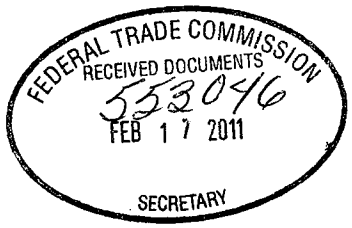
ORIGINAL



HEARING REQUESTED

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	
POM WONDERFUL LLC and	)	
ROLL INTERNATIONAL CORP.,	)	
companies, and	)	Docket No. 9344
	)	PUBLIC
	)	
STEWART A. RESNICK,	)	
LYNDA RAE RESNICK, and	)	
MATTHEW TUPPER, individually and	)	
as officers of the companies.	)	

RESPONDENTS' OPPOSITION TO COMPLAINANT'S MOTION TO LIMIT RESPONDENTS TO FIVE EXPERT WITNESSES

Complainant does not dispute that this case requires expert testimony from multiple distinct scientific areas and that the case involves numerous advertising pieces. Instead, Complainant contends that this case is "rather ordinary." Mot. at 3. This is plainly incorrect, as the record in the case already makes clear. Furthermore, Complainant's claim of prejudice is belied by their previous representations, and it is Respondents that would be severely prejudiced if not permitted to put on their defense to the myriad allegations in the Complaint.

Argument

The Commission's Rules of Practice expressly provide a "safety valve" empowering this Court to permit Respondents to designate experts in excess of the default limit where necessary. *See* FTC Interim Final Rules With Request for Comment, 74 F.R. 1804, 1814 (Jan. 13, 2009); Rule 3.31A(b). Exceptional circumstances are present here because the broad scope of the Complaint implicates multiple areas of scientific expertise as applied to dozens of unique advertisements and materials that relate to three separate products.

I. This Case Presents Exceptional Circumstances Warranting Departure from the Five Expert Rule

Since the Commission amended its Rules in 2009 to provide a default limit of five experts, the advertising substantiation cases before this Court have involved claims generally touching upon only one or two areas of science. *See, e.g., In re Daniel Chapter One*, 2009 WL 5160000 (Dec. 21, 2009). In contrast, the Complaint here implicates at least five scientific areas, three additional areas of expertise, numerous advertising pieces, and three Challenged Products.[1] Complainant's argument that the five expert rule applies elevates form over substance and fails to account for the exceptional number of scientific issues in this case, as well as the unprecedented amount of scientific research concerning the Challenged Products. That Complainant alone has already taken more than 20 depositions -- approximately half of which were of scientists -- demonstrates that this case is extraordinary. *C.f.* Fed. R. Civ. P. 30(a)(2)(A) (parties presumptively limited to ten depositions).

Unable to provide any legal authority in support of its argument for limiting Respondents from designating eight experts, Complainant resorts to citing two cases for its argument that the broad scope of this case is "ordinary" and does not require additional experts. Mot. at 3. Neither of these cases supports Complainant's position.

In one case cited by Complainant, *FTC v. National Urological Group*, 645 F.Supp.2d 1167 (N.D. Ga. 2008), involving only two areas of science (weight loss and erectile dysfunction), defendants designated more than seven (7) experts in order to address the myriad of issues raised. *See* Defendants' Amended and Supplemental Expert Designations in *FTC v.*

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[1] The number of Challenged Products is significant, as Complainant has taken the position in discovery that the science relating to one product is inapplicable to others. According to Complainant, the scientific attributes of the Challenged Products cannot be addressed collectively, thus necessitating additional expert testimony.

National Urological Group, attached hereto as Exhibit A.[2] The *National Urological* court never issued an order limiting Respondents' ability to designate these experts. This case involves more areas of science than *National Urological Group* and, accordingly, Respondents should be permitted to designate additional experts.

The other case cited by Complainant, *FTC v. Direct Marketing Concepts Inc.*, 569 F.Supp.2d. 285 (D. Mass. 2008), also fails to support Complainant's motion. In that case, which involved only two infomercials (as opposed to the more than twenty advertising pieces here), the court did not preclude the defendants from designating necessary experts, as Complainant urges the Court to do here. To the contrary, in granting summary judgment for the FTC, the court criticized defendants for failing to offer expert evidence. *Id.* at 302 ("Although the defendants assert that published studies and literature substantiate the claim...they have failed to submit their own expert evidence or produce any of the published studies or literature to substantiate this proposition.") (emphasis added).

Complainant's inability to provide relevant legal authority supporting its position that no more than five experts should be permitted is not surprising, as it would be highly prejudicial for this Court to preclude Respondents from introducing expert testimony needed to address the myriad allegations here.

II. Experts Designated by Respondents Are Not Duplicative

Complainant further argues that the experts designated by Respondents will present duplicative testimony and thus should be limited. Complainant is mistaken, as each of the

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[2] In addition to the experts listed in Exhibit A, defendants in *National Urological* also retained Eugene Abernathy. *See, e.g.,* 645 F.Supp.2d 1167 (referencing Dr. Abernathy's testimony). *National Urological* was resolved on summary judgment the experts designated were not involved in a trial.

experts designated will testify regarding independent and distinct areas of expertise. In particular, Respondents' experts will testify in the following areas, each warranting its own expert:

- **Prostate Health:** Respondents will need to introduce an expert to testify regarding the role of the Challenged Products with regard to prostate health. Complainant has designated an expert in this area, and Respondents are clearly entitled to present their own expert testimony on this topic.

- **Cardiovascular Health:** Respondents will need to introduce an expert to testify regarding the role of the Challenged Products in cardiovascular health, including blood pressure, blood flow, and arterial plaque. Complainant has designated an expert in this area, and Respondents are entitled to present their own expert testimony on this topic.

- **Erectile Health:** Respondents will need to introduce an expert to testify regarding the role of the Challenged Products with regard to erectile health. Complainant has designated an expert in this area, and Respondents are entitled to present their own expert on this topic.

- **Human Nutrition:** Respondents will need to introduce an expert to testify regarding the role of the Challenged Products with regard to human nutrition, particularly the mechanisms of action and bioavailability of pomegranate polyphenols in the human body, especially as they relate to antioxidation and inflammation. Complainant has designated an expert in this area, and Respondents are entitled to present their own expert on this topic.

- **Nitric Oxide:** Respondents also are entitled to designate an expert on the complex chemistry of nitric oxide and the role of the Challenged Products in the availability of nitric oxide in the body. The underlying science of nitric oxide is relevant to both the alleged cardiovascular and erectile dysfunction claims, and, is critical to Respondents' case and defense. Moreover, a scientist with a specialization in cardiovascular or erectile health is not necessarily the best person to explain the chemistry of nitric oxide.

- **Scientific Substantiation:** The Complainant has put at issue how "competent and reliable scientific evidence," the Commission's traditional standard for advertising substation, should be applied to food marketing -- both as to liability and remedy. Although Complainant apparently disputes that this issue requires an independent expert, *see* Mot. at 5-6, its only support for such an argument is that in *Daniel Chapter One* it chose not designate an independent expert on substantiation. But, Complainant's strategy in *Daniel Chapter One* is irrelevant to the question of whether Respondents, here, are entitled to present expert testimony on this issue. Preventing

Respondents from addressing the proper level of substantiation required in the food marketing context would be prejudicial.[3]

- **Linguistics and Semiotics:** Respondents are entitled to present expert testimony regarding the interpretation of the claims made in the advertisements themselves, and proposes to introduce an expert with linguistic and semiotics expertise to address this issue. Although Complainant argues that such expert testimony is not "required" in advertising substantiation cases, *see* Mot. at 4-5, it cites no authority for the proposition that Respondents should be prevented from introducing expert testimony for the Court's consideration in making this determination. Indeed, courts routinely consider expert testimony on these issues and Respondents are entitled to present such testimony here.[4] Most important, Complainant has made allegations regarding claims that it contends are "implied" by the ads, *see, e.g.,* Compl. at §§ 12, 14, 16, 19, 20, and expert testimony is appropriate for the Court to consider in evaluating these claims.

- **Consumer Science and Materiality:** Respondents are also entitled to introduce expert testimony regarding the way that consumers perceive the advertisements at issue, including whether the alleged claims are material to their decisions to purchase the Challenged Products. Complainant has stated that it intends to introduce an expert in rebuttal to address these issues, and Respondents are, likewise, clearly entitled to present expert testimony on this issue.

Accordingly, there are clearly more than five areas of expert testimony at issue.[5]

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[3] To the extent Complainant implies that Respondents do not need a separate expert on substantiation because respondents in *National Urological* and *Direct Marketing Concepts* failed to introduce such an expert, *see* Mot. at n. 6, it is important to note that the court criticized Respondents in *Direct Marketing* for failing to introduce such testimony.

[4] Notably, Complainant itself relied on experts with linguistic expertise in other substantiation cases. *E.g., In re Kraft*, 114 F.T.C. 40, 106 (1991).

[5] This distinguishes the instant case from the cases cited by Complainant. Mot. at n. 5. For example, the court in *Washington v. Greenfield* found, after reviewing expert statements, that the experts would have presented "essentially the same" testimony. 1986 WL 15758 at *1-2. Moreover, the court stated that it would adjust the expert limit if defendants could demonstrate "good cause", as Respondents have done here. *Compare id. with Wiles v. Department of Education*, 2008 WL 6808425, *1 (D. Hawaii Sept. 22, 2008) (denying motion *in limine* to preclude testimony from additional doctor); *Beller v. United States*, 2003 WL 25694923, *1 (D. N.M. Dec. 16, 2003) (accountant and economist damages experts were not cumulative); *Banks v. United States*, 93 Fed. Cl. 41 (2010) (mere presence of overlap, reference to another expert's report, or similar conclusion does not render expert report unnecessarily cumulative); *THK America, Inc. v. NSK, Ltd.*, 917 F. Supp. 563 (N. D. Ill. 1996) (denying motion *in limine* to exclude experts despite potential overlap in testimony).

(continued...)

To the extent that Complainant remains concerned that these experts will present overlapping or duplicative testimony (and the experts will not), the remedy is not to prevent Respondents from designating its proposed experts; rather, Complainant may move to strike, at a later stage of the proceedings and after it receives expert reports and takes depositions, testimony that it believes is unnecessarily cumulative or duplicative.

III. Respondents Will Suffer Substantial Prejudice Should The Court Grant Complainant's Motion

Complainant's only remaining argument in support of its motion is that it is prejudiced by Respondents' designating more than five experts. This argument is without merit.

Complainant first argues that it is prejudiced by the fact that Respondents filed their expert list in advance of a determination by this Court on the question of whether they could designate eight experts. This argument is in stark contrast to the position Complainant took during the meet-and-confer process, in which Complainant stated that Respondents should proceed with their designations of more than five witnesses and then Complainant would decide whether to object. *See* E-mail from Heather Hippsley, Jan. 28, 2011, attached hereto as Exhibit B. ("We will see your list of experts on Monday and then let you know if we oppose your motion or not."). Complainant also threatened to move to strike experts not disclosed. *Id.* At no time prior to Respondents' designation did Complainant indicate that merely listing more than five witnesses (subject to the Court's permission) would cause undue burden.

Notably, it is Complainant -- not Respondents -- that has put the plethora of scientific areas and advertising pieces at issue. The Complaint is extremely broad and Complainant has

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In *Riley v. Dow Chemical*, which Complainant also cites, the court indicated that there is an exception to its normal practice of limiting experts to one per discipline for "extraordinary circumstances." 123 F.R.D. 639, 640. Such circumstances are present here.

resisted Respondents' attempts to clarify the allegations.

Further, Complainant has at least eight attorneys staffing this matter and Respondents are confident that this many attorneys can prepare to depose Respondents' experts. Moreover, Complainant has successfully litigated prior advertising cases where respondents had more than five experts.[6]

In contrast to Complainant, Respondents will be significantly prejudiced if prevented from designating experts to address the breadth of Complainant's allegations. Such prejudice is evidenced by the fact that Complainant can point to no case in which this Court (or any other) has denied respondents the right to designate experts to testify to the distinct areas of expertise proposed here.

Conclusion

Accordingly, Complainant's motion should be denied.

Respectfully Submitted,

/s John Graubert

John D. Graubert
Skye L. Perryman
COVINGTON & BURLING LLP
1201 Pennsylvania Ave. NW
Washington, DC 20004-2401
Telephone: 202.662.5938
Facsimile: 202.778.5938
E-mail: JGraubert@cov.com
SPerryman@cov.com

[6] Respondents have offered to consent to Complainant introducing additional experts, if necessary. Renewed Mot. at 9.

Kristina M. Diaz
Alicia Mew
Paul A. Rose
Johnny Traboulsi
Adam P. Zaffos
Roll Law Group P.C.
11444 West Olympic Boulevard, 10th Floor
Los Angeles, CA 90064
Telephone: 310.966.8775
E-mail: kdiaz@roll.com

Counsel for Respondents

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

COMMISSIONERS: Jon Leibowitz, Chairman
William E. Kovacic
J. Thomas Rosch
Edith Ramirez
Julie Brill

In the Matter of	)	
	)	
POM WONDERFUL LLC and	)	
ROLL INTERNATIONAL CORP.,	)	
companies, and	)	Docket No. 9344
	)	PUBLIC
	)	
STEWART A. RESNICK,	)	
LYNDA RAE RESNICK, and	)	
MATTHEW TUPPER, individually and	)	
as officers of the companies.	)	

CERTIFICATE OF SERVICE

I hereby certify that this is a true and correct copy of the Respondents' **OPPOSITION TO COMPLAINANT'S MOTION TO LIMIT RESPONDENTS TO FIVE EXPERT WITNESSES**, and that on this 17th day of February, 2011, I caused the foregoing to be served by FTC E-File and hand delivery on the following:

Donald S. Clark
The Office of the Secretary
Federal Trade Commission
600 Pennsylvania Avenue, NW
Rm. H-159
Washington, DC 20580

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Avenue, NW
Rm. H-110
Washington, DC 20580

I hereby certify that this is a true and correct copy of the Respondents' **OPPOSITION TO COMPLAINANT'S MOTION TO LIMIT RESPONDENTS TO FIVE EXPERT WITNESSES,** and that on this 17th day of February, 2011, I caused the foregoing to be served by e-mail on the following:

Mary Engle
Associate Director for Advertising Practices
Bureau of Consumer Protection
Federal Trade Commission
601 New Jersey Avenue, NW
Washington, DC 20580

Heather Hippsley
Mary L. Johnson
Tawana Davis
Federal Trade Commission
601 New Jersey Avenue, NW
Washington, DC 20580

/Skye Perryman

John D. Graubert
Skye L. Perryman
COVINGTON & BURLING LLP
1201 Pennsylvania Ave. NW
Washington, DC 20004-2401
Telephone: 202.662.5938
Facsimile: 202.778.5938
E-mail: JGraubert@cov.com
SPerryman@cov.com

Kristina M. Diaz
Alicia Mew
Paul A. Rose
Johnny Traboulsi
Adam P. Zaffos
Roll Law Group P.C.
11444 West Olympic Boulevard
10th Floor
Los Angeles, CA 90064
Telephone: 310.966.8775
E-mail: kdiaz@roll.com

Counsel for Respondents

Bertram Fields
Greenberg Glusker
1900 Avenue of the Stars
21st Floor
Los Angeles, CA 90067
Telephone: 310.201.7454

Counsel for Respondents Stewart Resnick and Lynda Rae Resnick

Dated: February 17, 2011

2009 WL 5160000 (F.T.C.)

Federal Trade Commission (F.T.C.)

In the Matter of DANIEL CHAPTER ONE, a corporation, and JAMES FEIJO, individually, and as an officer of Daniel Chapter One

Docket No. 9329

December 24, 2009

COMMISSIONERS:

Jon Leibowitz, Chairman

Pamela Jones Harbour

William E. Kovacic

J. Thomas Rosch

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

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

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

VI.

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

A. All advertisements and promotional materials containing the representation;

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

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

VII.

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

VIII.

IT IS FURTHER ORDERED that Respondent Feijo, for a period of ten (10) years after the date of issuance of this or-

der, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment. The notice shall include the individual Respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Paragraph shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

IX.

IT IS FURTHER ORDERED that Respondent DCO and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation(s) that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. **Provided, however**, that, with respect to any proposed change in the corporation about which Respondent DCO learns less than thirty (30) days prior to the date such action is to take place, Respondent DCO shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Paragraph shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

X.

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

XI.

IT IS FURTHER ORDERED that this order will terminate on December 18, 2029, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; **provided, however,** that the filing of such a complaint will not affect the duration of:

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

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

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

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

By the Commission.

Donald S. Clark
Secretary

Seal:

Issued: December 18, 2009

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

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);[FN1] (2) Respondents claim that the ALJ misinterpreted various statutes, including, among others, Section 5 of the FTC Act, as well as the Due Process Clause and the First Amendment of the United States Constitution, by banning truthful statements about dietary supplements, improperly shifting the burden of proof to Re-

spondents, 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 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 of the FTC; 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; *see 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 neces- sary.

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.[FN2]

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 *43-44; *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 Re-

spondents 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),[FN3] "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."

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.[FN4] 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.

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.[FN5] 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.[FN6] The proposed order limits what Respondents may say without substantiation relating to the sale of certain products, but it does not otherwise reach into the Respondents' religious speech or practices.

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.

FN1. References to the record are abbreviated as follows:

IDF	Initial Decision Finding
ID	Initial Decision
RAB	Respondents' Appellate Brief
CAB	Complaint Counsel's Answering Brief
RRB	Respondents' Reply Brief
Tr.	Transcript of Trial Testimony
CX	Complaint Counsel's Exhibit
RX	Respondents' Exhibit

FN2. 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.

FN3. 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).

FN4. "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.

FN5. 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).

FN6. The Commission generally considers three factors in determining whether an order bears a reasonable relationship

to a particular violation: (1) the seriousness and deliberateness of the violation; (2) the ease with which the violation may be transferred to other products; and (3) whether the respondent has a history of prior violations. *See In re Stouffer Foods Corp.*, 118 F.T.C. 746, 811 (1994). All three elements need not be present to warrant fencing-in. *See Sears, Roebuck & Co. v. FTC*, 676 F.2d 385, 392 (9th Cir. 1982). The ALJ considered these factors and found the relief ordered was reasonably related to the Respondents' violations of the FTC Act. Respondents do not seem to challenge the ALJ's analysis of these elements. ID at 120-21.

FTC

2009 WL 5160000 (F.T.C.)

END OF DOCUMENT

Slip Copy, 2008 WL 6808425 (D.Hawai'i)
(Cite as: 2008 WL 6808425 (D.Hawai'i))

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Only the Westlaw citation is currently available.

This decision was reviewed by West editorial staff and not assigned editorial enhancements.

United States District Court, D. Hawai'i.
Ann Kimball WILES and Stanley Bond, individually and as next friend of their son, Bryan Wiles-Bond, a minor, Plaintiffs,
v.
DEPARTMENT OF EDUCATION, State of Hawaii, Defendant.

Civ. Nos. 04-00442 ACK-BMK, 05-00247 ACK-BMK.
Sept. 22, 2008.

Named Expert: Dr. Daniel B. LeGoff, Ph.D., Dr. Betty Jo Freeman
Anne L. Williams, Michael K. Livingston, Stanley E. Levin, Davis Levin Livingston Grande, Honolulu, HI, Carl M. Varady, Honolulu, HI, for Plaintiffs.

Daniel K. Obuhanych, Gregg M. Ushiroda, John T. Komeiji, Leighton M. Hara, Ross Tatsuo Shinyama, Watanabe Ing Kawashima & Komeiji LLP, Honolulu, HI, Holly T. Shikada, Lonomaikalani P.V. Beamer, Department of the Attorney General, Honolulu, HI, Kenneth S. Robbins, Robbins & Associates, Honolulu, HI, Melvyn M. Miyagi, Watanabe Ing, Honolulu, HI, for Defendant.

ORDER DENYING DEFENDANT'S MOTION IN LIMINE # 4 TO PRECLUDE TESTIMONY OF DANIEL B. LEGOFF, PH.D., AS IT IS CUMULATIVE OF THE TESTIMONY OF B.J. FREEMAN, PH.D.

ALAN C. KAY, Senior District Judge.

*1 Defendant seeks to exclude cumulative expert testimony of Dr. Daniel B. LeGoff and Dr. Betty Jo Freeman, pursuant to Rule 403 of the Federal Rules of Evidence. Defendant argues that both witnesses are expert psychologists with respect to liability and damages and that testimony by both expert witnesses on the same topic(s) will be cumulative, prejudicial, unnecessarily overemphasize liability and damages, and cause undue delay. However, Defendant recognizes that "Plaintiffs' objectives may be reached-without confusion and cumulative delay-by limiting the testimony of these experts only to those areas in which they provided opinions focused on different areas and elements in support of Plaintiffs' case." *See* Def. Motion in Limine # 4 at 3.

Plaintiffs contend that the testimony of the two expert witnesses will be complementary, not cumulative. According to Plaintiffs, Dr. LeGoff undertook individual psychological testing of Bryan in 2005 and 2007. In contrast, Dr. Freeman performed individual psychological testing in 2006 (a year in which Bryan was not tested by Dr. LeGoff) and obtained data in 2007 through third party social-behavioral inventories she administered to Bryan's parents and teachers.[FN1] *See* Pls. Opposition to Def. Motion in Limine # 4 at 9. According to Plaintiffs, the data and testimony of both doctors is necessary for the jury to obtain a complete picture of Bryan from 2005 to the present.

> FN1. Additionally, Dr. Freeman will attempt to critique and rebut testimony offered by Defendant's experts, Dr. Siegel and Dr. Goka. *See* Pls. Opposition to Def. Motion in Limine # 4 at 10-14.

The Court concludes that Defendant has not demonstrated that Dr. LeGoff's testimony (as a whole or any particular portion thereof) will be needlessly cumulative. *See* Fed.R.Evid. 403. Although there may be some slight overlap between the two doctors' testimony, it does not appear at this time to the Court that such overlap will confuse the jury, prejudice Defendant, cause undue delay, or result in needless presentation of cumulative evidence. *Id.* However, if at trial it appears that

Plaintiffs are attempting to elicit needlessly cumulative evidence from the two doctors, Defendant may raise an objection at that time.

CONCLUSION

For the foregoing reasons, the Court DENIES Defendant's Motion in Limine # 4 to Preclude Testimony of Daniel B. LeGoff, Ph.D., as It Is Cumulative of the Testimony of B.J. Freeman, Ph.D.

IT IS SO ORDERED.

D.Hawai'i,2008.
Wiles v. Department of Educ.
Slip Copy, 2008 WL 6808425 (D.Hawai'i)

END OF DOCUMENT

Not Reported in F.Supp.2d, 2003 WL 25694923 (D.N.M.)
(Cite as: 2003 WL 25694923 (D.N.M.))

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Only the Westlaw citation is currently available.

United States District Court,
D. New Mexico.
James J. "Jim" BELLER, as Personal Representative of Larry Beller and Rita Beller, deceased, and Terry Pfeifer, as Personal Representative of Edward Ramaekers and Alice Ramaekers, deceased,
Plaintiffs,
v.
UNITED STATES of America, and the Bureau of Indian Affairs, Defendants.

Civil No. 02-1368 WPJ/LFJ (ACE).
Dec. 16, 2003.

Named Expert: David K. Johnson, Dr. George Rhodes, Ph.D.
Kathleen J. Love, Randi McGinn, McGinn & Carpenter, P, Albuquerque, NM, for Plaintiffs.

Traci L. Colquette, Robert D. McCallum, Jr., James G. Touhey, Jr., U.S. Department of Justice, Washington, DC, David C. Iglesias, Elizabeth M. Martinez, Jan E. Mitchell, U.S. Attorney's Office, Albuquerque, NM, for Defendants.

MEMORANDUM OPINION AND ORDER

WILLIAM P. JOHNSON, District Judge.

*1 THIS MATTER comes before the Court upon Plaintiff Pfeifer's Motion to Strike Cumulative Expert Witness Designation, filed September 30, 2003 **(Doc. 225).** Defendants intend to offer David Johnson, a certified public accountant, and George Rhodes, Ph.D., an economist, as expert witnesses in the area of damages. Plaintiff contends that since both individuals will testify regarding the same valuation of damages in this case, allowing both to testify at trial would be unnecessarily burdensome, time consuming and confusing, and that the Court should require Defendants to strike one of the experts.

The admission or exclusion of evidence rests within the sound discretion of the trial court. *Pacific Employers Ins. Co. v. P.B. Hoidale Co., Inc.,* 782 F.Supp. 564 (D.Kan.,1992). Defendants assures the Court that while the information contained in the two reports overlap in some areas, each expert will testify to different categories of damages. Referring to a chart on page five in their response brief, Defendants explain that only David Johnson, if called as a witness, will testify about economic losses such as lost earnings and household services, and only George Rhodes would testify regarding aggravating circumstances damages and hedonic damages. Because Plaintiff has claimed several types of damages, it is not unlikely that certain portions in these experts' reports would overlap. Plaintiff argues that he will be put in a position of "guessing" about which expert will testify about which areas of damages under 20 days prior to trial, when parties are required to exchange witness lists and file them with the Court. This is not a situation where Plaintiff is deluged with a number of experts, all of whose testimony will be repetitive. Thus, I am not convinced that the identification of two experts who may testify in the same areas is necessarily cumulative.[FN1] *See Green Constr. Co. v. Kan. Power & Light Co.,* 1 F.3d 1005, 1014 (10th Cir.1993) (court has discretion to limit number of experts, "provided the witnesses are not excluded arbitrarily, or on the basis of mere numbers"). Any prejudice to Plaintiff, and any confusion he may be experiencing at this point, is most likely due to the fact that he has chosen not to depose either Mr. Johnson or Dr. Rhodes, rather than to Defendants' identification of both these experts, even if they were both to testify on the same category of damages.

FN1. My review of these reports as attached to Plaintiff's motion, Exs. A and B, reveals that the information contained in both these reports are not identical. For example, Dr. Rhodes opines that there are no

> net losses of household services, while Mr. Johnson states ranges of losses for Plaintiff from approximately $46,000.00 to $129,000.00. *See* Ex. A, Bates No. 4938, and Ex. B, Bates No. 5017.

At this point, Plaintiff has not shown a valid reason for his contention that allowing both David Johnson and George Rhodes to testify would prejudice him. Particularly given that Defendants have compartmentalized each expert's areas of testimony, there is little chance of confusion, prejudice to Plaintiff, or of a waste of time or resources. *See Pacific Employers Ins. Co. v. P.B. Hoidale Co., Inc.,* 782 F.Supp. 564 (D.Kan.,1992) (motion to limit witnesses denied absent showing that expert testimony was needlessly cumulative or unfairly prejudicial). Therefore, I will not require Defendants to strike one of these experts. *See Nalder v. West Park Hosp.,* 254 F.3d 1168 (10th Cir.2001) (motion to strike expert witnesses denied where plaintiff's amended expert designations contained little or no actual overlap of the experts' proffered testimony). The Court may revisit the issue on counsel's motion or *sua sponte* should it become apparent at trial that the testimony of one or the other expert witness is approaching repetition. *See, e.g., Wetherill v. University of Chicago,* 565 F.Supp. 1553, 1566 (D.C.Ill.,1983) (court restricted party to one expert for each area of testimony in order to avoid repetitive testimony).

***2 THEREFORE,**

IT IS ORDERED that Plaintiff Pfeifer's Motion to Strike Cumulative Expert Witness Designation **(Doc. 225),** is hereby DENIED.

D.N.M.,2003.
Beller v. U.S.
Not Reported in F.Supp.2d, 2003 WL 25694923 (D.N.M.)

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Not Reported in F.Supp., 1986 WL 15758 (D.D.C.)
(Cite as: 1986 WL 15758 (D.D.C.))

Only the Westlaw citation is currently available.

United States District Court, District of Columbia.
Jacinta WASHINGTON, Plaintiff,
v.
Robert T. GREENFIELD, M.D. and Sylvester C. Booker, M.D., Defendants.

Civ. A. No. 86-930.
October 15, 1986.

William John Hickey, Donahue, Ehrmantraut & Montedonico, Chtd., Rockville, Maryland, for defendants.

Elizabeth Lanser, Boasberg & Norton, Michael B. Waitzkin, Blumfeld & Cohen, Washington, D.C., for plaintiff.

MEMORANDUM ORDER

JOHN H. PRATT, District Judge.

***1** Plaintiff Jacinta Washington has brought this medical malpractice action against two of her former physicians. The parties have been engaged in extensive discovery, and now bring before the court motions to limit each other's witnesses, along with related motions on costs and fees.

Background

Jacinta Washington claims the two defendant doctors were negligent in their 1973 treatment of her. According to plaintiff, defendants operated on her specifically to remove a Lippes Loop intrauterine device (IUD), but actually failed to remove the IUD during the operation. Some months later, the defendants inserted a Dalkon Shield IUD while the first one was still in place. In 1985, plaintiff had to undergo a complete hysterectomy, and the Lippes Loop was discovered embedded in the uterus during a pre-operative sonogram. Plaintiff claims the defendants were negligent in failing to remove the Lippes Loop and in inserting the Dalkon Shield.

After plaintiff filed her complaint in this action, the parties began extensive discovery and an initial discovery cut-off of September 18, 1986 was ordered. This deadline was later revised when the court approved a stipulation of the parties extending discovery for another 30 days, or until October 17, 1986. In their attempts to close discovery, the parties have filed the four motions before us now. Plaintiff moves to limit the defendants to one expert in gynecology out of the four they listed in their Rule 26(b)(4) statement of expert witnesses. She also moves for a protective order requiring defendants' to pay the costs of plaintiff's depositions of defendants' experts. In their opposition to these motions, defendants move for attorneys' fees as a sanction for having to respond to plaintiff's motions. They also move to preclude plaintiff from using her psychiatrist as a witness at trial.

A. Plaintiff's Motion to Limit Defendants' Expert Witnesses

In this motion, plaintiff seeks to limit defendants' to the use of one expert in the field of gynecology at trial, rather than the four experts they plan to present. Plaintiff asserts that she doesn't have the financial resources to adequately prepare for four adverse expert witnesses; she also claims that the testimony of these witnesses will be cumulative, unnecessary, and unfairly prejudicial to her. Defendants counter plaintiff's motion by noting that plaintiff need not incur any expenses associated with these experts since she can choose not to depose them.

This court has discretion to limit the number of expert witnesses when their testimony would be cumulative, a waste of time, or present a danger of unfair prejudice. See, e.g., Aetna Casualty & Surety Co. v. Guynes, 713 F.2d 1187, 1193 (5th Cir. 1983) ; Federal Rules of Evidence 403; Federal Rules of Civil Procedure 16(c)(4). The real issue here is whether the testimony of four experts would be cumulative or whether each expert will add to the evidence presented at trial in a meaningful way.

After examining defendants' 26(b)(4) statements about these gynecology experts, their opinions, and expected testimony, we have concluded that use of all four expert witnesses would indeed present cumulative, unnecessary evidence at trial. Of the four experts, the testimony of Dr. Sewell and Dr. Cutts is essentially the same; Dr. Hill and Dr. Armstrong likewise will present very similar testimony. In addition, all four of the doctors have the same credential of board certification in gynecology; none appear to have a particular sub-specialty that would make his testimony non-cumulative. Cf. Johnson v. United States, 780 F.2d 902 (11th Cir. 1986) (district court abused its discretion in excluding third medical expert witness when the witness had different credentials and would have offered slightly different evidence and analysis).

***2** Because allowing defendants to present four expert witnesses in the same field would be unnecessarily cumulative, we will limit the defendants to two expert witnesses in gynecology. However, this limitation is subject to change if defendants can show good cause and the need for additional experts to testify as to non-cumulative matters.

B. Plaintiff's Motion for a Protective Order

Plaintiff Jacinta Washington has also moved for a protective order that would require defendants to pay for their experts' time when plaintiff deposes them. Such an order would be contrary to the usual rule that the party seeking discovery of an expert witness pays the expert's fees for that discovery. Federal Rule of Civil Procedure 26(b)(4)(c). This rule of procedure is only to be suspended if 'manifest injustice' would result from its application. Although we sympathize with plaintiff's distress at the high costs of litigation, we find that she has not shown the manifest injustice necessary to disturb the usual practice of requiring the discovering party to pay the costs of their own discovery.

C. Defendants' Motion for Attorney's Fees

In their opposition to plaintiff's motion, defendants move for the attorneys' fees incurred in having to respond to what they term plaintiff's 'frivolous' motion to limit witnesses and for a protective order. Under Federal Rules of Civil Procedure 26(c) and 37(a)(4), such an award can be made if the court finds plaintiff's motion was unjustified. However, we find that plaintiff's motion was substantially justified, because the planned testimony of four expert witnesses would be cumulative and a waste of time and resources. Therefore, an award of attorney's fees would be unjust and will not be granted.

D. Defendants' Motion to Exclude Plaintiff's Expert

Defendants also move for an order precluding plaintiff from calling a 'psychiatric expert witness' at trial that was not listed in plaintiff's 26(b)(4) statement and from putting the 'psychiatric condition of the plaintiff into issue in this lawsuit.' Def. Supp. Mot. at 3. Plaintiff has opposed this motion, saying that psychological injury has always been an issue in the case, and that she has a right to call her treating psychiatrist as an ordinary witness at trial.

After considering the record as a whole, we find that psychological injury to plaintiff has indeed always been part of this case. See Complaint at ¶24; Pl. Ans. to Defs' Ints. 2, 6, 8. Plaintiff has complained of emotional trauma, fear, depression, and grief resulting from defendants' allegedly negligent treatment. Thus, we see no reason why plaintiff should not be allowed to call her treating psychiatrist as an ordinary witness at trial. See Adkins v. Morton, 494 A.2d 652 (D.C. 1985).

Accordingly, it is by the court this 15th day of October 1986,

ORDERED that plaintiff's motion to limit witnesses is granted in part, and defendants will be limited to presenting two expert witnesses in gynecology at trial, unless they show good cause within ten (10) days of this order of the need for additional experts to testify to non-cumulative matters, and it is

***3** ORDERED that plaintiff's motion for a protective order is denied, and it is

ORDERED that defendants' motion for attorney's fees is denied, and it is

FURTHER ORDERED that defendants' motion to exclude plaintiff's treating psychiatrist is denied.

D.D.C., 1986.
Washington v. Greenfield
Not Reported in F.Supp., 1986 WL 15758 (D.D.C.)

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

FEDERAL TRADE COMMISSION, Plaintiff, v. NATIONAL UROLOGICAL GROUP, INC., et al., Defendants.	)	Case No. 1:04-CV-3294-CAP

AMENDED DEFENDANTS' EXPERT WITNESS DESIGNATION[1]

Pursuant to the February 28, 2005 Scheduling Order, Defendants hereby designate those persons whom they currently contemplate calling to present expert testimony at trial in this matter:

1.

John W. Olney, M.D., and another expert[2] whose anticipated testimony will be described in expert reports, which will be produced to Plaintiff on or before September 18, 2005, as required by the Scheduling Order. The general subject

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[1] This amended version corrects several typographical errors contained in the earlier filing.

[2] The expert has not yet returned an executed engagement contract. Defendants will supplement these designations to include the identity of the experts once the engagement contracts are executed.

matter of this testimony will include, but not be limited to, the reliability of the evidence utilized by Defendants to advertise their weight loss products and the safety and efficacy of using ephedra as an ingredient in weight loss dietary supplement products.

2.

William J. Morton, M.D., whose anticipated testimony will be described in his expert report, which will be produced to Plaintiff on or before September 18, 2005, as required by the Scheduling Order. The general subject matter of this testimony will include, but not be limited to, the reliability of the evidence utilized by Defendants to advertise their product for sexual enhancement and the safety and efficacy of the ingredients in that product.

3.

Terrill Mark Wright, M.D., whose anticipated testimony will be described in his expert report, which will be produced to Plaintiff on or before September 18, 2005, as required by the Scheduling Order. The general subject matter of this testimony will include, but not be limited to, the reliability of the evidence utilized by Defendants to advertise their products and the safety and efficacy of those products and their ingredients.

4.

Timothy Gaginella, Ph.D., whose anticipated testimony will be described in his expert report, which will be produced to Plaintiff on or before September 18, 2005, as required by the Scheduling Order. The general subject matter of this testimony will include, but not be limited to, the reliability of the evidence utilized by Defendants to advertise their products and the safety and efficacy of those products and their ingredients.

5.

An expert on deceptive advertising and consumer surveys[3] whose anticipated testimony will be described in his expert report, which will be produced to Plaintiff on or before September 18, 2005, as required by the Scheduling Order. The general subject matter of this testimony will include, but not be limited to, the type, nature, and reliability of the evidence utilized by Defendants to advertise the products at issue in this case and consumers' perceptions of that advertising.

6.

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[3] The expert has not yet returned an executed engagement contract. Defendants will supplement these designations to include the identity of the experts once the engagement contracts are executed.

An expert on consumer behavior[4] whose anticipated testimony will be described in an expert report, which will be produced to Plaintiff on or before September 18, 2005, as required by the Scheduling Order. The general subject matter of this testimony will include, but not be limited to consumers perceptions of the advertising at issue in this case.

7.

James F. Hart and Gene Abernathy, whose anticipated testimony will be described in an expert report, which will be produced to Plaintiff on or before September 18, 2005, as required by the Scheduling Order. The general subject matter of this testimony will include, but not be limited to, the economic aspects of the products at issue, including any costs and expenses in developing, manufacturing and marketing the products and any profits earned from the sales of such products.

CERTIFICATE OF COMPLIANCE

Undersigned counsel certifies the foregoing document has been prepared with one of the font and point selections (times new roman, 14 point) approved by the court in local rule 5.1 (b) and 7.1 (d).

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[4] The expert has not yet returned an executed engagement contract. Defendants will supplement these designations to include the identity of the experts once the engagement contracts are executed.

This 21st Day of June, 2005,

/s/ EDMUND J. NOVOTNY

Edmund J. Novotny, Jr.
Georgia Bar No. 547338
BAKER DONELSON BEARMAN
CALDWELL & BERKOWITZ, P.C.
5 Concourse Parkway
Suite 900
Atlanta, Georgia 30328
(678) 406-8700
ednovotny@bakerdonelson.com

Attorney for National Urological Group, Inc., National Institute for Clinical Weight Loss, Inc., and Hi-Tech Pharmaceuticals, Inc.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

FEDERAL TRADE COMMISSION, Plaintiff, v. NATIONAL UROLOGICAL GROUP, INC., et al., Defendants.	)	Case No. 1:04-CV-3294-CAP

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **DEFENDANTS' AMENDED EXPERT WITNESS DESIGNATION** has been electronically filed and a Court-issued Notice sent to counsel of record. A true and correct copy of this electronically filed document will also be sent via U.S. Mail, as indicated, to the following counsel of record:

Tawana E. Davis
Sydney M. Knight
Edward Glennon
William E. Kovacic
Federal Trade Commission
601 New Jersey Avenue, NW
Room NJ-3202
Washington, D.C. 20580
Service via First Class Mail and Service via Electronic Filing with the ND Ga. Clerk of Court using the CM/ECF system.

James T. Rohrer
Federal Trade Commission
Federal Trade Commission,
Southeast Region
225 Peachtree Street, Room 1500
Atlanta, GA 30303
Service via Electronic Filing with the ND Ga. Clerk of Court using the CM/ECF system.

Timothy M. Fulmer
Natter & Fulmer, P.C.
3800 Colonnade Parkway
Suite 450
Birmingham, AL 35243
COUNSEL FOR National Urological Group, Inc., Hi-Tech Pharmaceuticals, Inc., National Institute for Clinical Weight Loss, Inc.
Service via First Class Mail

Thomas J. Spina
Fawal & Spina
1330 21st Way South, Suite 200
Birmingham, AL 35205
COUNSEL FOR Thomasz Holda
Service via First Class Mail

Jerome J. Froelich, Jr.
McKenney & Froelich
Two Midtown Plaza
1349 West Peachtree Street
Atlanta, GA 30309
COUNSEL FOR Thomasz Holda
SERVICE via Electronic Filing with the ND Ga. Clerk of Court using the CM/ECF system

Brett M. Bloomston
Bloomston & Callaway
1330 21st Way South
Suite G-10
Birmingham, AL 35205
(205) 212-9700 (Telephone)
COUNSEL FOR Stephen Smith
SERVICE via Electronic Filing with the ND Ga. Clerk of Court using the CM/ECF system

Bruce S. Harvey
Jennifer Sullivan Hanson
Office of Bruce S. Harvey
146 Nassau Street, N.W.
Atlanta, GA 30303-2009
COUNSEL FOR Mark Wright, M.D., and Stephen Smith
Service via Electronic Filing with the ND Ga. Clerk of Court using the CM/ECF system.

Michael Anthony Howell, *pro se*
941 Virginia Avenue, NE
Atlanta, GA 30306
Service via First Class Mail

J. Stephen Salter
100 Age Herald Building
2107 5th Avenue North
Birmingham, AL 35203
(205) 252-9751 (Telephone)
UMSTAKWIT@aol.com
COUNSEL FOR Jared Wheat
SERVICE via Electronic Filing with the ND Ga. Clerk of Court using the CM/ECF system

Kimberly Alice Dymecki
Office of Kimberly Alice Dymecki
146 Nassau Street
Atlanta, GA 30303
COUNSEL FOR Jared Wheat
SERVICE via Electronic Filing with the ND Ga. Clerk of Court using the CM/ECF system

Charles R. Bridgers
DeLong Caldwell & Bridgers, LLC
3100 Centennial Tower
101 Marietta Street
Atlanta, Georgia 30303
(404) 979-3150 (Telephone)
charlesbridgers@dcnblaw.com
Counsel for National Urological Group, Inc., National Institute for Clinical Weight Loss, Inc., and Hi-Tech Pharmaceuticals, Inc.
SERVICE via Electronic Filing with the ND Ga. Clerk of Court using the CM/ECF system

Respectfully submitted this 21st day of June, 2005.

/s/ EDMUND J. NOVOTNY
Edmund J. Novotny, Jr.
Georgia Bar No. 547338
BAKER DONELSON BEARMAN
CALDWELL & BERKOWITZ, P.C.
5 Concourse Parkway
Suite 900
Atlanta, Georgia 30328
(678) 406-8700
ednovotny@bakerdonelson.com

Attorney for National Urological Group, Inc., National Institute for Clinical Weight Loss, Inc., and Hi-Tech Pharmaceuticals, Inc.

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SUPPLEMENTAL DEFENDANTS' EXPERT WITNESS DESIGNATION

Pursuant to the February 28, 2005 Scheduling Order, Defendants hereby supplement their designations of persons whom they currently contemplate calling to present expert testimony at trial in this matter:

1.

Thomas J. Maronick, DBA, an expert on deceptive advertising and consumer surveys whose anticipated testimony will be described in his expert report, which will be produced to Plaintiff on or before September 18, 2005, as required by the Scheduling Order. The general subject matter of this testimony will include, but not be limited to, the type, nature, and reliability of the evidence utilized by Defendants to advertise the products at issue in this case and consumers' perceptions of that advertising.

2.

R. Glenn Richey, Jr., Ph.D., whose anticipated testimony will be described in an expert report, which will be produced to Plaintiff on or before September 18, 2005, as required by the Scheduling Order. The general subject matter of this testimony will include, but not be limited to, consumers' perceptions of the advertising at issue in this case.

3.

Defendants reserve the right to further supplement these disclosures in order to respond to any unexpected expert testimony proffered by Plaintiff.

CERTIFICATE OF COMPLIANCE

Undersigned counsel certifies the foregoing document has been prepared with one of the font and point selections (times new roman, 14 point) approved by the court in local rule 5.1 (b) and 7.1 (d).

This 24th Day of June, 2005.

[SIGNATURE ON FOLLOWING PAGE.]

/s/ EDMUND J. NOVOTNY

Edmund J. Novotny, Jr.
Georgia Bar No. 547338
BAKER DONELSON BEARMAN
CALDWELL & BERKOWITZ, P.C.
5 Concourse Parkway
Suite 900
Atlanta, Georgia 30328
(678) 406-8700
ednovotny@bakerdonelson.com

Attorney for National Urological Group, Inc., National Institute for Clinical Weight Loss, Inc., and Hi-Tech Pharmaceuticals, Inc.

B

From: Graubert, John
Sent: Friday, January 28, 2011 1:11 PM
To: 'HHIPPSLEY@ftc.gov'
Cc: 'mjohnson1@ftc.gov'; 'SVISWANATHAN@ftc.gov'; 'kdiaz@roll.com'; Perryman, Skye; 'bfields@ggfirm.com'
Subject: Re: experts

I believe the designations are due Tuesday: isn't that correct?

Thanks for your response. For now, I will note in the motion that we have consulted and were unable to agree. If you want to revisit the question after seeing our list, of course that is fine and indeed I think there is ground for a mutually satisfactory resolution of the issue.

John

From: Hippsley, Heather <HHIPPSLEY@ftc.gov>
To: Graubert, John
Cc: Johnson, Mary <MJOHNSON1@ftc.gov>; Viswanathan, Serena <SVISWANATHAN@ftc.gov>
Sent: Fri Jan 28 13:05:30 2011
Subject: experts

Hi John, I got your message. I'm at the office. We will not agree to exceed the limit of experts set by the rules and scheduling order at this point. We will see your list of experts on Monday and then let you know if we oppose your motion or not. Without seeing the named individuals and what they are going to be used for it is impossible for us to judge the merits of your request to exceed the set number of experts. Again as I reiterated last week when you raised this issue, we expect your client to meet its obligations under the scheduling order to provide the required expert disclosures on Monday. If they don't, we will move to strike any non-disclosed experts as waived because of the failure to meet the deadline. Thanks, Heather