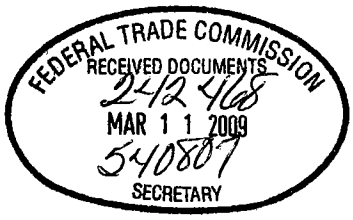
ORIGINAL



UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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

COMPLAINT COUNSEL'S MEMORANDUM IN OPPOSITION TO RESPONDENTS' MOTION FOR SUMMARY DECISION

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

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

TABLE OF CONTENTS

TABLE OF AUTHORITIES

FEDERAL CASES

FEDERAL STATUTES

OTHER

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

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

COMPLAINT COUNSEL'S MEMORANDUM IN OPPOSITION TO RESPONDENTS' MOTION FOR SUMMARY DECISION

Complaint Counsel oppose Respondents' Motion For Summary Decision (the "Motion"). For the reasons set forth below, Complaint Counsel respectfully request that Respondents' Motion be denied.

I. INTRODUCTION

Respondents' Motion for Summary Decision asks this Court to throw out the FTC's lawsuit, despite the overwhelming evidence that Respondents made unsubstantiated claims that their products Bio*Shark, 7 Herb Formula, GDU, and BioMixx (collectively referred to as the "DCO Products") prevent, treat, or cure cancer or tumors. As a threshold matter, Respondents' Motion was improperly filed, failing to contain a statement of material facts as required by Rule 3.24. In their Motion, Respondents provide a flawed interpretation of the summary decision standard, misinterpret the Federal Trade Commission's (the "FTC" or the "Commission") deception doctrine, and confuse the FTC's advertising substantiation requirements with the FTC's "net impression" analysis. Respondents also rely upon a distinction between

"structure/function" claims and health claims that is not relevant under Section 5 of the FTC Act. They also attempt to use inadequate disclaimers under the Dietary Supplements Health and Education Act (DSHEA) to negate their unsupported disease claims, which cannot be done. Furthermore, Respondents advance a strained interpretation of Due Process that is not supported by the case law.

As explained more fully in Complaint Counsel's Motion for Summary Decision and Memorandum in Support thereof (hereinafter collectively referred to as "Complaint Counsel's Motion for Summary Decision" and incorporated herein by reference throughout), the uncontroverted evidence is as follows: (1) Respondents distribute the DCO Products in commerce; (2) Respondents claim that the DCO Products prevent, treat, or cure cancer or tumors; (3) Respondents disseminate these claims about the DCO Products to consumers; and (4) Respondents did not possess substantiation for such claims at the time they were made. Therefore, Respondents' Motion should be denied, and Complaint Counsel's Motion for Summary Decision should be granted.

II. RESPONDENTS' MOTION FOR SUMMARY DECISION IS IMPROPERLY FILED.

Rule 3.24(a) of the Rules of Practice provides that motions for summary decision "shall be accompanied by a separate and concise statement of material facts as to which the moving party contends there is not genuine issue." Rule 3.24(a). This Court's October 14, 2008 Scheduling Order established February 24, 2009 as the deadline for filing motions for summary decision. Respondents, however, did not submit a "statement of material facts" with the Motion on February 24, 2009.

Nearly a week after the February 24, 2009 filing deadline for motions for summary decision, on March 2, 2009, Respondents filed a document titled "Second Errata for Respondents' Motion for Summary Decision" (the "Second Errata"), attaching Respondents' "Statement of Undisputed Facts." In the Second Errata, Respondents misrepresented that this filing simply was a "new copy" of Respondents' Statement of Undisputed Facts, suggesting that they previously submitted such a document. That same day, at Complaint Counsel's insistence, Respondents withdrew the Second Errata and filed a "Request for Leave to Amend Respondents' Motion for Summary Decision," requesting that this Court accept their untimely filed "Statement of Undisputed Facts."

As explained more fully in Complaint Counsel's Opposition to Respondents' Request for Leave to Amend Respondents' Motion for Summary Decision (and incorporated herein by reference), Respondents not only failed to offer good cause as to why they did not file a statement of material facts with their summary decision as Rule 3.24(a) requires, they failed to offer any cause.

In addition to being untimely filed, the "Statement of Undisputed Facts" that Respondents belatedly seek to attach to their Motion consists of no more than bald conclusory assertions. Not a single "statement of fact" is supported by a reference to the evidence – there are no references to any documents or deposition testimony. As a result, Complaint Counsel (and the Court) are left guessing as to exactly what evidence Respondents contend support their conclusions.

Respondents' failure to comply with the Rules of Practice and this Court's Scheduling Order should be reason alone to deny Respondents' Motion for Summary Decision. Nevertheless, Complaint Counsel will address Respondents' arguments below.

III. RESPONDENTS MISAPPREHEND ESTABLISHED FTC LAW.

A. Respondents' Interpretation of the Summary Decision Standard is Flawed.

In their Motion for Summary Decision, Respondents distract the Court with a discussion of *Addington v. Texas* and what they believe is the applicable standard of "clear and convincing evidence." *Respondents' Mot. Summ. Decision* at 7-9. Respondents assert that Complaint Counsel "must produce clear, cogent & convincing evidence to defeat DCO's Motion."[1] *Id.* at 8. Respondents are wrong. As Rule 3.24(a)(2) provides, the correct standard is that summary decision "shall be rendered . . . if the pleadings and any depositions, answers to interrogatories, admissions on file, and affidavits show that there is no genuine issue as to any material fact and that the moving party is entitled to such decision as a matter of law." 16 C.F.R. § 3.24(a)(2). Rule 3.24(a)(2) is applied consistent with case law interpreting the summary judgment standard set out in Federal Rule of Civil Procedure 56. *In re Kroger, Co.*, 98 F.T.C. 639, 726 (1981); *In re Hearst Corp.*, 80 F.T.C. 1011, 1014 (1972). To prevail, Complaint Counsel must satisfy the preponderance of the evidence standard, as has been done in Complaint Counsel's Motion for Summary Decision. *See In the Matter of Rambus, Inc.*, No. 9302, 2006 FTC LEXIS 101, at *57 (Aug. 20, 2006) ("Complaint Counsel have the burden to prove the necessary elements of liability by a preponderance of the evidence"); *In re Automotive Breakthrough Sciences, Inc.*, 126 F.T.C. 229, 306, n.45 (1998) ("To find liability . . . the Commission must be persuaded that each of its findings is supported by a preponderance of the evidence on the record"); *In re*

[1] It defies belief that Respondents claim that Complaint Counsel must produce "clear, cogent & convincing evidence to defeat DCO's Motion" when they themselves have provided no citations to the record in their "Statement of Undisputed Facts" and very few citations to the record in their Motion.

Adventist Health Sys. West, 117 F.T.C. 224, 297 (1994) ("Each element of the case must be established by a preponderance of the evidence").

As Respondents themselves acknowledge, *Addington* involved the standard of proof in an involuntary civil commitment proceeding. *Respondents' Mot. Summ. Decision* at 8. *Addington* is not relevant to this proceeding, and Respondents cite this case to resurrect their argument that "the Constitutional interests include the First Amendment rights to free speech and religious freedom possessed by both DCO and its constituents."[2] *Id.* The Court already considered and rejected Respondents' argument in this proceeding. In its Order Denying Respondents' Motion to Dismiss, the Court stated that "contrary to Respondents' argument, commercial speech does not rise to the level of fully protected speech merely because it is linked to matters that might otherwise be protected. . . . To do so would enable advertising to obtain full constitutional protection simply by linking the product to religion or political discussion." Feb. 2, 2009 *Order Denying Respondents' Mot. to Dismiss Compl.* at 7-8 (citation omitted). The Court also found that "the proposed cease and desist order would affect only the sale of the products, and would not affect Respondents' right to advocate alternative medicine or faith-based healing." Feb. 2, 2009 *Order Denying Respondents' Mot. to Dismiss Compl.* at 8; s*ee also* Feb. 23, 2009 *Order Denying Respondents' Mot. for Reconsideration* at 5. Respondents insist on pressing this point to distract from the substantive issues at hand.

---

[2] For the first time in this case, Respondents now seem to claim that they are attempting to protect the First Amendment rights of their purported "constituents." Respondents ignore well-established principles of third-party standing to assert a Constitutional claim. *See Hodak v. City of St. Peters*, 535 F.3d 899, 906 (8th Cir. 2008) (stating that "[t]he Supreme Court has required that a litigant must actually assert the rights of the third party, supported by the allegations in the record, in order for a litigant to have third-party standing") (citing *McGowan v. Maryland*, 366 U.S. 420, 429 (1961)).

As more fully explained in Complaint Counsel's Motion for Summary Decision, the party moving for summary judgment bears the initial burden of identifying evidence that demonstrates the absence of any genuine issue of material fact. *Green v. Dalton*, 164 F.3d 671, 675 (D.C. Cir. 1999) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986)). Here, Respondents have not produced any evidence showing why the Court should grant their Motion for Summary Decision. Rather, the uncontroverted evidence reveals that there is no genuine issue as to any material fact relating to: (1) whether Respondents made the representations challenged in the Complaint and (2) whether these representations were unsubstantiated and misleading in a material respect. Thus, Complaint Counsel is entitled to summary decision as a matter of law.

B. Respondents Misinterpret the FTC's Deception Standard

To conduct its deception analysis, "the [FTC] examines the overall net impression of an ad[vertisement] and engages in a three-part inquiry: (1) what claims are conveyed in the advertisement; (2) are those claims false or misleading; and (3) are those claims material to prospective consumers." *Kraft, Inc. v. FTC*, 970 F.2d 311, 314 (7th Cir. 1992).

As a preliminary matter, Complaint Counsel note that Respondents admit in their Answer to making the representations at issue in the Complaint. Although Respondents belatedly moved to amend their Answer to reverse this admission, the Court denied their motion in its March 4, 2009 Order. Thus, there is no dispute that Respondents' advertisements conveyed the representations listed in the Complaint. In addition, as discussed below, Complaint Counsel assert that they have met their burden of proof of demonstrating that Respondents' advertising claims are wholly unsubstantiated and misleading.

1. Respondents Misapprehend "Net Impression."

Even had Respondents not admitted that they made the representations alleged in the Complaint, their "net impression" analysis of the advertising at issue is neither accurate nor credible. Respondents claim that "the FTC's Complaint is based on charges that DCO has created an 'overall net impression' of cancer cures via its website. The FTC does not contend that DCO has made express claims of cancer cures." *Respondents' Mot. for Summ. Decision* at 3. Respondents misstate the FTC's position and the law. As set forth in Complaint Counsel's Motion for Summary Decision, the "net impression" is based on an evaluation of both express and implied claims. Indeed, in determining whether an advertisement conveys a claim, the Commission looks to the overall, net impression created by the advertisement, through the interaction of different elements in the advertisement, rather than focusing on the individual elements in isolation. *Stouffer Foods Corp.*, 118 F.T.C. 746, 799 (1994); *Kraft*, 114 F.T.C. 40 at 122 (1991); *American Home Prods. Corp. v. FTC*, 695 F.2d 681, 688 (3d Cir. 1982); *FTC Policy Statement on Deception*, 103 F.T.C. 174, 179 (1984) (appended to *Cliffdale Assocs.*) (emphasizing the importance of considering "the entire mosaic, rather than each tile separately"). Courts have given substantial deference to the FTC's determinations of deception. *See Thompson Medical Co. v. FTC*, 791 F.2d 189, 193 (D.C. Cir. 1986) ("The FTC has substantial expertise in evaluating claims of drugs' absolute and comparative efficacy, and in assessing whether advertisements are misleading or deceptive"); *Porter & Dietsch, Inc. v. FTC*, 605 F.2d 294, 300 (7th Cir. 1979). Complaint Counsel conducted detailed analyses of the net impressions created by Respondents' advertisements and set forth those analyses in Complaint Counsel's Motion for Summary Decision. (*See* pages 6-9, 14-21 of Complaint Counsel's Motion for Summary Decision).

In light of these detailed analyses, Respondents' assertion that "the FTC has omitted several indisputable features from the mosaic that is DCO and its claims" is wrong. *Respondents' Mot. for Summ. Decision* at 4. Respondents list two purported omissions: (1) an excerpt from the DCO Web site that purportedly highlights "the name of Daniel Chapter One itself"; and (2) the disclaimer Respondents claim accompanies "every description of every product offered on the DCO website." *Id.* at 4-5. As to the first item, this alleged "undisputed fact" is irrelevant and immaterial to any viable legal defense in Respondents' Motion for Summary Decision. Respondents fail to explain why this language in any way changes the misleading nature of their cancer claims. As to the second item, the disclaimer Respondents' cite as an "undisputed fact" does not even appear on the Web pages contained in Complaint Counsel's Summary Decision Exhibits. *See Complaint Counsel's Counter-Statement of Material Facts in Response to Respondents' Statement of Undisputed Facts* (hereinafter referred to as "CC - CSF") at ¶ 4. Moreover, this fact is irrelevant and immaterial to any viable legal defense in Respondents' Motion for Summary Decision. As set forth below at pages 16-17, this disclaimer is ineffective as a matter of law in curing the deceptive nature of Respondents' claims.

Respondents raise these purported "omissions" to argue that "it cannot reasonably be disputed that the DCO ministry – including but not limited to its product offerings – is directed to a unique religious constituency." *Respondents' Mot. for Summ. Decision* at 5-6. A review of the Respondents' marketing materials, however, establishes that the audience for those claims are cancer patients. *See generally* Complaint Counsel's Statement of Material Facts as to Which There is No Genuine Issue (hereinafter referred to as "CCSF") ¶¶ 104-06, 111-12, 141-44, 147. Moreover, Patricia Feijo, Respondent James Feijo's wife, confirmed that purchasers of the DCO

Products do not have to believe in God for the products to work. *See* Deposition Transcript of Patricia Feijo at 118, l. 3-7 (submitted to Court on February 24, 2009). Respondents' argument is just another attempt by Respondents to press their distorted and incorrect interpretation of the First Amendment.[3]

2. Extrinsic evidence is not required to evaluate DCO's deceptive claims.

Respondents' assertion that extrinsic evidence "is required to prove deception and unfairness" is unsupported.[4] *Respondents' Mot. for Summ. Decision* at 11. Respondents cite the *FTC Policy Statement Regarding Advertising Substantiation* for the proposition that "'extrinsic evidence' is useful, including qualified expert testimony and consumer surveys." *Id.* Respondents refer to the *Policy Statement* out of context. The *Policy Statement* actually states that "[e]xtrinsic evidence, such as expert testimony or consumer surveys, *is useful to determine what level of substantiation consumers expect to support a particular product claim and the adequacy of evidence an advertiser possesses.*" *FTC Policy Statement Regarding Advertising Substantiation, appended to Thompson Med. Co.*, 104 F.T.C. 648, 839 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert denied*, 479 U.S. 1086 (1987) (emphasis added). As noted below, the appropriate level of substantiation required in cases involving health and safety claims is competent and reliable scientific evidence. Therefore, extrinsic evidence is not needed to determine the level of substantiation Respondents must possess to support their advertising claims.

---

[3] Respondents belabor this faulty interpretation in a Second Motion to Dismiss for Lack of Jurisdiction and Violation of Respondents' Constitutional Rights, which they filed alongside their Motion for Summary Decision on February 24, 2009.

[4] Respondents also argue that 15 U.S.C. § 45(n) requires Complaint Counsel to produce extrinsic evidence. *See Respondents' Mot. for Summ. Decision* at 13. Their argument is misplaced as § 45(n) sets forth no such requirement.

To the extent that Respondents assert that extrinsic evidence is necessary to determine the net impression of an advertisement, courts routinely have held that such evidence is not necessarily required, even when claims are implied. *See FTC v. Bronson Partners*, 564 F. Supp. 2d 119, 126-27 (D. Conn. 2008) (citing *Kraft*, 970 F.2d at 318, and *Thompson Med.*, 104 F.T.C. 648, 789-90, 794).

3. Respondents confuse the FTC's advertising substantiation requirements with the FTC's "net impression" analysis.

According to Respondents, "where the charges against a respondent are based on the 'overall net impression,' rather than on any express claims, those charges must be proved by substantial evidence of consumer expectations in order for the FTC to prevail." *Respondents' Mot. for Summ. Decision* at 10. Respondents claim that "such substantial evidence must address . . . 6 factors:

1. The type of claim;
2. The Products;
3. The consequences of a false claim;
4. The benefits of a truthful claim;
5. The cost of developing substantiation for the claim; and
6. The amount of substantiation experts in the field believe is reasonable." *Id.*

First, Respondents confuse the distinction between "overall net impression" and express claims. As noted above, when evaluating the net impression of an advertisement, the FTC considers both express and implied claims. Second, the six factors Respondents identify, which have come to be known as the "*Pfizer* factors," because they originated from the *Pfizer* case, are part of the FTC's substantiation doctrine, as adopted in the FTC's Substantiation Policy Statement. *See Pfizer, Inc.*, 81 F.T.C. 23 (1972); *FTC Policy Statement Regarding Advertising Substantiation*. Thus, the *Pfizer* factors are used to determine the level of evidence needed to

substantiate a claim, not, as Respondents claim, to determine "substantial evidence of consumer expectations."

As more fully explained in Complaint Counsel's Motion for Summary Decision, health and safety representations must be substantiated with "competent and reliable scientific evidence." *See FTC v. Nat'l Urological Group, Inc.*, No. 1:04-CV-3294-CAP, 2008 U.S. Dist. LEXIS 44145, at *77 (N.D. Ga. June 4, 2008) (granting the FTC's motion for summary judgment and finding that since all of defendants' "claims regard the safety and efficacy of dietary supplements; [] they must be substantiated with competent and reliable scientific evidence"); *FTC v. Natural Solution, Inc.*, No. 06-6112-JFW, 2007 U.S. Dist. LEXIS 60783, at *11-13 (C.D. Cal. 2007) (granting the FTC's motion for summary judgment and applying the "competent and reliable scientific evidence" standard to defendants' claims that their product prevents and treats cancer); *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 961 (N.D. Ill. 2006) ("Reasonable basis" required defendants to have "competent and reliable scientific evidence" when they made the claim that "the Q-Ray bracelet provides immediate, significant, or complete relief from various types of pain").

The uncontroverted evidence demonstrates that Respondents simply do not have any competent and reliable scientific evidence to substantiate their representations. Respondents conducted no scientific testing on the DCO Products, have not conducted any double-blind studies on the DCO Products, and have not conducted any controlled studies on any of the DCO Products. *See* CCSF ¶¶ 149-151, 159, 166-68. Respondents have not engaged any others to conduct scientific tests on any of the DCO Products. CCSF ¶¶ 152, 162-63, 169, 171. It was not Respondents' practice to obtain scientific studies about any of the components in their products. CCSF ¶ 154. Moreover, none of the five witnesses Respondents proposed as experts knows of,

or has conducted, any scientific studies on the DCO Products. CCSF ¶¶ 250-51, 263, 267, 299-300, 304-05, 340-41, 368, 372-73, 376-77, 380-81, 402-06, 415-17, 418-20, 440, 444-49, 469-477.

Complaint Counsel's cancer expert, Denis R. Miller, M.D., confirmed that there is no competent and reliable scientific evidence to substantiate the claims that the DCO Products treat, cure, or prevent cancer or tumors. CCSF ¶¶ 182-190, 195-97. Indeed, in his expert report and deposition testimony, Dr. Miller even noted the potential harm to cancer patients who use complementary medicine as a substitute for traditional medicine. *See generally* Deposition Transcript of Denis R. Miller, M.D. at 90, 122, and 176 (submitted to the Court on February 24, 2009). Furthermore, Respondents' expert, Sally LaMont, N.D., testified that there is a danger if consumers do not continue with traditional cancer therapy and stated that there always is a danger that people will take DCO products and not go and see their physicians.[5] CCSF ¶¶ 361, 363.

4. The distinction between "structure/function" claims and "health" claims is not relevant under Section 5 of the FTC Act.

Despite admitting in their Answer that they made the cancer and tumor claims alleged in the Complaint, Respondents insist that they have made only "structure/function," and not health claims, in their advertisements. *Respondents' Mot. for Summ. Decision* at 15. Respondents also seek to discredit Complaint Counsel's cancer expert with their contention that DCO's

---

[5] Respondents accuse Complaint Counsel of "try[ing] this case by presumption in the absence of actual harm . . . ." *Respondents' Mot. for Summ. Decision* at 25. Again, Respondents misapprehend well-established FTC law. Although deceptive claims are actionable only if they are material to consumers' decisions to buy or use the product, an element of proof that Complaint Counsel have met as detailed in their Motion for Summary Decision, the FTC need not prove actual injury to consumers. *See Deception Policy Statement, appended to Cliffdale Associates, Inc.*, 103 F.T.C. 110, 174 (1984), *cited with approval in Kraft, Inc. v. FTC*, 970 F.2d 314 (7th Cir. 1992), *cert. denied*, 507 U.S. 909 (1993).

advertising representations "are proper structure/function" claims" and that only "experts who are specifically qualified about dietary supplements (e.g. naturopaths and phyto-nutritionists)" could evaluate the claims at issue. *Id.* at 14.

(a) Respondents make disease claims, not simply structure/function claims.

Respondents' attempt to improvise a defense for their deceptive representations by invoking DSHEA and masquerading their serious disease claims as "structure/function" claims cannot change the nature of their advertisements. Respondents' advertisements make disease claims. Respondents' advertising claims on their Web site are or were replete with claims such as "**Bio*Shark Shark Cartilage** Stops tumor growth in its tracks," "**7 Herb Formula battles cancer**," "[i]f you suffer from any type of cancer, Daniel Chapter One suggests taking this products [sic], to fight it: . . . GDU Caps™," and "Bio*Mixx . . . is used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatments." CCSF ¶¶ 122, 125, 133, 137. Indeed, Respondents even disseminate a publication titled "The Most Simple Guide to the Most Difficult Disease: The Doctors' How-to Quick Reference Guide," (hereinafter referred to as the "Disease Guide") which recommends DCO products for 90 diseases, including cancer. CCSF ¶¶ 68, 106. Respondents also publish a "Cancer Newsletter." CCSF ¶¶ 65-67, 111-13, 140.

(b) Dr. Miller is properly qualified to evaluate these disease claims.

Respondents' argument that Dr. Miller is unqualified to evaluate the representations at issue because he is not an expert in dietary supplements is wrong. Respondents, in representing that their products are effective in preventing, treating, and curing cancer, have made serious disease claims, not structure/function claims. Because of the nature of these claims, Dr. Miller,

an oncologist, who as Respondents themselves concede, has "impressive" credentials, was thoroughly and uniquely qualified to evaluate whether there was competent and reliable scientific evidence supporting Respondents' representations. In addition, Respondents' own purported experts agreed with Dr. Miller's assessment, as borne out by their deposition testimony. *See generally* CCSF ¶¶ 230-31, 239, 258, 314, 321-22, 324, 340-42, 355, 358, 370, 386, 389-94, 402-13, 419, 423, 425, 427, 437-39.

(c) All advertising claims must be truthful, not misleading, and substantiated.

Respondents' attempt to seek refuge under DSHEA is similarly unavailing. The FDA's regulatory distinctions between "structure/function" and "health" claims under DSHEA do not apply to Section 5 of the FTC Act. As noted in the FTC staff's guide, *Dietary Supplements: An Advertising Guide for Industry* (hereinafter referred to as the "*Dietary Supplements Guide*"), "advertising for any product – including dietary supplements – must be truthful, not misleading, and substantiated." FTC, *Dietary Supplements: An Advertising Guide for Industry* at 1 (2001). The FTC staff warned "*all parties who participate directly or indirectly in the marketing of dietary supplements have an obligation to make sure that claims are presented truthfully and to check the adequacy of the support behind those claims.*" *Id.* at 2 (italics in original). Respondents never adequately supported their cancer claims, as they were required to do.[6]

---

[6] Example 32 in the *Dietary Supplements Guide* warns that, even if a supplement advertisement claims that a particular liquid mineral solution was "a popular American folk remedy since early pioneer days for shrinking tumors," the advertisement should not be used because it "is likely to convey to consumers that the product is an effective treatment for cancer;" "[t]here is no scientific support for this disease benefit;" and "[b]ecause of the potential risks to consumers of taking a product that may or may not be effective to treat such a serious health condition, possibly without medical supervision, the advertiser should not make the claim." *Dietary Supplements Guide* at 22. The Respondents here should have heeded that advice and not made their unsubstantiated cancer claims.

DSHEA in no way altered the FTC's approach to truth in advertising, and, in fact, as Respondents acknowledge in their Motion, DSHEA is fully consistent with this approach. *See* 21 U.S.C. § 343(r)(6); *Respondents' Mot. for Summ. Decision* at 15. FTC staff explained in the *Dietary Supplements Guide* that "a statement about a product's effect on a normal 'structure or function' of the body may also convey to consumers an implied claim that the product is beneficial for the treatment of a disease. If elements of the ad imply that the product also provides a disease benefit, the advertiser must be able to substantiate the implied disease claim even if the ad contains no express reference to disease." *Dietary Supplements Guide* at 4. Respondents cannot explain how their "Disease Guide," "Cancer Newsletter," and other cancer-related advertisements do not make disease claims. As detailed at pages 6-9 of Complaint Counsel's Motion for Summary Decision and page 13 *supra*, there are express references to disease, and the net impressions conveyed by both the express and implied claims – that the DCO Products can treat, prevent, or cure cancer or tumors – must be substantiated. This year, the FDA even released guidance stating that it would adopt the FTC's substantiation standard of "competent and reliable scientific evidence":

> The FTC has typically applied a substantiation standard of "competent and reliable scientific evidence" to claims about the benefits and safety of dietary supplements and other health-related products. FDA intends to apply a standard for the substantiation of dietary supplement claims that is consistent with the FTC approach. FDA, *Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act* (December 2008), available at http://www.cfsan.fda.gov/~dms/dsclmgu2.html.

(d) Respondents did not use proper DSHEA disclaimers, but even if they did, DSHEA disclaimers cannot negate unsupported disease claims.

Respondents' reference to their use of disclaimers also is unavailing. As noted above, contrary to what they state is an "undisputed fact," one only needs to review the attachments to the Complaint to see that Respondents' advertisements do not even contain the DSHEA disclaimer that "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent disease," a disclaimer that must be "prominently displayed and in boldface type." *See* 21 U.S.C. § 343(r)(6); CC - CSF ¶ 4. Instead, any disclaimers Respondents do make, where they do appear, are in fine-print. For example, at the bottom of their product pages on the DCO Web site, under the copyright line, Respondents simply state: "The information on this website is . . . not intended to diagnose a disease." CC - CSF ¶ 3. Such disclaimers are inadequate to cure Respondents' deceptive claims, which are prominently featured on the Web site. It is well-established that advertisers cannot use fine print to contradict other statements in an advertisement or to clear up misimpressions the advertisement would otherwise leave. *Deception Policy Statement*, 103 F.T.C. at 180-81. To be effective, disclosures must be clear and conspicuous. *See, e.g., Thompson Med.*, 104 F.T.C. at 842-43 (1984). *U.S. v. Lane Labs* – a case cited by Respondents in their Motion – makes it clear that any such disclaimer also must be in boldface type and is permissible only if the claim is properly substantiated. *U.S. v. Lane Labs, Inc.*, 324 F. Supp. 2d 547. 564 (D.N.J. 2004) (stating that "[t]hese types of claims are permissible under DSHEA **only if the manufacturer of the dietary supplement has "substantiation" that the "statement is truthful and not misleading" and if the label contains the following disclaimer in boldface type**: "This statement has not been

evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease")(emphasis added).

Even if a prominent, bold-type DSHEA disclaimer had been used, that could not cure Respondents' deceptive statements. As the *Dietary Supplements Guide* states, "the inclusion of the DSHEA disclaimer is not likely to negate the explicit disease claims made in the ad, and will not cure the fact that the claims are not substantiated." *Dietary Supplements Guide* at 24 (quoting "Example 34").

IV. THE FTC'S ACTION DOES NOT VIOLATE RESPONDENTS' DUE PROCESS RIGHTS.

In their Motion for Summary Decision, Respondents claim that the Commission is "try[ing] this case by presumption" and "improperly shift[ing] the primary burden of proof to DCO." *Respondents' Mot. for Summ. Decision* at 25. Respondents further claim that with this lawsuit, the FTC is acting "as the arbiter of what is good and healthy" and casting itself "as the *parens patriae* of healthcare for all citizens." *Id.* Respondents' assertion is wrong.

Respondents cite no relevant case authority that the way the FTC proceeds in this matter (which is the same way the Commission has proceeded in all advertising cases) is a violation of Due Process rights or represents the Commission serving as "*parens patriae* of healthcare for all citizens." Contrary to Respondents' repeated protestations, the law that governs this case is FTC law. Here, Complaint Counsel simply are enforcing Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), which prohibits unfair or deceptive acts or practices in or affecting commerce.

Complaint Counsel have submitted uncontroverted evidence that (1) Respondents distribute the DCO Products in commerce; (2) Respondents claim that the DCO Products prevent, treat, or cure cancer or tumors; (3) Respondents disseminate these claims about their

products to consumers; and (4) Respondents did not possess substantiation for such claims at the time they were made. The Commission is not violating Respondents' Due Process rights with this action or serving as the "*parens patriae* of healthcare for all citizens." Rather, the Commission is enforcing the FTC Act, passed by Congress, that regulates deceptive advertising.

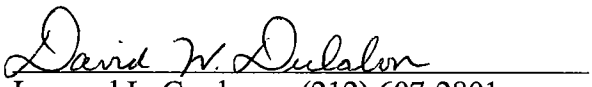
Well-established FTC law states that when disseminating advertisements, advertisers must have a reasonable basis for advertising claims before they are disseminated. *FTC Policy Statement Regarding Advertising Substantiation.* Advertisers must possess at least the level of substantiation expressly or impliedly claimed in the ad. *See Honeywell, Inc.*, 126 F.T.C. 202 (1998). For health or safety claims, it is well-recognized that the FTC requires "competent and reliable scientific evidence" as substantiation for those claims. *See Nat'l Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *77 (granting the FTC's motion for summary judgment and finding that since all of defendants' "claims regard the safety and efficacy of dietary supplements; [] they must be substantiated with competent and reliable scientific evidence"); *Natural Solution*, 2007 U.S. Dist. LEXIS 60783, at *11-13 (granting the FTC's motion for summary judgment and applying the "competent and reliable scientific evidence" standard to defendants' claims that their product prevents and treats cancer). The "competent and reliable scientific evidence" standard typically is defined as "tests, analyses, research, studies, or other evidence based upon the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." *See, e.g., Brake Guard Prods., Inc.*, 125 F.T.C. 138 (1998); *Automotive Breakthrough Sciences, Inc.*, 126 F.T.C. 229 (1998). Specifically, to prove that a cancer prevention and treatment claim is likely to deceive or mislead, the FTC must demonstrate *either* that "the express or implied message conveyed by the

ad is false" *or* that "the advertiser lacked a reasonable basis for asserting that the message was true." *Natural Solution*, 2007 U.S. Dist. LEXIS 60783, at *10. Here, Complaint Counsel have alleged and have proven that Respondents lacked a reasonable basis to substantiate their representations that the DCO Products prevent, treat, or cure cancer or tumors – just as Complaint Counsel and the Commission routinely have done in other advertising cases.

V. CONCLUSION

For the reasons set forth above, Complaint Counsel respectfully request that the Administrative Law Judge deny Respondents' Motion For Summary Decision.

Respectfully submitted,



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

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

Dated: March 10, 2009