims, including implied ones, are conveyed in a challenged advertisement'" (Opinion, pp. 10-11).

In this case Complaint Counsel is acting untethered to flesh-and-blood complainants — as he presented not even one witness who was injured by, or even had a complaint against, Respondents' products. Complaint Counsel never even alleged a "significant" or "grave" health risk in his complaint. *See* Complaint. Nor did Complaint Counsel present any evidence of complaints against DCO by any vulnerable consumer whose conventional cancer treatment might have theoretically been impaired by any of Respondents' four Challenged Products. Indeed, the sum total of evidence regarding alleged harm came from the testimony of a single

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[1] Attorney General Robert H. Jackson, The Federal Prosecutor, April 1, 1940.

[2] Although Complaint Counsel personally today may believe whatever he is told by oncologists and may not care about access to alternatives, DCO is fighting for his right to make health care decisions for himself only — not decisions for others. To deny this stay for the reasons advanced by Complaint Counsel would hold the FTC up to disrespect by a citizenry that is increasingly fed up with a government run by lawyers that is perceived to misuse their money, usurp their liberties, and intrude upon their lives.

expert witness[3] — Dr. Denis Miller — a physician who admitted that he makes his living designing and conducting studies to show the efficacy of chemotherapy, not engaging in the practice of medicine serving actual cancer patients. *See* Tr. 1/47-48. At the hearing, Dr. Miller exhibited no understanding of herbs — not even knowing whether herbs were plants. When asked by the ALJ: "I just want to know, is an herb a plant, is a plant an herb. How do you define it?" Dr. Miller replied: "I think a botanist could that question better than I. I just know where some of these agents come from, but I'm not that person to answer that question." Tr. 1/168-69.

There is no record evidence of danger to the public from DCO products, or that a stay pending judicial review would do anything more than preserve the status quo. Complaint Counsel urges reliance only on "competent and reliable" scientific evidence (*e.g.*, Opp., pp. 2, 12), but a continuous flow of medical developments reveals that placing faith in so-called scientific studies is like unto building a house on sand. Just in the last few weeks it has been revealed that "scientific studies" published in "peer-reviewed journals" had been faked.

> Pfizer had given some $74,000 to [Dr. Scott] Reuben for a **placebo-controlled study** of celecoxib (Celebrex) as part of a "multimodal" painkiller regimen for outpatient knee ligament surgery. The study was to enroll 100 patients. Reuben subsequently reported to Pfizer and in the journal article that 200 patients entered the trial and that the celecoxib regimen was effective. "In fact, **Dr. Reuben had not enrolled any patients into that study**, and the results reported both to Pfizer and to *Anesthesia & Analgesia* and, in turn, to the public were wholly made up by Dr. Reuben and therefore false…." [John Grever, "Research Fraud Probe Leads to Criminal Charge," MedPage

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[3] The Holy Bible teaches that facts are to be established by the testimony of two or more witnesses. II Corinthians 13:1. *See also* Deuteronomy 17:6.

Today (Jan 15, 2010) (emphasis added).]
http://www.medpagetoday.com/PublicHealthPolicy/Ethics/17985

Moreover, while it had been long believed cancer cells that leave the primary tumor metastasize and spread cancer elsewhere in the body, traveling away from the primary tumor, a new study at Memorial Sloan-Kettering Cancer Center demonstrates that circulating cancer cells show a proclivity to re-seed the site of the original cancer, calling into question the theory by which surgeons announce to patients "we got it all." *See* Mi-Young Kim, Thordur Oskarsson, Swarnali Acharyya, "Tumor Self-Seeding by Circulating Cancer Cells," *Cell* 139, 1315, 1323 (Dec. 24, 2009). Increasingly, medical oncologists are more candid about the limitations of their craft.[4]

In an area of increasing medical uncertainty, a stay would allow people to continue to access DCO products as they have in the past.

2. Respondents' Challenge to the Legality and Constitutionality of the FTC's "Substantiation Doctrine" is Substantial.

Acknowledging Respondents are waging an attack on "the FTC's substantiation doctrine," Complaint Counsel has finally conceded that, under that doctrine, the burden of proof is shifted to Respondents. How else could one explain Complaint Counsel's statement that "Respondents made no effort to produce competent evidence to substantiate their cancer

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[4] In a book published in the last few weeks describes a "pioneer overview study, 'The Contribution of Cytotoxic Chemotherapy to 5-year Survival in Adult Malignancies,' by Drs. Graeme Morgan, Robyn Ward, and Michael Barton in *Clinical Oncology* reports that 'The overall contribution of curative and adjuvant cytoxic chemotherapy to a 5-year survival in adults was estimated to be … 2.1% in the USA.'" Gary Null, Ph.D., Martin Feldman, M.D., Debora Rasio, M.D., and Carloyn Dean, M.D., N.D. Death by Medicine, Praktikos Books, (2010), pp. 95-96.

cure claims"? Opp., p. 5. Indeed, how else could one justify Complaint Counsel's statement that "[t]he substantiation doctrine … require[s] advertising touting the effectiveness of a product to have competent and reliable evidence that the claim is true"? *Id.* After all, if the FTC had to shoulder the burden to prove that Respondents' claims were misleading or false, it would not matter whether Respondents could "substantiate" their claims — unless and until the FTC produced evidence affirmatively substantiating that Respondents' claims were deceptive or false, as the language of sections 5 and 12 of the FTC Act clearly requires.[5]

Nor is this contest over the meaning of sections 5 and 12 of the FTC Act resolved by Complaint Counsel's claim that for "more than twenty-five years" the FTC has relied on its "substantiation doctrine." *Id.* As Oliver Wendell Holmes once said, "It is revolting to have no better reason for a rule of law than that … it was laid down in the time of Henry IV." O.W. Holmes, "The Path of the Law," 10 *Harv. Law Rev*. 457, 469 (1897). Complaint Counsel purports to undergird the practice with "an unbroken string of judicial decisions **approving** the doctrine." Opp., p. 5 (emphasis added). But the string cite contains only cases wherein courts have **applied** the doctrine without **approving** it.

FTC v. Pantron I Corp., 33 F.3d 1088 (9th Cir. 1994) and Thompson Medical Co., Inc. v. FTC, 791 F.2d 189 (D.C. Cir. 1986) — two of the cases cited by Complaint Counsel as having "approved" the substantiation doctrine — were also relied upon by both the ALJ and the Commission. *See* Opinion, p. 11. As noted in Respondents' Memorandum in Support of

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[5] By implying at every turn that Respondents' advertisements have been proven "deceptive" in some direct and nefarious sense (*see* Opp., pp. 3, 7, 8, 9,and 11), Complaint Counsel seeks to avoid addressing the merits of the Respondents' demonstration that the balance of the factors weigh in favor of a stay pending judicial review.

Respondents' Application for Stay of the Modified Final Order ("Resp."), "it appears that the courts [in these two cases] simply assumed that the FTC's [substantiation doctrine] is authorized by law." *Id.*, p. 6. In fact, the court in Pantron I did not even apply the doctrine, the FTC having "abandoned" it on appeal so that the court only "discuss[ed] the falsity theory." Pantron I, 33 F.3d at 1096. In a footnote, the court recognized the existence of the FTC's "reasonable basis theory," but did not approve it. *See id.*, 33 F.3d at 1096 n.23. *See also* Resp., pp. 7, 11. While the propriety of a particular "reasonable basis standard" — one that required the establishment of an efficacy claim by "two clinical studies" before a specific claim could be made — was challenged in Thompson Medical, the legitimacy of the "reasonable basis theory," itself, was not. *Id.*, 791 F.2d at 192-94. Thus, the court in Thompson Medical **only applied** the FTC substantiation doctrine. *Id.,* 791 F.2d at 194-96.

In like manner, the courts of appeals in Sterling Drug, Inc. v. FTC, 741 F.2d 1146 (9th Cir. 1984), Removatron International Corp. v. FTC, 884 F.2d 1489 (1st Cir. 1989), and FTC v. QT, Inc., 512 F.3d 858 (7th Cir. 2008), only addressed issues of application of the substantiation doctrine. In Sterling Drug, the advertiser raised a number of issues addressing the nature and scope of the claims that the FTC claimed that it was making about a number of products, and whether there was sufficient evidence that such claims had not been substantiated. *Id.*, 741 F.2d 1150-54. In Removatron, the advertiser contested "various evidentiary rulings," the "sufficiency of the evidence," and a "requirement" that it "possess one well-controlled study" before making certain claims about its product. *Id.*, 884 F.2d at 1493. In QT, the advertiser "maintain[ed] that the magistrate judge subjected their statements to an excessively rigorous **standard** of proof," namely, "placebo-controlled, double-blind

stud[ies]." *Id.*, 512 F.3d at 861 (emphasis added). Thus, none of these cases supports Complaint Counsel's claim that these courts approved the FTC's substantiation doctrine.

The district court opinions in FTC v. Sabal, 32 F. Supp. 2d 1004 (N.D. Ill. 1998), FTC v. Bronson Partners, LLC, 564 F. Supp. 2d 119 (D. CT. 2008), and FTC v. Natural Solution, Inc., 2007 U.S. Dist. LEXIS 60783 (C.D. Calif. 2007) demonstrate Complaint Counsel's seeming confusion about the difference between a case that **applies** the FTC substantiation doctrine and one that **approves** it. In Sabal, the court simply assumes that the "reasonable basis theory" applies and proceeds "to ascertain the appropriate level of substantiation for the disputed claims and then determine whether it was met." *Id.*, 32 F. Supp. 2d at 1007. In Bronson Partners, the court accepted without question the reasonable basis theory, embarking only upon a discussion and analysis of whether the advertising claims have been substantiated. *Id.*, 564 F. Supp. 2d at 123-37. Similarly, in Natural Solution, the court recognized that case was based upon the "reasonable basis theory," and simply reviewed the record to ascertain whether the advertiser carried the substantiation burden. *See id.*, 2007 U.S. Dist. LEXIS at *13-*17.

Finally, the district court opinions in FTC v. National Urological Group, Inc., 645 F. Supp. 2d 1167 (N.D. Ga. 2008) and FTC v. Direct Marketing Concepts, Inc., 569 F. Supp. 2d 285 (D. Mass. 2008), clearly demonstrate the difference between the uncontested application of a rule and a contested one. In National Urological, the court assumes the FTC's "promulgated regulations require advertisements … to be supported by adequate substantiation" (*id.*, 645 F. Supp. 2d at 1177), erroneously relying upon the FTC's

Advertising Guide for the Industry to supply the rule[6] by which the sufficiency of the substantiation is to be measured. *Id.*, 645 F. Supp. 2d at 1190. In Direct Marketing, the court applies the "reasonable basis" theory, even though it recognizes that "the FTC could also proceed under a more stringent 'falsity' theory," on the ground that "[e]ither approach suffices." *Id.*, 569 F. Supp. 2d at 298 n.6. In neither of the two cases is the substantiation doctrine contested, nor is the court's use of the Industry Guide in National Urological disputed. Respondents contest both issues here. *See* Resp., pp. 6-13.

In sum, Complaint Counsel has been unable to identify any case where the "reasonable basis" theory and its "substantiation doctrine" have been upheld against a frontal challenge, such as the one that Respondents have advanced here.

3. The First Amendment Commercial Speech Doctrine Applies.

Complaint Counsel dismisses Respondents' claim that the First Amendment's commercial speech doctrine applies on the sole ground that the doctrine "does not extend to speech that is **deceptive**," citing Central Hudson Gas & Electric Corp. v. Public Service Commission, 447 U.S. 557 (1980). Opp., p. 7 (emphasis added). As the district court in Direct Marketing points out, however, under the commercial speech doctrine as "refine[d]" by the Supreme Court, only "commercial speech that 'is ***actually* misleading**' may be prohibited entirely." *Id.,* 569 F. Supp. 2d at 306 (italics original, bold added).

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[6] The court mistakenly assumed that by issuing an Industry Guide, the FTC promulgated a rule. This is not true. *See* Resp. pp. 7-8. The two are governed by wholly different processes. *Compare* 16 CFR §§1.1 - 1.6 *with* §§1.7 - 1.18.

Having chosen to proceed against Respondents under the FTC's "reasonable basis" theory, the FTC did not even attempt to prove actual deception. *See* ALJ Decision, pp. 90-91. Thus, as the Commission itself has acknowledged, it has found Respondents' "advertising claims … to be deceptive," not because they are actually untrue or misleading, but "because they were not substantiated by competent and reliable scientific evidence." *See* Order, Attachment A. Thus, as the district court concluded in Direct Marketing, under the reasonable basis theory, all that the FTC may claim here is that Respondents' representations respecting the four Challenged Products are "*likely* to mislead consumers." *See id.*, 569 F. Supp. 2d at 307 (italics original). Thus, the First Amendment commercial speech doctrine protects Respondents. *Id.*

In short, Complaint Counsel cannot have it both ways. It cannot take advantage of its "reasonable basis theory" to lower the bar of proof from "actual" deception to "failure to substantiate," and then make a 180-degree turn to block the door to Respondents' First Amendment commercial speech claim. *See* Pearson v. Shalala, 164 F.3d 650, 655 (D.C. Cir. 1999). *See also* Direct Marketing, 569 F. Supp.2d at 307 n.11.

4. Daniel Chapter One is Not a Commercial Enterprise.

Complaint Counsel insists that "DCO operates as a commercial enterprise" and, as such, is not only subject to the jurisdiction of the FTC (Opp. pp. 4-5), but outside the protection of the free exercise of religion and freedom of speech guarantees of the First Amendment. Opp., pp. 6-7.

In its "legal analysis" addressing the question whether the FTC had jurisdiction over DCO, the Commission purported to apply California Dental Ass'n. v. FTC, 526 U.S. 756

(1999) and Community Blood Bank v. FTC, 405 F.2d 1011 (8th Cir. 1969) as the "controlling authorities respecting [Respondents'] challenge to the FTC's jurisdiction." Opinion, p. 7. Again, Complaint Counsel cannot have it both ways. As the Commission has acknowledged, both precedents relate to FTC jurisdiction over nonprofit entities, not commercial enterprises. *Id.*, pp. 7-8. If DCO "operates as a commercial enterprise," as Complaint Counsel contends, then neither case would be applicable. But the Commission did not find that DCO was a sham. Rather, it found that "DCO is currently a 'corporation sole,'" and thus, a non-profit entity, even though "prior" to its incorporation as a corporation sole, "DCO was a for-profit corporation organized under the laws of Rhode Island." Opinion, p. 4. The jurisdictional question, then, is not one of the sufficiency of the evidence to support a finding that DCO operates as a for-profit commercial enterprise, as Complaint Counsel has contended (Opp., 4-5.), but whether the Commission misapplied the rule of Community Blood Bank governing FTC jurisdiction over a nonprofit entity. *See* Resp., pp. 2-5. Thus, the jurisdictional issue that would be before a court of appeals on a petition for review would **not** be subject to the rule of deference set forth in 15 U.S.C. section 45(c) and FTC v. International Federation of Dentists, 476 U.S. 447, 454 (1986), as contended by Complaint Counsel. *See* Opp., p. 4 n.3.

According to Complaint Counsel, "DCO sells cancer cures as part of a commercial enterprise," not as a religious ministry. Opp., p. 5. In Complaint Counsel's eyes, DCO is no different than Youngs Drug Products Corp., a for-profit company "engaged in the manufacture, sale, and distribution of contraceptives." *See* Opp., p. 7. Thus, Complaint Counsel dismisses Respondents' First Amendment free exercise and free speech claims as

"fiction," unworthy of serious consideration. Opp., p. 6. Complaint Counsel's argument, however, is based upon a totally erroneous understanding of the nature of a Christian ministry.

Complaint Counsel mistakenly believes that "the hallmarks of a religious endeavor" would require DCO to operate in a cocoon, limiting the use of its products to "religious services," and selling those products only "to DCO religious adherents." Opp., p. 5. Indeed, in Complaint Counsel's world view, the "free exercise of religion" guarantee of the First Amendment extends only to the use of products in "religious rites" participated in by only true believers (Opp., p. 7):

> Respondents' advertisements are disseminated broadly on the Internet, their products are sold to consumers regardless of religious affiliation, their products are not used as part of a religious service or ritual, and the advertisements are essentially devoid of religious content. [Opp., p. 8.]

By these statements Complaint Counsel demonstrates unfamiliarity with both the free exercise of religion guarantee and the Christian faith.

As the Supreme Court observed in Employment Division, Dept. Of Human Resources v. Smith (Smith II), 494 U.S. 872 (1990), the Free Exercise Clause of the First Amendment "involves not only belief and profession but the performance of (or abstention from) **physical acts**[,] [including] **proselytizing** …." *Id.*, 494 U.S. at 877. The very meaning of "proselytizing" comprehends engaging in actions designed to convert persons who are of different, or of no, "religious affiliation." Webster's Third International Dictionary, p. 1821 (1964). Indeed, Jesus Christ began His ministry with a proselytizing message urging a small band, including fishermen, to "come follow me … and I will make you fishers of men." *Matthew* 4:19. And from the beginning Christ's proselytizing effort included acts of "healing

every disease and sickness among the people" (*Matthew* 4:23), as a sign that He was the Messiah promised in the Hebrew scriptures. *Matthew* 8:16-17.

As a Christian ministry, DCO is organized to share the Good News of Jesus Christ, teaching the whole counsel of God — body, mind and spirit (*Luke* 4:18-19) — and to exercise all of the gifts of the Holy Spirit, including the healing of the human body. *See I Corinthians* 12:1-11. DCO's ministry is to the world, and is not limited to operating within the box that Complaint Counsel would care to put it. DCO understands the Word of God to teach the use of natural products, not to use artificial drugs.[7] As the Smith II Court observed, the free exercise of religion includes "abstaining from certain foods." *Id.*, 494 U.S. at 877.

Complaint Counsel has not cited a single case where the FTC has ever previously successfully asserted jurisdiction over a nonprofit organization other than a trade association, and certainly no cases where it successfully asserted jurisdiction over a religious organization like DCO. Yet, according to Complaint Counsel's rigid and narrow understanding of the nature of religion and of the free exercise thereof, FTC jurisdiction would be extended to any Christian healing ministry that sells or distributes literature making representations about human health and well-being that cannot be substantiated by what the FTC deems to be

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[7] In the Holy Bible, the Greek word translated as "sorceries" (*Revelation* 9:21) or "witchcraft" (*Galatians* 5:20) is "pharmacopeia" (*see* Abingdons Strong's Exhaustive Concordance of the Bible, pp. 958, 1176 (1984)), from which we get the English words, pharmacy and pharmaceuticals.

competent and reliable scientific evidence. Such action would not only violate the free exercise clause, but the freedom of speech guarantee as well.[8] *See* Smith II, 494 U.S. at 881-82.

5. Respondents' Due Process Claim is Not an *Ad Hominem* Attack.

Complaint Counsel pejoratively labels Respondents' due process argument as "*ad hominem*" attacks against certain Commissioners, which Complaint Counsel would "not dignify" by any further response. Opp. at 3 n.2. By choosing to make no response on the merits of Respondents' claim, Complaint did the Commission no favor. Respondents' contention, *inter alia*, about the importance of the appearance of impropriety with respect to administrative proceedings has strong support in the case law.[9] Moreover, Respondents' Due Process argument is not directed at the person of any Commissioner. Rather, it targets the impropriety of specific actions and words that strongly indicate bias or prejudice — actions and words that compromise the integrity of the administrative process. Surely, Complaint Counsel would agree that partiality has no place in the administration of the FTC Act, but if he truly believed that there had been no breach of the impartiality principle, he should have given support for his view.

6. Respondents' Claims Are Substantial.

Complaint Counsel has guaranteed the Commission that "Respondents will not prevail on appeal." Opp., p. 2. Respondents' counsel, on the other hand, do not purport to know

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[8] Complaint Counsel's claim that Respondents' First Amendment rights would be overridden by a "compelling government interest" in "protecting the health of cancer patients" (Opp., p. 10) has no factual support in the record. *See* Part 1, *supra*.

[9] *See, e.g.,* Cinderella Career and Finishing Schools, Inc. v. FTC, 425 F.2d 583 (1970).

what will be the outcome of the appeal — but they know that Respondents are not required to allege or prove they will prevail. As recognized in the cases, an argument before a tribunal that just ruled against Respondents that it is wrong on the merits normally would be unavailing. It is, therefore, enough for Respondents to have raised a substantial legal issue on at least one legal or constitutional claim, if the other factors considered by the Commission under Rule 3.56 — the irreparable harm that will be suffered if a stay is not granted, and the absence of injury to other parties if the stay is granted — weigh in their favor. *See* Resp., pp.1-2.

7. Respondents Will Suffer Irreparable Harm.

Complaint Counsel asserts that Respondents' argument that they will suffer irreparable harm is "unpersuasive given the **fact** that there are hundreds of other supplemental retailers that manage to thrive without making unsubstantiated disease claims." Opp., p. 9. Thus, he argues, the only thing that Respondents will lose if a stay is not granted is "the competitive advantage that their deceptive advertising previously provided them over their competitors." *Id.* Neither claim is supported by any citation to the record or by any appended declaration regarding the marketing of dietary supplements. Without such support, Respondents have been afforded no opportunity to evaluate or even understand the basis for Complaint Counsel's claims, aside from repeating the facts and arguments already submitted in support of Respondent's Application for a Stay.

Further, such unsupported statements are also belied by Complaint Counsel's understanding of the breadth of the cease and desist order in this case. While he states that the "Order **only** applies to the manufacturing, labeling, advertising, promotion, offering for sale,

sale, or distribution of products," Complaint Counsel would except from that mandate only "non-promotional discussions." Opp., p. 8 (emphasis added). Additionally, while Complaint Counsel, on the one hand, declares that "Respondents are free to say what they wish," he admits, on the other, that Respondents "**just** cannot make unsubstantiated claims while trying to sell their products." *Id.* (emphasis added).

In truth, even Complaint Counsel does not know what Respondents may say and do. And he only purports to know what they may not say and do. Indeed, at oral argument three times the ALJ asked Complaint Counsel "What could they say?" about their products, and he was unable to provide a clear response, except to say "They can say the truth." Tr. Closing Arguments, July 9, 2009, pp. 77-78. In a world where the government defines truth, and threatens draconian penalties if one is unable to satisfy the FTC "substantiation" requirements, the Order would have a chilling effect, leading Respondents to say virtually nothing about their products.

8. Respondents' Declarations Support a Stay.

Complaint Counsel argues that the declarations submitted in support of Respondents' application for stay "should be stricken," treating them as if they were submitted by Respondents to reopen the record in this case in an effort to substantiate the safety and efficacy of DCO's many products, including the four products challenged in this case. *See* Opp., pp. 11-12. To the contrary, as clearly indicated in Respondents' supporting memorandum, the Declarations were submitted in support of Respondents' claims that (a) the denial of a stay would cause irreparable harm to Respondents, whereas (b) the granting of the requested stay would harm no one, but instead, would actually be in the public interest. *See* Resp., pp. 24-

35. Because none of these three factors — irreparable harm, injury to party, and public interest — have been relevant and before the Commission until now, it is most appropriate and indeed, anticipated by Commission Rule 3.56(b) that relevant information concerning the consequences of the stay being granted or not be submitted in the form of sworn declarations. It is submitted that Complaint Counsel's call for the several declarations to be stricken is utterly without merit.

Apparently, Complaint Counsel has no response to the declarations of three licensed healthcare practitioners (two chiropractors and a general dentist) who speak to the importance to their patients to have continued access to DCO products. Complaint Counsel could have submitted declarations to respond to those of DCO, but he chose not to. As such, the declarations submitted in support of Respondents' Application for Stay stand unrebutted.

CONCLUSION

For the foregoing reasons, as well as those set forth in the Respondents' Application for Stay and accompanying documents, the FTC should stay its Order pending judicial review.

Respectfully submitted,

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March 10, 2010

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

DANIEL CHAPTER ONE, a corporate sole, and JAMES FEIJO, individually, and as an officer of Daniel Chapter One, Petitioners, v. FEDERAL TRADE COMMISSION, Respondent.	)	No. 10-1064

PETITIONERS' EMERGENCY MOTION FOR STAY
PENDING REVIEW OF FTC MODIFIED FINAL ORDER

EXHIBIT G

In the Matter of Daniel Chapter One and James Feijo
Docket No. 9329

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

[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

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 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

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RRB Respondents' Reply Brief
Tr. Transcript of Trial Testimony
CX Complaint Counsel's Exhibit
RX Respondents' Exhibit

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 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-

[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.

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 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.

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[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.

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. 10-141) ("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

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[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).

[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)

substantiation relating to the sale of certain products, but it does not otherwise reach into the Respondents' religious speech or practices.

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.

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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.