ORIGINAL

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

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

RESPONDENTS SECOND MOTION TO AMEND ANSWER & MEMORANDUM IN SUPPORT

MOTION

COME NOW Respondents and move the Administrative Law Judge for an Order under 16 CFR §3.15 granting Respondents leave to amend their Answer to the Federal Trade Commission ("FTC") complaint. Specifically, Respondents seek leave to amend their Answer by the addition of a First Affirmative Defense to read as follows:

> FIRST AFFIRMATIVE DEFENSE
>
> As and for a first separate, distinct and affirmative defense, Respondents allege that the action of the Federal Trade Commission in filing the Complaint and seeking the Order included therewith substantially burden Respondents' free exercise of religion in violation of 42 U.S.C. Section 2000bb-1(a) and (c).

This Motion is based on the subjoined Memorandum.

MEMORANDUM IN SUPPORT

FTC Rule of Practice 3.15 (16 CFR § 3.15) allows for the amendment of a pleading "whenever determination of a controversy on the merits will be facilitated thereby [and] to avoid prejudicing the public interest and the rights of the parties." *See* 16 CFR §13.5(a)(2).

A. The Proposed Amendment Facilitates the Determination of This Controversy and Prevents Prejudice to Respondents.

One of Respondent's foremost claims in this proceeding is that the FTC standards governing deceptive and false advertising, as applied to Respondents, substantially burden Respondents' free exercise of religion. *See Respondents'* Objection and Memorandum in Opposition to Complaint Counsel's Motion to Compel Production of Documents, pp. 13-17. 42 U.S.C. Section 2000bb-1(a) provides that the "Government shall not substantially burden a person's free exercise of religion even if the burden results from a rule of general applicability...." 42 U.S.C. Section 2000bb-1(c) further provides that "[a] person whose religious exercise has been burdened in violation of this section may assert that violation as a ... defense in a judicial proceeding and obtain appropriate relief against a government." *See* Gonzales v. O Centro Espirita Beneficente Uniao Do Vegetal, 546 U.S. 418, 424 (2006).

According to 42 U.S.C. Section 2000bb-2(1), the FTC is subject to the provisions of 42 U 2000bb-1 in that the FTC is a "branch, department, agency, [or] instrumentality ... of the United States." According to 42 U.S.C. Section 2000bb-1(c), Respondents — as a party defendant to this case and controversy, having alleged in their first affirmative defense a personal injury fairly traceable to the FTC's unlawful conduct and for which they are likely to be redressed by the

requested relief — has standing under Article III of the United States Constitution. See Allen v. Wright, 468 U.S. 737, 751 (1984).

Allowing Respondents to invoke the protections of their free exercise of religion under the Religious Freedom Restoration Act ("RFRA") conforms with Congress's statement that one of its purposes is "to provide a claim or defense to persons whose religious exercise is substantially burdened by government." 42 U.S.C. section 2000bb(b)(2).

B. The Proposed Amendment Conforms to the Evidence.

According to RFRA Section 2000bb-2(4), "the term 'exercise of religion' means religious exercise, as defined in section 2000cc-5." Section 2000cc-5(7)(A) states that "'religious exercise' includes **any** exercise of religion, whether or not compelled by, or central to, a system of religious belief." (Emphasis added). The discovery process in this case has uncovered substantial evidence that the FTC complaint and proposed orders would substantially burden Respondents' "religious exercise."

C. Justice Requires Leave for Granting the Amendment.

RFRA's Section 2000bb(a) includes the findings that "laws 'neutral' toward religion may burden religious exercise as surely as laws intended to interfere with religious exercise," and that "governments should not substantially burden religious exercise without compelling justification." Thus, Section 2000bb-(b) announces that the purpose of 2000bb-1 is: (1) "to restore the compelling interest test set forth in Sherbert v. Verner ... and Wisconsin v. Yoder and to guarantee its application **in all cases** where free exercise of religion is substantially burdened," and (2) to provide a ... defense to persons whose religious exercise is substantially burdened by government." Otherwise, the constitutional right of free exercise of religion would not be

"secured" as an "unalienable right," as provided for by the First Amendment guarantee of free exercise of religion. *See* 42 U.S.C. Section 2000bb(a).

The FTC may claim that its rules governing false and deceptive advertising are "neutral," but the application of those rules "burden [Respondents'] religious exercise as surely as laws intended to interfere with religious exercises." Thus, it would be in the interest of justice for Respondents to invoke RFRA's Section 2000bb-1(a) and (c) as a defense in this case.

D. No Prejudice Will Result.

Citing Foman v. Davis, 371 U.S. 178, 182 (1962), the United States District Court for the Northern District of California observed that "[i]n the absence of any apparent or declared reason — such as undue delay, bad faith or dilatory motive ... undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc. — leave sought should, as the rules require, be 'freely given.'" Reiffen v. Microsoft, 270 F. Supp. 2d 1132, 1159 (N.D. Cal., 2003).

Respondents' amendment does not create the need for any additional discovery, nor will it delay the proceedings. Thus, Complaint Counsel is not prejudiced. To the contrary, Complaint Counsel has been amply forewarned of the religious nature of Respondents' ministry and of their claims of religious freedom based upon the free exercise guarantee of the First Amendment. *See, e.g.,* Respondents' Motion to Dismiss and Supporting Memorandum of Points and Authorities, pp. 1-4, 17-21. As RFRA's Section 2000bb(a) states, Section 2000bb-1 is simply and specifically designed to secure the full scope of that guarantee.

For the foregoing reasons, Respondents' request that this Motion be granted.

Respectfully submitted February 24, 2009.

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

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

SWORN STATEMENT OF COUNSEL FOR RESPONDENT

This statement is being submitted in accordance with Additional Provision #5 of the Court's Scheduling Order of October 28, 2008, and in support of Respondents' Second Motion to Amend their Answer to the Complaint.

I certify that I have conferred with Complaint Counsel Theodore Zang, Jr. in a good faith effort to resolve the issues raised by the attached Second Motion to Amend Answer and have been unable to reach an agreement. I conferred with Counsel Zang about the possibility of Complaint Counsel agreeing to the proposed amendment on February 24, 2009.

I swear under penalty of perjury that the foregoing statement is true and correct.

Dated this 24th day of February, 2009.

Swankin & Turner
Attorneys for Respondents

By: _____
James S. Turner

IN THE UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
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In the Matter of	)	**Docket No.: 9329**
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Daniel Chapter One	)	
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[PROPOSED] ORDER
GRANTING RESPONDENTS' MOTION TO AMEND ANSWER

On February 24, 2009, counsel for Respondents filed their Second Motion to Amend Respondents' Answer *In the Matter of Daniel Chapter One*, Docket No. 9329. The Court being fully advised,

IT IS ORDERED that Respondents' Answer *In the Matter of Daniel Chapter One*, Docket No. 9329, be, and is hereby amended as stated in Respondents' motion.

Dated this___ day of _____, 2009.

_____
D. Michael Chappell
Administrative Law Judge

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

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

Respondents' Motion for Summary Decision and Memorandum in Support

COME NOW Respondents Daniel Chapter One and James Feijo (hereinafter collectively, "DCO") who move this Court for an Order on Summary Decision declaring that the FTC lacks sufficient evidence at the close of discovery to proceed with its charges against DCO as a matter of law.

This Motion is based on the Memorandum below, on the records and files herein, and on the Sworn Declarations of DCO's counsel supplied herewith.

I. Introduction

DCO is a religious ministry, organized as such under the laws of Washington State.[1] The DCO website states that DCO was formed "as a health and healing ministry in the summer of 1986."[2] The organizing principle of DCO's ministry is reflected by its very name. Daniel Chapter One is a book from the

[1] DCO incorporates herein the details of its ministry and history as a religious organization as described in its companion Motion to Dismiss on Constitutional grounds, which is filed contemporaneously with this Motion.

[2] dc1pages.com/danielchapterone/index.php?option=com_content&task=view&id=57&Itemid=76

Bible's Old Testament, the text of which states that proper religious practice includes a natural diet. This principle is reflected throughout DCO's religious and educational communications, which are accessible to DCO followers and constituents via the DCO website and other media.

Part of DCO's religious ministry involves the supply of natural dietary supplements. It is these DCO supplements, and DCO's claims about them, that prompt the FTC's Complaint here. In light of the connection between DCO's ministry and its dietary supplements, this case is unlike any to have come before the FTC to date.

The FTC's Complaint against DCO contends that DCO has created an "overall net impression" that four specific supplements are offered to cure or treat cancer. The FTC Complaint charges that this activity is therefore false and misleading under 15 USC § 52, and unfair and deceptive under 15 USC §45.

DCO disputes the FTC charges as a matter of substance, and based on several Constitutional grounds. However, this Motion is not about the substantive controversy involved in the FTC's charges. There are no issues of material fact relevant to the legal issue raised in this Motion.

By this Motion, DCO will show that the FTC's charges must be dismissed due to the FTC's inability at this stage of the proceedings to meet its evidentiary burden of proof. There can be no factual dispute. Discovery is now closed, and the record reveals that the FTC has ignored or otherwise failed to produce the evidence required to prove essential elements of the statutory charges against DCO. Instead, the FTC has relied almost exclusively on presumptions. A

defendant/respondent is entitled to summary judgment when it can show the plaintiff/prosecution lacks the necessary evidence to sustain its burden at trial. Such is the case here.

II. Analysis of the DCO Mosaic

In the present case, the FTC's Complaint is based on charges that DCO has created an "overall net impression" of cancer cures via its website.[3] The FTC does not contend that DCO has made express claims of cancer cures. FTC case law, guidelines and policy statements have stated clearly over the years that when allegations of deception are based on the "overall net impression," the entire framework and context of the representations must be considered, along with other important factors.

> "It is necessary in these cases to consider the advertisement in its entirety, and not to engage in disputatious dissection. The entire mosaic should be viewed rather than each tile separately." *FTC v. Sterling Drug*, 317 F. 2d. 669, 674 (2nd Cir. 1963).

To evaluate the DCO mosaic, it is important to know two things: first, what the FTC's Complaint omits about DCO claims; and second, what the FTC's Complaint misrepresents about DCO claims.

A. What the Complaint Omits

[3] See FTC Answers to DCO Interrogatories # 1 and 3 through 10, attached as Exhibit A to the McCormack Declaration.

The FTC Complaint is based on DCO representations that appear in the DCO website and other media. The DCO representations on which the FTC relies are contained in the Exhibits attached to the Complaint.[4] FTC investigators and legal staff discovered DCO by means of an "internet surf" (i.e., google search) that targeted DCO along with over a hundred other dietary supplement manufacturers.[5] The investigators who designed the surf, who targeted DCO and who researched DCO's claims had no background in health care.[6] The FTC administrator who instigated this particular web surf testified that the decision to pursue the DCO Complaint was based on "common sense" and FTC policy. [7] The FTC's only disclosed expert did not review this case until after the Complaint in this matter was filed.[8]

The FTC's myopic pursuit of DCO resulted in at least two errors in the DCO Complaint. The first of these errors is an error of omission, i.e. what the FTC Complaint leaves out about DCO's website. The second error is one of commission, i.e. what the FTC misrepresents about the DCO website and other materials.

In the first instance, the FTC has omitted several indisputable features from the mosaic that is DCO and its claims. The first omission is the name Daniel Chapter One itself, a book of the Old Testament. The following comes from the DCO website:

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[4] See FTC Answers to DCO Interrogatories 1 at Exhibit A to McCormack Declaration.
[5] Lynne Colbert Dep, at _____. Exhibit B to McCormack Declaration.
[6] Colbert Dep, at _____; Richard Cleland Dep, at _____, Exhibit C to McCormack Declaration.
[7] Cleland Dep at _____.
[8] See Miller Dep at ____, in which he testified that his source for review of DCO alleged claims was the Complaint itself. Exhibit D to McCormack Declaration.

Welcome to Daniel Chapter One Online!

Daniel Chapter One got its name from the Old Testament, book of Daniel, first chapter. In that account, Daniel and his men were being held in Babylonian captivity, and were expected to eat the king's food -so as to be fit and strong servants.

But Daniel asked permission to eat a vegetable diet and to drink only water, rather than partake of the rich meats and wine of the king. The king's men said no; surely Daniel would get sick, maybe die! So Daniel asked for a trial of 10 days. At the end of Chapter One, it is recorded that Daniel and men, after that trial, were strong in flesh, with bright eyes, and continued to grow in knowledge and wisdom.

So it was that the founders of Daniel Chapter One®, since trying their own "Daniel Chapter One" diet for 10 days and discovering that indeed they felt fantastic, decided to name the health food store they began, after that portion of the bible. The company, then and now, does not push a vegetarian diet for wellness, but simply a healthy diet of wholesome, natural foods - rather than the unwholesome, artificial food of the modern world. It's about eating with purpose, and partaking of the good food God has given us for health and healing. Good food for physical, mental, and emotional health includes herbs and nutrients.

The tiny health food supplement store Daniel Chapter One® grew and grew, from one to several locations. As the store grew, so the founders grew - in knowledge and wisdom, as in fact Daniel had experienced! The store quickly became more of a natural healing center. From their hands-on expertise, the couple began next to design the nutritional supplement product line now known world over as Daniel Chapter One.[9]

Every page of the DCO website contains the following statement:

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

The description of every product offered on the DCO website includes the following language:

**These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent disease.* (Italics and "*" supplied in original.)[10]

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[9] dc1pages.com/danielchapterone/index.php?option=com_content&task=view&id=16&Itemid=33

[10] See e.g. dc1store.com/component/page,shop.product_details/category_id,46/flypage,shop.garden_flypage/product_id,25/option,com_virtuemart/Itemid,44/

From this more complete picture of the DCO mosaic, it cannot reasonably be disputed that the DCO ministry – including but not limited to its product offerings – is directed to a unique religious constituency. This indisputable fact bears on the burden of proof that the FTC is required to meet.

B. What the Complaint Misrepresents

The FTC Complaint also contains errors of commission, i.e. what the Complaint misrepresents. The Complaint identifies DCO representations about 4 DCO products: (1) Bioshark; (2) 7 Herb Formula; (3) GDU; and (4) BioMixx. At ¶18 of the Complaint, the FTC sets forth the representations attributed to DCO for each product.

The following chart juxtaposes what the FTC attributes to DCO with what DCO actually wrote on its website. This juxtaposition is important not only to a fair evaluation of DCO's "structure/function" claims and the substantiation for those claims, but also to an understanding of the "overall net impression" that the FTC must now prove with substantial evidence consistent with the required standards of proof.

The FTC's attribution to DCO	DCO's actual claim
About Bioshark: *"Bioshark inhibits tumor growth"* *"Bioshark is effective in the treatment of cancer"*	*"Bioshark is pure skeletal tissue of sharks which provides a protein that inhibits angiogenesis -- the formation of new blood vessels. This can stop tumor growth and halt the progression of eye diseases . . ."*
About 7 Herb Formula: *"7 Herb Formula is effective in treating and curing cancer"*	*"purifies the blood, promotes cell repair, fights tumor formation, and fights pathogenic bacteria"*

"7 Herb Formula inhibits tumor formation"	
About GDU: *"GDU eliminates tumors"*	*"contains natural proteolytic enzymes (from pineapple source bromelain to help digest protein --even that of unwanted tumors and cysts. This formula also helps to relieve pain and heal inflammation. . .GDU is also used for. . .and as an adjunct to cancer therapy. GDU possesses a wide range of actions including anti-inflammatory and antispasmodic activity. . ."*
About BioMixx: *"BioMixx is effective in the treatment of cancer"* *"BioMixx heals the destructive effects of radiation and chemotherapy"*	*"boosts the immune system, cleanses the blood and feeds the endocrine system to allow for natural healing. It is used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatments."*

Each of the statements that DCO actually made about its products is truthful and substantiated, as explained in more detail below. In contrast, the FTC has no qualified proof to the contrary that will support its charge of "overall net impression."

III. Basis and Standard for Summary Decision

It bears emphasizing that this Motion for Summary Decision is based on the FTC's lack of competent, qualified evidence altogether, notwithstanding some potential factual issues that are not relevant to this Motion. To survive this Motion, the FTC must offer sufficient qualified evidence, not mere allegations. A "scintilla" of evidence, evidence that is "merely colorable", and evidence that "is

not significantly probative" will not defeat the motion. See e.g. *Anderson v. Liberty Lobby*, 477 U.S. 242 (1986). It is also true, according to the elements of proof described below, that presumptions about the facts will not defeat this Motion.

This Brief shows that the FTC does not have the evidence to meet its burden in this case under the *preponderance of evidence* standard. Nevertheless, DCO contends that the standard of proof required of the FTC in this case is *clear, cogent and convincing* evidence in light of the Constitutional liberty and property interests involved in this case. See e.g. *Addington v. Texas*, 441 U.S. 418 (1970). This standard applies even in the summary judgment context, i.e. the FTC must produce clear, cogent & convincing evidence to defeat DCO's Motion. See *Anderson*.

Addington articulated the reasons for the *clear, cogent & convincing* standard in a case like this one. Though that case concerned the standard of proof in an involuntary civil commitment proceeding, the *Addington* Court's analysis properly fits the circumstances here. For instance, *Addington* states that the nature and importance of the Constitutional interest determines the proper standard of proof. In this case, the Constitutional interests include the First Amendment rights to free speech and religious freedom possessed by both DCO and its constituents.

Addington states that proper standard of proof flows from the relative importance attached to the ultimate decision, i.e., the more important the decision, the higher the burden of proof. Id. at 423. *Addington* established that there is a constitutional necessity for an intermediate standard of proof (i.e.,

"clear," "cogent," "unequivocal," and/or "convincing") in circumstances where the interest is greater than a mere money judgment but less than a generic criminal proceeding. *Id.* at 424. The intermediate *clear, cogent & convincing* standard is required in a variety of civil situations "to protect particularly important individual interests," namely Constitutional interests that are more important than the interest against erroneous imposition of a mere money judgment. *Id.*

Addington also noted that while the interest of the individual may dictate a higher standard of proof to avoid erroneous deprivation, important interests of the state are likewise vindicated by the higher burden because state interests would be compromised by a lower burden of proof, thus needlessly increasing the incidents of erroneous results. *Addington*, at 425.

Indeed, it is not just DCO's constitutional interests that are at stake. Also involved here is the interest of the public, constituents of DCO's ministry who exercise their right to access DCO's religious and educational messages, and the related wellness products and information. The public's interest is as much a part of this case as is DCO's interest.

In any event, now that discovery has closed, DCO contends that the FTC charges are wholly unsupported by the required evidence as a matter of law, even if this Court applies a *preponderance* standard.

IV. The Law Requires the FTC to Produce Extrinsic Evidence

There are a number of factors that bear on the FTC's burden of proof, and the elements of that proof required in a case like this one. First, in evaluating the FTC charges under 15 USC §§ 45 and 52, the Commission employs a "reasonable

basis" test for evaluating whether claims about Challenged Products are unfair, deceptive and/or misleading. See, e.g. *FTC v. Pharmatec*, 576 F. Supp. 294 (D.C.D.C. 1983); accord, FTC Policy Statement appended to *Thompson*[11]. This test requires the FTC to consider whether there is a "reasonable basis" for the claims, i.e. is there reliable and competent information to substantiate the efficacy claims made for the Products. *Thompson*, 791 F. 2d at 193-194.

The FTC must also address several other considerations in order to prove violations of §§45 and 52. For instance, 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. *Thompson*, 791 F. 2d at 197. Accord, *Thompson* Policy Statement at p. 2.

Absent actual evidence of consumer expectations, according to the *Thompson* Policy Statement, the FTC's substantial evidence must address the following 6 factors:

- The type of claim;
- The Products;
- The consequences of a false claim;
- The benefits of a truthful claim;
- The cost of developing substantiation for the claim; and
- The amount of substantiation experts in the field believe is reasonable.

See *Thompson* Policy Statement at p. 2.

The *Thompson* Policy Statement states clearly that these factors apply to charges of false/misleading advertising, deception and unfairness. "The Commission's determination of what constitutes a reasonable basis depends, as it

[11] *Thompson Medical*, 104 FTC 648 (1984), aff'd 791 F. 2d 189 (D.C Cir 1986).

does in an unfairness analysis, on a number of factors relevant to the benefits and costs of substantiating a particular claim. These factors include [the list described above.]"

These factors are identical to the statutory requirements of 15 USC 6§45(n) applicable to claims of unfairness. In other words, the FTC must effectively meet the same standards of proof for false advertising and deception, as §45(n) requires for unfairness.

The *Thompson* Policy Statement goes on to say that "extrinsic evidence" is useful, including qualified expert testimony and consumer surveys. In fact, under 15 USC §45(n), extrinsic evidence is required. Presumptions and policy guidance alone will not suffice.

The Courts and the Commission have explained why extrinsic evidence about these factors is required in a case like this one. For instance, at the outset, evaluation of the 6 factors in an "overall net impression" case involves a "highly factual inquiry. "[12] One reason for that inquiry is because even the most orthodox commercial advertisers "are not required to substantiate claims that were not made." *Thompson* Policy Statement at footnote #3. Only a "highly factual inquiry" can justify overall net impression claims.

A. Extrinsic Evidence is Required to Prove Deception and Unfairness.

As an adjunct to the required evidence that bears on the 6 factors of the *Thompson* Policy Statement, the FTC must also examine the allegedly deceptive practice from the perspective of a reasonable consumer. If the representation is

[12] Bene*ficial Corp. v. FTC*, 542 F.2d 611, 617 (3rd Cir. 1976).

directed *primarily* to a particular group, the FTC is required to examine reasonableness from the perspective of that group.[13] See FTC Policy Statement appended to *Cliffdale Associates*[14] (hereinafter *Cliffdale* Statement). That is, the FTC must determine the effect of the challenged claims on a reasonable member of the target group, e.g. constituents of a religious ministry devoted to natural health and wellness.[15]

When such a specific group of recipients is involved, extrinsic evidence about that group's reasonable perceptions is necessary. *Id.* See e.g. *Thompson*, 791 F. 2d at 197, where the Circuit Court made special note that "The issue of [consumer perception of the claims] was extensively addressed by expert testimony." This is just one of the reasons why understanding the full mosaic of DCO as a religious ministry is so important, because it underscores the requirement for actual extrinsic evidence.

The FTC understands why it's necessary to prove consumer perception with actual extrinsic evidence:

> "[Consumer perception scores] may reflect basic consumer skepticism of promotional claims, however worded."[16]
>
> "Although some variations in consumer interpretation of qualified health claims is inevitable given what are almost certainly broad differences in [consumers'] background beliefs, the degree of variation observed in the research is nonetheless surprising . . ."[17]

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[13] Note that the representation need not be directed *exclusively* to a particular group.
[14] See FTC Statement on Deception, appended to *Cliffdale Associates*, 103 FTC 110, 174 (1984), hereinafter *Cliffdale* Statement.
[15] See *Cliffdale* Statement at footnotes 13 and 29.
[16] See p. *In the Matter of Assessing Consumer Perceptions of Health Claims*, FTC Staff Comments, p. 10. Complaint Counsel produced this document as indicative of FTC policy bearing on this matter under Bates document nos. FTC-DCO 870 to 894. See Appendix 1 attached hereto.
[17] Id, at footnote 39.

These statements reveal an understanding that consumer perceptions vary greatly, and in surprising ways. Presumptions about consumer perception do not pass muster under the standards of the *Thompson* and *Cliffdale* Policy Statements, just as they do not pass muster under §45(n). The FTC must produce substantial evidence about consumer perception, and the 6 factors articulated by the *Thompson* and *Cliffdale* Policy Statements. This requirement is in accord with, as well as independent from §45(n).

B. Qualified Expert Evidence is Required to Challenge Substantiation.

Qualified expert testimony or other extrinsic evidence is required not just to satisfy the FTC's burden on the issue of consumer perception. Qualified expert testimony is also required to address the substantiation for "overall net impression" claims. This is especially true for cases involving natural dietary supplements, where science and law has prompted standards for dietary supplement claims that are dramatically different from the standards applied to drugs.

As a general matter, the FTC's Official Guidance to the Dietary Supplement Industry says that the amount and type of substantiation evidence required for dietary supplements is determined by what experts *in the relevant field* would consider to be adequate.[18] This is consistent with the qualifications required of an expert under the relevancy prong of the *Daubert* standard.[19]

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[18] *Dietary Supplements: An Advertising Guide for the Industry*, produced by Complaint Counsel as evidence of policy in this case. A copy is provided at Appendix 2, Bates no. FTC-DCO 1041 to 1070. See p. 1052, specifically.

[19] *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

In other words, without testimony from experts who are specifically qualified about dietary supplements (e.g. naturopaths and phyto-nutritionists), the FTC cannot meet its burden of proof about DCO's claims and the alleged lack of substantiation for those claims as a matter of law.

1. DCO's Structure/Function Claims are Not the Same as Health Claims for Drugs.

The FTC's need for expert testimony from the field of dietary supplements is drawn from the sharp distinction expressed by Congress between the regulation of dietary supplements claims on the one hand, and the regulation of drugs and drug claims on the other hand. Few, if any, FTC cases have addressed this distinction, as this case now must.

The Dietary Supplement Health and Education Act (DSHEA) authorizes dietary supplement manufacturers to make "structure/function" claims about their products:

> [A] statement for a dietary supplement may be made if:
>
> (A) the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, **describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans**, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient,
>
> (B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and
>
> (C) the statement contains, prominently displayed and in boldface type, the following: "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.".
>
> A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.

See 21 USC §343(r)(6). [Bold emphasis added.]

The meaning of this statute is well settled: a natural supplement provider is lawfully allowed to make structure-function claims describing how a particular nutrient or dietary supplement may affect a structure or function of the human body. See *Pearson v. Shalala*, 164 F. 3d 650 (1999); and *U.S. v. Lane Labs*, 324 F. Supp. 2d 547, 565 (2004). A fair reading of the actual DCO claims, as opposed to the inferences drawn by the FTC Complaint, shows that DCO claims are proper structure/function claims. Nowhere on the face of the actual DCO statements does DCO state that its products "diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases," which are the claims prohibited by DSHEA. Each of the DCO statements on their face describe how the products and/or their constituent ingredients support the structure/function of the human body, as "adjuncts" to – not in lieu of - cancer treatment. The efficacy of these DCO claims is corroborated by DCO's experts qualified in natural healing modalities, as discussed below.

It is well settled, and self-evident, that FTC law corresponds with DSHEA. Logic dictates that DSHEA influences FTC actions just as significantly as it does FDA actions. Lest there be any doubt as to the role DSHEA must play on FTC law, the FTC's own words put the issue to rest:

> "[S]tructure/function claims . . . refer to representations about a dietary supplement's effect on the structure or function of the body for maintenance of good health . . . This [FDA] requirement is fully consistent with the FTC's standard that advertising claims be truthful, not misleading and substantiated."[20]

[20] FTC Dietary Supplement Advertising Guide, footnotes 2 and 3; Bates page FTC-DCO 1068.

In light of DSHEA, it stands to reason that expertise on health claims for drugs is not the same field as expertise on structure/function claims for dietary supplements. Without expert testimony properly qualified for dietary supplements, the FTC does not meet its burden of proof.

To summarize this section, the FTC must address the 6 factors identified by the *Thompson* Policy Statement. It must do so with substantial evidence. These factors apply to FTC charges of deception, just as they apply to charges of unfairness. These factors mirror the requirements of 15 USC §45(n). As part of this inquiry, the FTC must also produce extrinsic evidence bearing on these factors especially when the charges are based on the "overall net impression," as opposed to express claims. The required extrinsic evidence must address the perceptions of a reasonable person within the target audience to whom the Respondent's activity is primarily directed. And the extrinsic evidence must include qualified expert testimony about dietary supplements, about the structure/function claims made for those dietary supplements, and about the substantiation that supports those claims.

The record of discovery taken in this case reveals that the FTC has not met any of these requirements.

V. The FTC Lacks the Evidence to Sustain the Charges.

The FTC has properly identified only three witnesses in this case. Two of those are FTC investigators who are identified as fact witnesses. The third witness is an expert witness qualified in the area of conventional cancer treatment and

research. As revealed by their testimony, as well as the testimony of the FTC administrator who conceived of the internet surf that resulted in this action, the FTC has failed to address the required elements of proof in almost every instance.

A. The FTC did not consider the required elements of proof.

1. FTC witness Michael Marino is an investigator whose role was limited to gathering evidence: he "recorded" the DCO website; he made an undercover website purchase of DCO products; he purchased recordings of two radio programs, and he did BBB, Lexis and Dunn & Bradstreet searches for DCO.[21] Mr. Marino had virtually no experience that he could recall investigating dietary supplement manufacturers before this DCO matter.[22] He played no role in the evaluation of DCO claims, and exercised no discretion about the investigation. That is, he did what he was told to do.[23]

Mr. Marino has no training in health matters, and no understanding of what a structure/function claim is.[24] He has no understanding of what is meant by "overall net impression."[25] He investigated, but could not find any complaints about DCO products.[26] He has no knowledge about any consumer injury connected with DCO or its products.[27]

2. FTC witness Lynne Colbert was the supervising investigator for the internet surf involved here; her role includes supervision of FTC staff paralegals

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[21] See Deposition of Michael Marino, at p20:line 5-7; 34:1-5; 37:8-10 and 38:19-25. Exhibit E to the McCormack Declaration.
[22] Marino dep at 28:24-29:15.
[23] Id., at 30:17-31:17.
[24] Id. at 43:6-25.
[25] Id. at 53:20-54:1.
[26] Id., 49:16-25.
[27] Id., 52:11-20.

and legal technicians.[28] Ms. Colbert was the one primarily in charge of the internet surf involved in this case, including the development and direction of the internet search parameters, using google and other search engines.[29] She performed the preliminary evaluation of all claims discovered in the internet surf, and it was based on her discretion whether a particular target case moved on in the administrative process toward a Complaint.[30] She spent an average of 10 to 15 minutes evaluating the data from each dietary supplement provider's web site.[31]

She has paralegal training, but no background, training or qualifications in health care.[32] She has no training or education about consumer perceptions of health claims.[33] She has no training in regard to structure/function claims other than what she has read on her own.[34] She does not consider any religious speech that may exist in the context of alleged advertising claims.[35]

The investigators whom Ms. Colbert supervised received no instructions about how to evaluate implied claims, or how to evaluate consumer perceptions; the investigators used their own discretion in making those evaluations.[36] The FTC's Division of Advertising Practices has no health care experts on staff.[37]

Ms. Colbert generally uses an online data base accessible to FTC staff to search for information about dietary supplements; she cannot remember doing

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[28] See Colbert deposition at p. 7; lines 1-7. Exhibit B to McCormack Declaration.
[29] Id., at 8:1-15; 10:16-11:7
[30] Id,. 23:14-18; 24:1-16.
[31] Id. 28:9-18
[32] Id., at 7:21-25; 44:18-25
[33] Id. at 24:15-25:5
[34] Id. at 34:1-24; 36:21-37-8
[35] Id. 60:2-22
[36] Id. at 14:5-16; 17:14-25
[37] Id. 44:18-25

so in regard to the DCO products.[38] She does not know if DCO was ever asked to provide substantiation for its claims.[39]

3. Richard Cleland is the Assistant Director for the Division of Advertising Practice at the FTC.[40] He testified for the FTC in this case as a designee on FTC policies and procedures. Mr. Cleland supervised the internet surf involved here, and he was the one who titled it "Operation False Cures."[41] He participated in the exercise of prosecutorial discretion in this case.[42]

Mr. Cleland testified that it is within the FTC's discretion to evaluate implied claims based on policy and case law; the Commission on its own determines the perspective of a reasonable consumer, and the target audience is presumed from the face of the ad alone.[43]

Mr. Cleland testified that he FTC conducted its "reasonable basis" analysis on the basis of presumptions about consumer perceptions and consumer harm; he testified that those presumptions are based on common sense and general FTC institutional knowledge.[44]

Mr. Cleland has no knowledge of economic or physical injury that resulted from DCO activity, and the FTC made no effort to evaluate the users of DCO products.[45] The FTC conducted no analysis under 15 USC §45(n) about whether there were benefits to users of the DCO products, nor did the FTC conduct any

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[38] Id. 42:2-43:6
[39] Id. 40:13-22
[40] Cleland Deposition, at p. 10, line 23 to page 11:line 2. Exhibit C to McCormack Declaration.
[41] Id. 11:9-19; 16:15-19.
[42] Id. 15:13-18.
[43] Id. 18:23-19:22; 20:5-13; 60:10-19; 60:21-61:4.
[44] Id. 68:21-69:21; ; 70:19-71:12.
[45] Id. 61:5-23; 67:17-68:7

analysis about the costs of substantiating dietary supplements.[46] He testified that the FTC used an expert in the field of cancer treatment to evaluate the DCO claims in this case.[47]

4. Dr. Denis Miller is the FTC's testifying expert. Dr. Miller's credentials as a cancer researcher for large pharmaceutical companies, and as a professional expert witness, are impressive. See Exhibit H to the McCormack Declaration. Dr. Miller conducted his analysis on the basis of the FTC's version of the implied claims, not on the basis of DCO's structure/function claims. See Exhibit H, p.4 and see e.g. Miller Deposition, p. 97:7-24, Exhibit D to McCormack Declaration. To be more specific, Dr. Miller only evaluated substantiation for whether DCO products "treat, cure and prevent cancer," and not the actual DCO claims themselves. Exhibit H, §IV at p. 7. See also, e.g. Miller Dep, 142:15-25.

Dr. Miller has no training or certification in nutrition. His credentials are in oncology and hematology.[48]

The sum of this testimony shows that the FTC has brought the charges against DCO based on presumptions, and erroneous presumptions at that. These presumptions include:

- A presumption that DCO was not authorized to make structure/function claims;
- A presumption that DCO's claims were directed to the general population, rather than a specific constituency related to its ministry;
- A presumption that the DCO constituency was deceived by DCO structure/function claims;

[46] Id. 72:16-27; 85:20-86:3
[47] Id. 86:17-87:2
[48] Miller Dep, 14:18-25.

- A presumption that DCO products offered no benefits;
- A presumption that DCO had no substantiation for its structure/function claims;
- A presumption that the substantiation required for dietary supplements is equivalent to the substantiation required for prescription drugs.

Reliance on these presumptions does not meet the FTC's burden of proof required by the applicable statutes, guides and policy statements. Yet, the FTC has no other evidence to offer other than these presumptions. As a matter of law, the FTC's charges must be dismissed.

B. DCO's substantiation is more than adequate to meet the required legal standards.

Lest this Court be left with concern that the FTC's failings will allow a miscreant to walk free, DCO has substantiated its structure/function claims. And it has done so more than adequately. DCO supplied considerable substantiating documents to the FTC in discovery. Experts highly qualified in naturopathy and phyto-nutrition considered this substantiation, as well as additional confirming research, which allowed them to conclude that DCO's claims were proper and accurate structure/function claims.

By way of example, DCO expert witness Dr. Sally LaMont is a licensed naturopath and acupuncture practitioner. Her expertise includes the use of natural dietary supplements for healing and wellness. Dr. LaMont, who has testified before the California State Legislature in support of naturopathic

licensing and efficacy, has issued a written opinion in this case, stating that DCO's actual claims are accurate and substantiated by competent evidence.[49]

DCO expert witness Dr. Jim Duke is a world-renowned ethnobotanist who has written and lectured extensively on the medicinal qualities of plants and herbs. Dr. Duke co-authored the book *Herbs of the Bible: 2000 Years of Plant Medicine*.[50] Dr. Duke worked for 30 years at the USDA, where he established the USDA's ethnobotanical and phytochemical data base. Like Dr. LaMont, Dr. Duke is qualified about the qualities and effects on structure and function of natural products like those used in DCO products. Dr. Duke has also issued a written opinion in this case, stating that DCO's actual claims are accurate and substantiated by competent evidence.[51]

VI. In the Absence of Actual Harm, the FTC must prove its case with Actual Evidence or otherwise Violate Due Process.

There is a final point to be made about the FTC's flawed reliance on presumptions in a case involving dietary supplement structure/function claims. The principle of DSHEA is that dietary supplements are presumed safe unless and until they are proved harmful. The burden to prove harm is on the government. The FTC's approach in this case turns Congressional promulgation of DSHEA on its head by emasculating the dietary supplement providers' rights, and by ignoring the government's burden to prove harm.

Even without DSHEA, the FTC's near-exclusive reliance on presumptions in a case like this violates due process. It bears repeating: there are many factors

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[49] See LaMont Report, p. 40, attached to McCormack Declaration as Exhibit F.

[50] Duke & Telatnik, *Herbs of the Bible: 2000 Years of Plant Medicine* Interweave Press, 1999.

[51] See Duke Report, §IV at p. 3, and §VI at p. 13, attached to McCormack Declaration as Exhibit G.

that the FTC must consider in order to maintain charges of unfair, deceptive and misleading advertising. In circumstances like those presented here, those factors must be addressed with extrinsic evidence, including but not limited consumer surveys, expert testimony about consumer perceptions and expert testimony qualified in the specific field of dietary supplements.

Without such extrinsic evidence, in the absence of actual harm and in the context of an "overall net impression" case, the ability of the FTC to meet nearly every element of proof by means of presumption effectively shifts the burden of proof to the Respondent DCO. This type of procedural approach absolves the government of the most basic obligation to put on a prima facie case with competent evidence. This is unconstitutional, as it violates due process in the most fundamental of ways.

In *Mathews v. Eldridge*[52], the U.S. Supreme Court developed a three-part test to evaluate the minimum constitutional process due in a variety of procedural situations. In *Mathews* at p. 335, the Court considered whether a hearing prior to administrative termination of social security benefits was constitutionally required. The Court structured its consideration of procedural due process on three relevant factors: (1) the private interest that will be affected by the official action; (2) the risk of erroneous deprivation of such interest through the procedures used; and (3) the governmental interest in the added fiscal and administrative burden that additional process would entail.

DCO's companion Motion amply addresses the constitutionally protected First Amendment and Religious interests and deprivations involved in this case.

[52] 424 U.S. 319, 332 (1976)

For the purpose of this Motion, the third of the *Mathews* factors deserves an especially close look, i.e. the added fiscal and administrative burden that additional due process procedures would entail, i.e. the requirement to produce extrinsic evidence instead of presumptions. Mindful of the pages of FTC policy statements and guidelines that are devoted to First Amendment protections and the risk of deprivation, it is this third factor that especially drives the FTC to adopt "trial by presumption."

Trial by presumption has been explicitly considered and explicitly rejected by the U.S. Supreme Court. Indeed, almost in anticipation of this 3rd element of the *Mathews* test, the U.S. Supreme Court decided *Stanley v. Illinois*[53] just a few years earlier than *Mathews*. The *Stanley* case concerned the due process requirements involved in parentage cases. The Court there addressed the specific question of whether the State could forego due process requirements in the interest of efficiency by adopting a presumption in lieu of meeting a burden of proof. Here, in a quote that seems to have anticipated not only *Mathews* but this case also, the *Stanley* court said this:

> The establishment of prompt efficacious procedures to achieve legitimate state ends is a proper state interest worthy of cognizance in constitutional adjudication. But the Constitution recognizes higher values than speed and efficiency. Indeed, one might fairly say of the Bill of Rights in general, and the Due Process Clause in particular, that they were designed to protect the fragile values of a vulnerable citizenry from the overbearing concern for efficiency and efficacy that may characterize praiseworthy government officials no less, and perhaps more, than mediocre ones.

[53] 405 U.S. 645, 656-657 (1972).

> Procedure by presumption is always cheaper and easier than individualized determination. But when, as here, the procedure forecloses the determinative issues . . . when it explicitly disdains present realities in deference to past formalities, it needlessly risks running roughshod over the important interests . . . [Such a procedure] therefore cannot stand.

Allowing the FTC to try this case by presumption in the absence of actual harm, wherein the standard is a subjective "overall net impression," improperly shifts the primary burden of proof to DCO in violation of DSHEA, *Matthews* and *Stanley*.

A. Adjudication by presumption is the unauthorized use of *parens patriae* under the guise of police power.

The FTC uses its police power to protect citizens from harm and the unreasonable risk of harm. A similar power is conferred on a government agency as *parens patriae* – government as parent – to determine what is good and healthy for citizens who are deemed unfit to care for themselves. See e.g. *Addington*.

When a government agency exploit its police power in the absence of harm, and in the absence of authentic, qualified and credible extrinsic evidence, that agency casts itself not as the arbiter of what is harmful, but as the arbiter of what is good and healthy. It casts itself as the *parens patriae* of healthcare for all citizens. Nothing could be more systemically damaging and offensive, much less unconstitutional, to the burgeoning and valuable healthy effects offered by dietary supplements to consumers, to say nothing of the actual users of DCO products who benefited from their faith in DCO when they were left with nowhere else to turn.

CONCLUSION

For the foregoing reasons, the Motion to Dismiss should be granted and the Complaint dismissed.

Respectfully submitted February 24, 2009.

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

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

Sworn Declaration of Michael McCormack in Support of Respondents' Motion for Summary Decision

Michael McCormack swears under oath as follows:

1. I am one of the attorneys for Respondents in this matter. I have personal knowledge of the facts described below. I am competent to testify.

2. Attached hereto are the following documents, which are true and correct copies of documents produced in this matter through the course of discovery and expert disclosure:

Exhibit A: FTC Answers to DCO Interrogatories #1 through 10.

Exhibit B: Deposition excerpts from the deposition of Lynn Colbert, as referenced in Respondents' Motion.

Exhibit C: Deposition excerpts from the deposition of Richard Cleland, as referenced in Respondents' Motion.

Exhibit D: Deposition excerpts from the deposition of Dr. Denis Miller, as referenced in Respondents' Motion.

Exhibit E: Deposition excerpts from the deposition of Mike Marino, as referenced in Respondents' Motion.

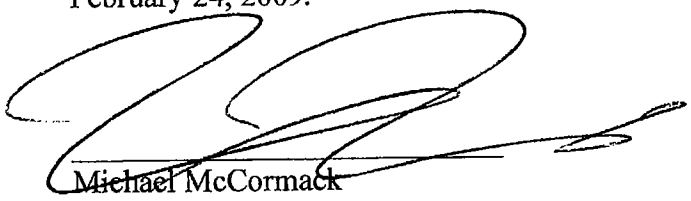
Exhibit F: Report of DCO expert Dr. Sally LaMont.

Exhibit G: Report of DCO expert Dr. James Duke.

Exhibit H: Report of FTC expert Dr. Denis Miller.

I certify under penalty of perjury that the foregoing is true and correct.

February 24, 2009.



Michael McCormack
Co-counsel for Respondents
26828 Maple Valley Hwy. #242
Maple Valley, WA 98038
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Exhibit
A

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, individually, and as an officer of Daniel Chapter One	)	**Public Document**

COMPLAINT COUNSEL'S ANSWERS TO RESPONDENTS' FIRST SET OF INTERROGATORIES

Pursuant to this Court's Scheduling Order dated October 28, 2008 and FTC Rule of Practice 3.35, Complaint Counsel submits the following Answers to Respondents' First Set of Interrogatories, subject to and without waiving both the General Objections and the Specific Objections contained in Complaint Counsel's Objections to Respondents' First Set of Interrogatories, dated December 24, 2008. By providing information in response to Respondents' Interrogatories, Complaint Counsel do not concede that such information is relevant, material, or admissible in evidence. Complaint Counsel's responses to these Interrogatories are based on information now known to Complaint Counsel. The FTC has not yet completed its discovery of the facts in this lawsuit or prepared for trial and therefore reserves its rights to amend, modify, or supplement its responses if it learns of new information. Subject to and without waiving these objections, Complaint Counsel provide the following responses.

INTERROGATORIES

1. For each of the representations that you attribute to Respondent in paragraph 14 a. through h. of your Complaint, state whether you believe the representation is "express" or "implied", and identify the specific statement or statements that you allege Respondents disseminated which constitutes that representation.

ANSWER:

Subject to Complaint Counsel's previously stated objections, through the means described in Paragraphs 6 through 13 of the Complaint, including, but not limited to, the statements contained in the advertisements attached to the Complaint as Exhibits A through D, as well as the statements contained in Respondents' documents produced to the FTC (under the heading "Web Pages from prior Daniel Chapter One Web Sites"), Respondents have created the overall net impressions caused by the challenged advertising, and thereby have made the representations alleged in paragraph 14 a. through h. of the Complaint. These statements include the following:

- "Bio*Shark: Tumors & Cysts. . .Pure skeletal tissue of sharks which provides a protein that inhibits angiogenesis - the formation of new blood vessels. This can stop tumor growth."
- "Bio*Shark Shark Cartilage Stops tumor growth in its tracks.
- "INFO CENTER
  Cancer News.
  7 Herb Formula
  - purifies the blood
  - promotes cell repair
  - **fights tumor formation** [emphasis in original]
  - fights pathogenic bacteria

  . . .

If you suffer from any type of cancer. Daniel Chapter One suggests taking this products [sic], to fight it:
7*Herb Formula ™. . .
Bio*Shark ™. . .
BioMixx ™. . .
GDU Caps ™. . .
[depiction of bottles of BioMixx, 7 Herb Formula, Bio*Shark, and GDU]
Daniel Chapter One's Cancer solutions
To Buy the products click here
How to fight cancer is your choice!..."

- **"7 Herb Formula battles cancer.**
  Tracey was given no hope!
  The doctors had pretty much given up on Tracey. She had leukemia and tumors on the brain, behind the heart and on her liver. . .
  This is Tracey's story in her own words as told in 1997: 'I had contracted leukemia and had three inoperable tumors. When I decided not to do chemotherapy or radiation, my father sent me Bio*Mixx and 7 Herb Formula. Each day as I took it and got it into my system more and more, the better I felt. Then I added Garlic Pur, Siberian Ginseng and BioShark. I am now in complete remission."

- "[GDU] Contains natural proteolytic enzymes (from pineapple source bromelain) to help digest protein - even that of unwanted tumors and cysts. This formula also helps to relieve pain and heal inflammation. . .and as an adjunct to cancer therapy."

- "GDU: With curcumin that research says may prevent cancer. . . .Daniel Chapter One - GDU caps contains proteolytic enzymes that metabolize protein and can aid the body in breaking down a tumor. The importance of oral enzymes in treating cancers has been the subject of scholarly papers and books for almost a century."

- "Bio*Mixx boosts the immune system, cleanses the blood and feeds the endocrine system to allow for natural healing. It is used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatments."

Complaint Counsel allege that Respondents' representations are both express and implied.

2. For each statement identified in your response to Interrogatory #1, identify the media source used by Respondents to disseminate the statements.

ANSWER:

Subject to Complaint Counsel's previously stated objections, to the best of Complaint Counsel's knowledge, the above statements appear or have appeared in a variety of media sources, including but not limited to, on Respondents' web sites, in Respondents' product literature and catalogs, and on Respondents' radio broadcasts.

3. Of the statements identified in Interrogatory #1, identify all statements that you contend are false.

ANSWER:

Subject to Complaint Counsel's previously stated objections, Complaint Counsel refer to Interrogatory Answer No. 1, which describes some of the statements made by Respondents that have contributed to the overall net impressions created by the challenged advertising. All of these statements are false because they are misleading in a material respect, as described more fully in response to Interrogatory No. 4.

4. State all facts upon which you based your contention that the statements identified in your response to Interrogatory #3 are false.

ANSWER:

Subject to Complaint Counsel's previously stated objection, the foregoing net impression claims are false, misleading, or lack substantiation for one or more of the following reasons as may be further delineated in expert reports produced in accordance with the applicable Scheduling Order:

a. There is no reliable study of the product that purports to test the claims;

b. There is no reliable study of the ingredients as formulated in the product that supports the claims;

c. There is no known biologically feasible mechanism of action to support the claims;

d. The scientific literature does not provide reliable scientific evidence to support the claims; and

e. Anecdotal or testimonial evidence regarding the product's purported efficacy is not sufficient to substantiate the claims.

5. Of the statements identified in Interrogatory #1, identify all statements that you contend are deceptive.

ANSWER:

Subject to Complaint Counsel's previously stated objections, Complaint Counsel refer to Interrogatory Answer No.1, which describes some of the statements made by Respondents that have contributed to the overall net impressions created by the challenged advertising. All of these statements are deceptive, as described more fully in response to Interrogatory No. 6.

6. State all facts upon which you based your contention that the statements identified in your response to Interrogatory #5 are deceptive.

ANSWER:

Subject to Complaint Counsel's previously stated objection, the foregoing net impression claims are false, misleading, or lack substantiation for one or more of the following reasons as may be further delineated in expert reports produced in accordance with the applicable Scheduling Order:

a. There is no reliable study of the product that purports to test the claims;

b. There is no reliable study of the ingredients as formulated in the product that supports the claims;

c. There is no known biologically feasible mechanism of action to support the claims;

d. The scientific literature does not provide reliable scientific evidence to support the claims; and

e. Anecdotal or testimonial evidence regarding the product's purported efficacy is not sufficient to substantiate the claims.

7. Of the statements identified in Interrogatory #1, identify all statements that you contend are misleading.

ANSWER:

Subject to Complaint Counsel's previously stated objections, Complaint Counsel refer to Interrogatory Answer No. 1, which describes some of the statements made by Respondents that have contributed to the overall net impressions created by the challenged advertising. All of these statements are misleading, as described more fully in response to Interrogatory No. 8.

8. State all facts upon which you based your contention that the statements identified in your response to Interrogatory #7 are misleading.

ANSWER:

Subject to Complaint Counsel's previously stated objection, the foregoing net impression claims are false, misleading, or lack substantiation for one or more of the following reasons as may be further delineated in expert reports produced in accordance with the applicable Scheduling Order:

a. There is no reliable study of the product that purports to test the claims;

b. There is no reliable study of the ingredients as formulated in the product that supports the claims;

c. There is no known biologically feasible mechanism of action to support the claims;

d. The scientific literature does not provide reliable scientific evidence to support the claims; and

e. Anecdotal or testimonial evidence regarding the product's purported efficacy is not sufficient to substantiate the claims.

9. Of the statements identified in Interrogatory #1, identify all statements that you contend are unfair.

ANSWER:

Subject to Complaint Counsel's previously stated objections, Complaint Counsel refer to Interrogatory Answer No. 1, which describes some of the statements made by Respondents that have contributed to the overall net impressions created by the challenged advertising. All of these statements are unfair, as described more fully in response to Interrogatory No. 10.

10. State all facts upon which you based your contention that the statements identified in your response to Interrogatory #9 are unfair.

ANSWER:

Subject to Complaint Counsel's previously stated objection, the foregoing net impression claims are false, misleading, or lack substantiation for one or more of the following reasons as may be further delineated in expert reports produced in accordance with the applicable Scheduling Order:

a. There is no reliable study of the product that purports to test the claims;

b. There is no reliable study of the ingredients as formulated in the product that supports the claims;

c. There is no known biologically feasible mechanism of action to support the claims;

d. The scientific literature does not provide reliable scientific evidence to support the claims; and

e. Anecdotal or testimonial evidence regarding the product's purported efficacy is not sufficient to substantiate the claims.

11. For all statements identified in your response to Interrogatory #9, state the injuries that have been caused, or are likely to be caused, to consumers as a result of the alleged practices or acts of Respondents.

ANSWER:

Subject to Complaint Counsel's previously stated objections, although injuries have been caused, or are likely to be caused, to consumers as a result of the alleged practices or acts of Respondents, proving specific injury is not a necessary element of the proof in this litigation. Consumer injury is inherent when products are promoted for the cure, mitigation, treatment, or prevention of diseases or other health-related benefits through false, misleading, or deceptive representations. To that extent that such injury can be quantified in terms of economic harm consumers have suffered, Respondents possess information setting forth Respondents' total revenue from the sale of products with false, misleading, or deceptive representations.

12. For all statements identified in your response to Interrogatory #9, identify the steps you have taken to determine whether or not the alleged injuries are reasonably avoidable by consumers.

consumers would not have less access to information about traditional use of natural remedies without information that comes from claims by supplement manufacturers about the traditional use of natural remedies, including dietary supplements.

ANSWER:

Subject to Complaint Counsel's previously stated objections, Complaint Counsel respond as follows: claims that are false, misleading, or lack substantiation do not provide any useful information to consumers, as set forth in the public policies expressed by Congress in Sections 5(a) and 12 of the FTC Act, the FTC Policy Statement on Deception, the FTC Policy Statement Regarding Advertising Substantiation, the FTC Food Policy Statement, the FTC Policy Statement on Unfairness, the FTC Guides Concerning Use of Endorsements and Testimonials in Advertising, and in relevant case law.

Respectfully submitted,

Theodore Zang, Jr. (212) 607-2816
Carole A. Paynter (212) 607-2813
David W. Dulabon (212) 607-2814

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

Dated: January 5, 2009

Exhibit
B

In the Matter of:

Daniel Chapter One, et al.

January 22, 2009
Lynne J. Colbert

Condensed Transcript with Word Index

For The Record, Inc.
(301) 870-8025 - www.ftrinc.net - (800) 921-5555

FEDERAL TRADE COMMISSION
I N D E X

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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

Thursday, January 22, 2009

Room 318
Federal Trade Commission
One Bowling Green
New York, New York 10004

The above-entitled matter came on for deposition, pursuant to notice, at 1:41 p.m.

APPEARANCES:

ON BEHALF OF THE FEDERAL TRADE COMMISSION:
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P R O C E E D I N G S
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Whereupon --
LYNNE J. COLBERT
a witness, called for examination, having been first duly sworn, was examined and testified as follows:

EXAMINATION
BY MR. McCORMACK:

Q. Good afternoon, Ms. Colbert.
A. Yes.
Q. My name is Michael McCormack again for the record.
And also for the record, can you state your full name and business address, please.
A. Yes. Lynn, L-Y-N-N-E, middle initial J, Colbert, C-O-L-B-E-R-T, 600 Pennsylvania Avenue, Northwest, Mail Drop NJ-3212, Washington, D.C. 20580.
Q. Ms. Colbert, have you ever had your deposition taken before?
A. Yes, I have.
Q. How many times roughly?
A. Roughly two or three times.
Q. Okay. And do you recall the most recent time?
A. No, I don't. It was approximately two years ago I believe.

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Q. Okay. The other instances when you've had your deposition taken, were they -- did you testify as an FTC witness or employee of some sort as opposed to a personal matter?

A. As an FTC employee.

Q. Do you remember the nature of the cases in which you testified?

A. One was a dietary supplement case.

And one was a device, but I was really a peripheral player in that.

Q. In the device case?

A. Yes.

Q. Okay. Generally let me just refresh your memory perhaps to the extent it's helpful that our court reporter is going to be transcribing everything we say on the record for possible use in the hearing that will occur as well as any appeals and other public relations purposes perhaps.

For that reason, I strive to try to make sure we have as clear and clean a record as possible. And if you will let me finish my question before answering and I'll try to let you finish answering before I ask my next question, that will probably be helpful.

Also, because nods and shakes of the head and uh-huhs and huh-uhs don't transcribe very well, if at

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all, if I prompt you to say is that a yes or is that a no, that's no disrespect intended. I just want to make sure the record is clear.

Okay?

A. I understand.

Q. Super.

Also, if I ask any questions that you don't understand -- and particularly as jet lag begins to seep into me, I may be prone to that -- please let me know, and I'll do my best to clarify.

Okay?

A. Okay.

Q. Great.

Ms. Colbert, you were recently identified as a witness for the FTC in the Daniel Chapter One case. And I'm familiar, for instance, with Mr. Marino's role, but I have to confess I'm not familiar with your role at all, so I'm going to do my best to ask generally what your role is here and what your responsibilities are for the FTC, and so forth, and try to understand more specifically essentially what your testimony is going to be at the hearing in this case.

So that's just a little bit of backstory.

With that in mind, can you tell me, what is your title with the FTC?

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A. I'm the supervisory investigator in the Division of Advertising Practices.

Q. And as the supervisory investigator in the Division of Advertising Practices what are your job responsibilities?

A. I supervise the paralegals and investigative staff and legal technician staff.

Q. Is Michael Marino one of your reports or subordinates?

A. No, he is not.

Q. Okay. How long have you been with the FTC?

A. 21 years.

Q. What other roles or job responsibilities other than your current job responsibilities have you held with the FTC, if any?

A. As investigator.

Q. Okay.

A. That's -- that's all.

Q. Okay. And what training did you have as an investigator for the FTC, if any?

A. Well, prior to my employment with the FTC, I worked for two law firms. But prior to that, my training -- I have a certificate in paralegal studies from the Institute for Paralegal Studies in Philadelphia, Pennsylvania. And prior to that, I have a

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BA degree from Mount Holyoke College.

Q. Okay. When did you first become familiar with Daniel Chapter One?

A. I became familiar with it through the 2007 cancer Internet surf.

Q. Is that also known as Operation False Cures?

A. Yes, it is.

Q. Okay. And were you -- strike that.

How were you involved in Operation False Cures generally?

A. I made sure that the database that we maintain was operational for data entry of Web site claims that we found. I sent -- I disseminated electronic mail to our regional office participants regarding the surf, announcing the surf, and providing instructions.

Q. Correct me if I'm misstating what I think I just heard.

But is it accurate to say that you're the person that kind of constructed at least the technology aspects of Operation False Cures?

A. Well, in connection with the technology, if you mean the database, I had assistance from our litigation support division. The database was preexisting. We used it as a prototype for all the surfs that we've conducted over the years.

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Q. Can you give me examples of other surfs that you've conducted over the years other than Operation False Cures?

A. In 2006 there was a surf for diabetes treatment and cure products.

MR. ZANG: Ms. Colbert, I'm sorry to interrupt, but before you go any further, I just want to caution you not to give testimony about surfs that have not been publicly identified, if any.

THE WITNESS: Okay.

MR. ZANG: Okay.

THE WITNESS: And prior to that, there had been some about ten -- eight to ten years ago.

There was one after the 9-11 catastrophe for biochemical and -- well, products related to terrorism.

Let's see.

And prior to that, in the late '90s, there was one that was conducted for serious disease claims such as HIV/AIDS, arthritis, cancer, and the like.

BY MR. McCORMACK:

Q. Okay. Is my understanding correct that in each of these surf situations, surf projects or operations that what the FTC was looking for were claims of some sort, health claims of some sort that were deemed false, misleading, unfair?

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A. Yes. In addition to efficacy claims because -- well, in connection with the 9-11, the terrorist products, it could have been apparatus or apparel, so performance claims, too.

Q. Okay. In terms of the diabetes claim, for instance, that was essentially directed, though, to health claims --

A. Yes.

Q. -- related to diabetes.

A. Yes.

Q. Okay. Moving forward to closer to the present time anyway, Operation False Cures was a surf exclusively directed to cancer claims; am I right about that?

A. Yes.

Q. Okay. And if you can, explain to me how the parameters of that surf were set up and how it was conducted.

A. The parameters included terminology, certain terminology that might be prevalent in claims of that sort. We were looking for express and implied claims for treatment and cure of cancer.

Q. Okay. Can I parse that out just a little bit.

You said terminology. I'm a -- as much as I've been around it, I'm a tech novice, so bear with me. I

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think of a surf as putting a word or a series of words in the Google search bar and hitting "go" and seeing what comes up.

Are the surf parameters kind of like that on a more sophisticated basis?

A. Yes. That's pretty much rudiment, fundamentally how it's done.

I mean, we use other -- a number of other search engines so that our results are varied.

Q. Okay.

A. But there are certain terms or phrases or vocabulary that was suggested or recommended to surfers to employ.

Q. And now, when you say "surfers," you're talking about investigators and paralegals?

A. Yes.

Q. Do you recall what the search terms were that were used for Operation False Cures?

A. Melanoma, carcinoma, tumor, and then phrases such as miracle cure, scientific breakthrough.

Q. Were any protocols for creating the database written up to guide the surfers?

A. I'm sorry. Would you repeat that, please.

Q. Sure.

Were any protocol -- well, let me rephrase it

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entirely.

Was there any list of terminology printed up for FTC surfers to use for Operation False Cures?

A. Yes, there was.

Q. Do you know if those lists still exist?

A. Yes. It does.

Q. Is Operation False Cures still going on to this day?

MR. ZANG: Let me just -- I want to interrupt for one minute. And Mr. McCormack, I just want to state a general objection. I'm going to allow Ms. Colbert to answer that question, but I do want to state for the record that any testimony going to investigations, either Daniel Chapter One or other ones, I do want to preserve our right to claim the investigatory and governmental deliberative privileges.

And Ms. Colbert, I'm going to allow you to testify generally about the mechanics, and so forth. If it sounds like you're getting too much into information that may involve discussions that you've had or advice you've been given with FTC attorneys, I may need to instruct you not to go further or answer.

THE WITNESS: Okay.

BY MR. McCORMACK:

Q. And so far it hasn't been my intention to ask

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you those questions. I'm just looking for the mechanics right now, so thank you.

So the terminology -- there's a terminology list that exists for the surfers to use for Operation False Cures; right?

A. Yes. The list contains some vocabulary, some phrases, just recommended, just suggested. It wasn't anything that had to be used.

Q. Okay. Did the sufferers have discretion to go beyond that list, to your knowledge?

A. Yes.

Q. And so what was -- if you know, what was the general direction or instruction given to the surfers for purposes of conducting their searches?

A. Looking for express or implied claims for treatment and/or cure of cancer.

Q. Was the word "treatment" included in the terminology list, do you know? Do you remember?

A. I don't remember.

Q. Okay. How about the word "cure"?

And not remembering is fine as you might remember.

A. I don't remember, but probably.

Q. Okay. And the surfers could certainly use their discretion in using those words for their search I

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presume.

A. Yes.

Q. Okay. You used the phrase "express or implied claims."

How, for purposes of preparing the database, are implied claims determined or evaluated?

MR. ZANG: Objection to the extent that that's calling for some sort of legal conclusion, but if you're asking for the witness' understanding, her own understanding, that's fine.

MR. McCORMACK: I'm certainly asking for her testimony and only her testimony.

THE WITNESS: Okay. Implied claims are understood to be not literal but suggestive.

For example, the URL might imply something to the surfer or the consumer.

BY MR. McCORMACK:

Q. Okay. Any other guidelines that you're familiar with to evaluate whether a claim is implied as opposed to express?

A. Well, I just don't remember verbatim what was in the instruction sheet that the surfers would have been reading.

Q. To your knowledge, who prepared the instruction sheet?

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A. I did.

Q. Okay. Do you know, is that instruction sheet a document that you'll be testifying about when the Daniel Chapter One case goes to hearing?

A. I don't know.

Q. Now, in terms of -- I want to stick with this notion of implied claims.

Strike that.

Let me go back to the instruction sheet.

Did you prepare the instruction sheet on your own or was that in collaboration with a team?

A. I used instructions that had been used in the past. I incorporated specifics for cancer, such as the terminology, the disease terminology or the -- but the phraseology "scientific breakthrough" or "miracle cure," those are really general, general phrases.

Q. Who came up with the -- that didn't sound very good.

How was Operation False Cures specifically developed and launched? Were you part of a team that made that decision?

A. No.

Q. Do you know who was?

A. Not really. No.

Q. Okay. All right.

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To whom do you report?

A. To Richard Cleland.

Q. And was it Mr. Cleland who gave you sort of the directive to prepare this database for Operation False Cures?

A. Well, when I became aware that there was going to be a surf, I just -- I knew from past experience that we were going to need a database, so I called the litigation support individual who helps with databases, helps construct databases, and got it set up and accessible.

Q. Okay. So to be more specific, I guess what I'm interested in, did at some point, before you prepared the database or to help guide you in preparing the database, did you receive instructions about your role in Operation False Cures, written instructions?

A. Written instructions about my -- what my role would be?

Q. Correct.

A. No.

Q. Okay.

A. No.

Q. Okay. Did you receive verbal instructions?

A. No.

Q. Okay. So you knew the surf was starting and

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you knew what your role was based on past experience and --
A. Just from past experience, yes.
Q. Got it. Okay. All right.
Now I'll go back to the notion of implied claims.
Are there any specific instructions given to surfers to guide them in determining what an implied claim entails?
A. There is a brief explanation in the instruction sheet.
Q. I couldn't do it if I were in your shoes, but I'm going to ask you anyway.
Do you remember any of those instructions from the instruction sheet or the definition of what an implied claim is from that instruction sheet?
A. No. Not from the instruction sheet, no.
Q. Do the surfers make any evaluation of what they think consumers would interpret from the alleged claims that they're searching?
A. No.
Q. Okay. What did they use to guide them? Their own sense of things?
A. I presume, yes, that's what they use to guide them. Some of the surfers are experienced investigators

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also.
MR. ZANG: Mr. McCormack, I've been giving you a lot of leeway on this line of questioning. I just want to point out that Ms. Colbert is not necessarily aware and no foundation has been established of, you know, what the investigators working on the surf, for example, actually did. I mean -- or you haven't established that.
And to the extent you're asking about their thought processes rather than hers, I would just point out that there's no foundation, so I'm giving you leeway --
MR. McCORMACK: Your objection is noted. Right?
We're objecting to form. Those are preserved. Object to form. You can strike them later.
We're doing fine. Thank you.
BY MR. McCORMACK:
Q. So are the surfers -- and let's stick with the surfers who were involved in Operation False Cures.
To your knowledge, are the surfers trained with respect, for instance, to -- trained in consumer awareness about implied claims, for instance?
A. Well, the surf was conducted among our regional offices, and I initially sent the invitation/instruction sheet to the office director, and from there surfers

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were selected, so I don't know how they were selected.
And I know some of them have been with the FTC for a while. It's possible that some of them had not been employed here that long and might not be as learned with surfing and identifying claims.
Q. Okay. To your knowledge, with respect to surfers who either you picked or with whom you may have worked, was there any policy information given to those surfers about what constitutes an implied claim?
A. I -- in my office in advertising practices in the Washington office, I gave information to the surfers in that office. What happened in the regional offices I don't know.
Q. Understood.
Do you remember what information you gave to the surfers in your office?
A. There's a booklet. It's for industry. Advertising for industry, a dietary supplement advertising for industry, but it's on our Web site.
MR. McCORMACK: Right.
Excuse me just a second. Off the record.
(Discussion off the record.)
(DCO Deposition Exhibit Number 4, FTC-DCO 1041-1070, Dietary Supplements: An Advertising Guide for Industry, was marked for identification.)

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BY MR. McCORMACK:
Q. Ms. Colbert, I'm handing you what's been marked DCO Exhibit Number 4, which I understand to be the dietary supplement guide provided to us by complaint counsel.
If you'd just take a moment to look through that and see if that's in fact the document to which you just referred.
A. Yes, it is.
Q. Okay. So what wee see there in Exhibit Number 4 is a piece of information that you supplied to your surfers in your regional office for use in Operation False Cures.
A. That's correct.
Q. Okay. Anything else that you provided to your surfers?
A. No. Only if they had questions to feel free to come to me, any confusion or questions.
Q. Now, let's -- I want to stick for the time being to how Operation False Cures unfolded within your experience, mindful that -- well, actually let me make sure of this.
When did you first become aware of Daniel Chapter One?
A. It would have been early July of 2007 because

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the surf lasted from June 25th through the 27th, and I would not have received the printouts from anyone for a couple days, so it would have had to have been the end of June, early July.

Q. Now, are we talking 2007?

A. Yes.

Q. Did the surf that uncovered Daniel Chapter One, if you will, originate out of your office, do you know?

A. I don't know. I only know that it was an FTC staffer who found it.

Q. Do you know which FTC staffer it was?

A. No, I don't.

Q. Okay. Do you know out of what office that FTC staffer worked?

A. No, I don't.

Q. Okay. So to the best of your recollection, share with me how it unfolded that you became familiar with Daniel Chapter One.

A. After the surf ended, surfers sent -- well, from the regional offices they sent via Federal Express printouts from the Web sites that they found and felt were pertinent.

From the surfers within advertising practices office, they would have handed them to me.

Q. Okay. So you were the central clearinghouse for

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all the results of the surfs from all the regional offices.

A. Yes.

Q. Okay. Do you recall how many you got? And by "how many" I mean how many different dietary supplement companies you got.

A. Well, there were well over a hundred.

Q. Okay. And if you would, walk me through the mechanics, without telling me about conversations you had with counsel, walk me through the mechanics of what you did with that data.

A. Okay. Well, we had to discard any duplicates, which there were several of.

Q. Okay.

A. We also were not interested in Web sites selling books.

Q. Okay.

A. So that's how we sifted out a lot of Web sites.

Q. Okay. Were there any other filters or parameters that prompted you to use some discretion or decision-making authority about which ones moved forward and which ones you tossed?

A. Well, the degree of egregiousness of the claims.

Q. Okay. I'll come back to that in just a second.

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Was any consideration given at -- strike that.

Help me with the time frame or sequencing.

The surf occurred roughly June 25 to June 27, 2007, and within roughly the next 30 days is when the data came in by Federal Express and otherwise from the offices?

A. Yes.

Q. Okay. Were you and your staff pretty much on top of that data and going through it immediately or was there some period of time before you got to it? Do you remember?

A. I don't remember.

Q. Okay. All right.

At the time that you were going through the initial data -- strike that -- initially going through the data, you're kind of the first threshold evaluator I gather; is that fair to say?

A. That's fair to say.

Q. Okay. Was any consideration given to, for instance, whether the company or organization was a nonprofit?

A. No.

Q. Okay. Was any consideration given to whether the organization was a religious organization?

A. No.

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Q. Back to the degree of egregiousness.

Can you explain to me what the parameters were for evaluating egregiousness?

A. Well, if the statements were -- made blatant claims of curing, reversing, stopping, any -- if the consumer could take away any understanding of the disease being deterred in any way.

Q. And I presume that during this process you're exercising your discretion in making that evaluation about the degree of egregiousness. Is that right?

A. Based on what I just said, yes.

Q. Correct.

A. Yes.

Q. Was that you exclusively or were you part of a team doing that?

A. Preliminarily it was just me.

Q. Okay. In the course of your work in exercising that discretion, have you been empowered or instructed or educated in consumer surveys or any other FTC information about what consumers are or are not aware of in regard to health claims for supplements or how they interpret health claims for supplements?

MR. ZANG: Objection. Compound question.

BY MR. McCORMACK:

Q. Do you understand that?

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A. Yes.
Just from 21 years of experience.
Q. So nothing specific or formal, just your work at the FTC for a long period of time.
A. Yes.
Q. Okay. So you talked about initially you were the one exercising your discretion. It sounds like there was a second phase to that process.
Did I understand that right?
A. That's correct.
Q. Okay. Can you describe the second -- just mechanically what the second phase was without getting into conversations with counsel that may have occurred.
A. Okay. After I had identified the Web sites that I thought should be sent advisory letters, I passed those on to Richard Cleland.
Q. Do you recall that this was the -- that during this phase was when you identified Daniel Chapter One?
A. Yes.
Q. Okay. Again, mindful that I couldn't do it if I were in your shoes, but do you recall specifically about the material you received about Daniel Chapter One that prompted you to put them in the -- I'll call it the egregious pile?
A. No, I don't. Not specifically, no.

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Q. One thing I should have asked you at the beginning, and I apologize for not remembering to do so, is: What, if anything, did you do to prepare for your deposition today?
Did you review any documents, for instance?
A. Not really, no.
Q. Okay. Sometimes that's the safe way to go.
Okay. So if you can remember specific to Daniel Chapter One -- let me stick with Daniel Chapter One.
Do you remember specifically the kind of data you received about them that you first evaluated?
A. The kind of data? We had -- well, we have several fields that we were entering data into.
Q. Okay.
A. And there's one field for claims.
Q. Okay.
A. And those were taken from the materials that were submitted.
Q. On the Web?
A. Yes.
Q. Was there any other media that was researched besides what was on the Web, to your knowledge?
A. No, there wasn't, not to my knowledge.
Q. You talked about claims being one field.

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Do you recall any of the other fields?
A. Yes, I do.
Q. And what were they?
A. The company name.
The product.
Product ingredients.
The URL, the Web site URL.
The company contact information, address, phone and fax.
Whether it was a domestic or foreign enterprise.
And the source of the surf material.
Q. When you say "source," again are you -- you mean Web site as opposed to brochures or --
A. Well, FTC, where the surfer was.
Q. Okay. Got you, got you, got you. Okay.
In the course of your work in evaluating the degree of egregiousness, as you've described it, did you keep any notations, either by hand or electronically, about the results and the process of your evaluation?
A. No.
Q. Can you estimate how much time you spent evaluating each of the supplement providers in terms of determining, yeah, they make the egregious pile, no,

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they don't make the egregious pile?
MR. ZANG: Objection. Lack of foundation with respect to supplementary or dietary supplementary manufacturers.
BY MR. McCORMACK:
Q. Do you understand the question?
A. Could you repeat it, please.
Q. Sure.
Can you estimate on average how much time you spent evaluating each supplement manufacturer?
MR. ZANG: The same objection, lack of foundation.
THE WITNESS: The printouts that I received?
BY MR. McCORMACK:
Q. Yes, ma'am.
A. I would say at least 10 to 15 minutes.
Q. Per manufacturer.
A. Yes.
Q. Okay. Do you recall on average how much data in terms of number of pages you received per manufacturer?
A. It varied.
Q. Okay. From one page to a hundred in some cases maybe?
A. Maybe not as many as a hundred, but from, you

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know, two or three pages to maybe --
Q. A lot.
A. -- forty or fifty. Yes.
MR. ZANG: Mr. McCormack, again I've been giving leeway, but I don't think a foundation has been established that all these companies are manufacturers. Maybe they are, but I don't believe --
MR. McCORMACK: Objection noted, counsel. Thank you. Yeah, again, I think the witness and I are doing just fine.
BY MR. McCORMACK:
Q. Do you recall how many pages of data you received about Daniel Chapter One?
A. No, sir, I don't.
Q. So again to get back to the mechanics of the process -- I'm not looking for conversations, yet anyway -- you passed the data on to Mr. Cleland.
A. Yes.
Q. Okay. What was the next step in Operation False Cures, to your knowledge, from there?
A. Mr. Cleland would review what I submitted to him and make a judgment call as to whether the Web site would receive an advisory letter or not.
Q. Okay. To your knowledge, what is Mr. Cleland's job title?

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A. He's the associate director in the Division of Advertising Practices.
Q. If you know, is that an administrative role or a legal counsel role?
A. It's a managerial role and legal counsel.
Q. Did Mr. Cleland communicate to you the results of his decisions?
A. Yes, he did.
Q. In what form?
A. Written form.
Q. Okay. Did you do anything with that information?
A. Yes. The pages on which he approved -- the pages which he approved are the Web sites, the URLs, that received advisory letters.
Q. And were you the one that engineered the advisory letters after he gave the information back to you?
A. I supervised the dissemination of them. One of our paralegals actually manually, you know, sent them out.
Q. Who crafted the language of the advisory letters?
A. I really am not sure about the collaboration of the letter, the final form of the letter.

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Q. Okay. Once the advisory letters were sent out, insofar as your role was concerned or has been concerned, what happened next?
A. I believe we alerted the Web site operator to get back to us about what they were going to do in connection with our letter within ten days I believe it was.
So after approximately I'd say fifteen -- we gave a grace period of maybe five days -- we went back -- or I went back to review the Web site to observe whether there had been any changes made, any revisions, any modifications.
Q. Do you recall doing so in the Daniel Chapter One instance specifically?
A. Specifically, no.
Q. Okay.
A. There were so many. I don't specifically remember.
Q. And are we still talking targets, I'll call them, numbering close to a hundred as best you can recall?
A. Yes. Yes.
Q. Okay. To the best of your recollection, of that hundred roughly, at this point in the process, how many of them had complied to your satisfaction by

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changing their Web site, for instance? Can you estimate?
A. I don't remember.
Q. Okay. Okay.
At this point in the process, though, it's still essentially your project; am I right?
I mean, you're the -- are you the primary person kind of managing the sequence of steps and the communication with the target?
A. Yes.
Q. Okay. All right.
So walk me through, to the best of your recollection, what happened with Daniel Chapter One, but I'm mindful you may not remember specifically, in which case let me know and just tell me what would have happened generally.
Once you sent the advisory letter, requested feedback, requested changes to the Web site, what happened next with Daniel Chapter One, if you recall?
A. I don't specifically recall if Daniel Chapter One communicated with us directly. I don't recall providing any additional guidance or information.
But generally speaking, if the Web site had e-mailed back to ask for additional information or

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additional guidance, I would have -- there would have been an e-mail exchange back and forth.

Q. When you say "additional information or additional guidance," can you be more explicit?

A. For example, it might have to do with whether the Web site linked to another site that made claims or whether there was historical use language at the Web site or whether there were animal studies being passed off as, you know, effective for humans, that type of thing to clarify, for clarification.

Q. The advisory letters that were sent out, were they specific in their direction about what needed to be done with respect to Web site language or was it generic direction, you need to change your language and let us know how it's changed?

A. It was a generic letter.

Q. So the idea -- correct me if I'm wrong -- was we have problems with your Web site, you need to change the language and we'll take another look at it kind of thing?

A. Yes. Correct.

Q. All right. And you don't recall specifically with respect to Daniel Chapter One what took place in terms of that kind of exchange?

A. No, I don't.

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Q. All right. To the best of your recollection, at the point in the process that we're talking about now, did you or anyone that you were working with on Operation False Cures investigate what "Daniel Chapter One" referred to, the title of this particular company?

A. No. Not that I know of. I did not. I don't know if anyone else did, but I don't think so.

Q. Do you know as you sit here today?

MR. ZANG: Objection. Relevance.

BY MR. McCORMACK:

Q. Do you know as you sit here today?

MR. ZANG: Go ahead.

THE WITNESS: Is it a bible chapter?

BY MR. McCORMACK:

Q. Well, I'm asking you if you know. I'll be happy to tell you, but --

A. I think it's a bible chapter. That may have illuminated in my head before today, but I never researched it.

Q. Okay. So you don't know what bible -- assuming it is a bible chapter, you don't know what it refers to.

A. No, I don't.

Q. Okay. All right.

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All right. So we have -- we're walking through this process, and this is very helpful. I appreciate it. As far as I'm concerned, you're doing fine.

You've sent out the advisory letter to Daniel Chapter One and others. There is or perhaps not an exchange of dialogue about the Web site language.

To the extent you can recall with Daniel Chapter One, what happened next?

A. Well, I really can't specifically recall Daniel Chapter One, but generally speaking?

Q. Yes, ma'am.

A. I would go back to review the Web site.

If no changes had been made, I would put that URL on a list of noncompliant Web sites.

If changes had been made and they were acceptable, we would acknowledge the changes and thank the Web site operator for cooperating.

Q. In terms of Operation False Cures, do you have a recollection of how many sites made changes that were acceptable?

A. I really don't recall.

Q. A percentage perhaps?

And I'm just looking for the best of your recollection.

A. I am guessing maybe approximately twenty.

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Q. Of the roughly 100?

A. Yes.

Q. Okay. So the other eighty or so were noncompliant?

A. Yes.

Q. Is there a -- I think you testified to this, but let me ask it specifically.

Is there a list of those sites that did comply?

A. There's no list, no.

Q. Okay. Is there any way -- is there any database with which one could evaluate the kind of changes that passed muster?

A. No.

Q. Okay. Who made the decision, in those twenty cases that passed muster, who made that decision that those sites -- the changes passed?

A. I did.

Q. And with anyone else or was that exclusively in your hands?

A. It was in my hands.

Q. Okay. Other than the considerable experience that you've had at the FTC, have you had any specific training about what a structure/function claim is?

A. No other additional training, no.

Q. Have you had training at the FTC about what a

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structure/function claim is?
A. Yes.
Q. Can you describe the training for me.
A. Well, it wasn't classroom training. It's mostly reading on my own.
Q. Okay.
A. And just in discussions, general discussions over the years.
Q. Has there been any -- was there any specific source of information or education on what is a structure/function claim that you relied on?
A. Well, this, this document --
Q. Are you talking about Exhibit 4?
A. -- Exhibit 4 --
Q. Okay.
A. -- and other like FDA pieces of literature I've read. I can't specifically identify them at this time.
Q. Okay. So continuing with the mechanics of what unfolded, for those who did pass muster after the changes or who were noncompliant, what happened next?
A. Well, may I add something?
Q. Absolutely.
A. That one of the changes -- a Web site would have been considered compliant because some of them just totally changed their marketing, their product, their

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format, totally -- they were totally different from what they started out as, so that was one, one of the -- the premise of their being considered compliant.
Q. Okay. Did any of them to your recollection shut down altogether?
A. Yes.
Q. Do you remember how many of those?
A. No, I don't.
Q. Within the 100?
A. I don't remember.
Q. Okay. Okay.
Actually before we take the next step in the mechanical process, in the course of your work sending out advisory letters, and so forth, did you and the FTC in these advisory letters ever ask for substantiating information?
MR. ZANG: Objection to the extent that's calling for a legal conclusion.
You may go ahead.
THE WITNESS: Okay.
Substantiation is typically requested after -- no, we did not.
BY MR. McCORMACK:
Q. Okay. Not at least in the advisory --
A. Correct.

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Q. -- letter phase.
A. Correct.
Q. Okay.
It sounds like we're getting to that point in the process, though, mechanically.
So you've identified -- you identified in the context of Operation False Cures those sites that remained noncompliant.
What happened next?
A. I'm sorry. Could you --
Q. Sure thing.
A. -- repeat that, please.
Q. Sure.
Once you identified those sites that were noncompliant, what happened next with respect to those sites and their operators?
A. I let Richard Cleland know which sites were noncompliant.
Q. In writing or e-mail?
A. In most likely -- I'm trying to remember. Probably -- most likely in writing. I can't really recall how, how it was transmitted, but most likely in writing.
Q. Okay. Do you recall, to the extent it was in writing, was it just a list or did you prepare comments

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about each site?
A. Well, I had a printout of each screen of the database and I would write -- I wrote on the page.
Q. On the printout of the page itself.
A. Yes. The database page, yes.
Q. And what did you write?
A. Compliant or noncompliant.
Q. Nothing more, though?
A. No.
Q. Okay. All right. What was the next step after that, if you know?
A. I really don't know.
Q. Okay. At what point in the process, if you know, was the request for substantiation sent out?
A. I don't know.
Q. Okay. Do you know that that did occur, you just don't know when?
A. I would assume that it was requested after the further law enforcement action, after further law enforcement action was deemed necessary.
Q. But you weren't involved in that process.
A. No, I was not.
Q. In terms of your role, what, if anything, happened next with those sites that were deemed noncompliant? Again, your role.

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A. Nothing. It was out of my hands after that.
Q. So that exhausted your part in Operation False Cures then I gather.
A. Yes. Yes.
Q. Okay. Since that time that you turned over the -- I'll call it the noncompliant list to Mr. Cleland, since that time and receiving notice that you were going to have to come up here and talk to me, did you track the results or the progress of what was happening on the Daniel Chapter One matter at all?
A. No. Not at all.
Q. How about any of the other cases, noncompliant sites, out of Operation False Cures?
A. No.
Q. While I'm reviewing my notes, would you review Exhibits DCO 1, 2 and 3, which are discovery requests made by Daniel Chapter One to the FTC. Essentially what I'm going to ask you to do, ma'am, is just tell me if you've ever seen these before.
But take a moment to review those. I'm going to review my notes.
(Pause in the proceedings.)
Have you reviewed those documents?
A. Yes, I have.
Q. Have you ever seen them before?

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A. No, I have not.
Q. Okay. During the course of your work on Operation False Cures, whether for Daniel Chapter One or any of the target companies, did you or your surfers make any efforts to determine the truth or falsity of the claims made?
A. I consulted some databases that we use in ad practices, herbal supplement databases, to find out what -- if there were any studies or any reports of efficacy and for any safety issues.
Q. Okay. So the FTC has a database of --
A. It's a subscription.
Q. Okay. It's a subscription to what?
A. Natural Standard and a thing called Natural Databases -- I'm not a hundred percent sure of the second one.
Q. Okay.
A. Or Natural Medicine Databases. I'm not a hundred percent sure.
Q. Okay. In the context of Operation False Cures, can you tell me at what point or different points in the process you would have done that exercise of getting into those two databases?
A. After responses from the Web sites, if I did get responses from the Web sites that questioned our

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advisory letter, I would have consulted with the databases.
Q. Okay. Do you recall specifically whether you consulted either or both of those databases with respect to Daniel Chapter One products?
A. I don't recall specifically, no.
Q. Do you know who maintains either of those databases?
A. No, I don't.
Q. Do you know -- okay.
Do you know -- a slightly different question -- who loads the data into them or the source, the sources for the data?
A. No, I don't.
Q. Okay. Is research into those databases standard operating procedure in surfs like this one?
A. It is for me.
Q. Okay. In the context of Operation False Cures, do you recall finding substantiating data for any of the products or ingredients for the manufacturers targeted?
MR. ZANG: Objection to the extent it's calling for a legal conclusion.
Go ahead and answer if you can.
THE WITNESS: If I did find any supporting

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data, it wasn't a hundred percent proof that something was effective. There might have been preliminary findings that suggested that something might be effective, but I don't recall finding anything for any of the products we found, you know, to really support efficacy.
BY MR. McCORMACK:
Q. Did you pass on any of that data that you found to Mr. Cleland along with the Web sites on a manufacturer-per-manufacturer basis or not? Do you remember?
A. Well, I don't believe I consulted the database for every single Web site, but for what I did consult, yes, I did attach information. Or if Mr. Cleland had a question about a specific ingredient or compound, I would have consulted the database and provided him with the results.
Q. Does the FTC, specifically the Division of Advertising Practices, have any healthcare providers on staff?
MR. ZANG: Lack of foundation.
THE WITNESS: No.
BY MR. McCORMACK:
Q. Do you have any healthcare training?
A. No.

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Q. Okay. I'm going to go back to reviewing my notes. Bear with me here just a minute. That's a sign that I'm drawing to a close, that I can't think of any more questions.

MR. J. TURNER: We have some, too.

MR. McCORMACK: I figured you would.

(Pause in the proceedings.)

BY MR. McCORMACK:

Q. Ms. Colbert, do you have any specific recollection of speaking directly with anyone from Daniel Chapter One itself?

A. No. I never spoke with anyone from Daniel Chapter One.

Q. Okay. Do you recall speaking with anyone who used Daniel Chapter One products?

A. No.

Q. In the course of your Operation False Cures work, did you speak with consumers of any of the products at issue?

A. No.

Q. Did you conduct any purchases of Daniel Chapter One products?

A. No.

MR. McCORMACK: What I'm going to suggest is we take just a five-minute break. You can run down the

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hall, I can confer with my co-counsel, capture lingering questions, and then we'll travel the last mile home.

THE WITNESS: Okay.

MR. McCORMACK: All right.

Thank you. You've been very patient.

(Recess)

BY MR. McCORMACK:

Q. Back on the record.

A. I'd like to amend a previous answer.

When you had asked if I had reviewed any documents in preparation for the deposition, I did look at like a little summary page that I had where I had counted up how many Web sites we had sent e-mails to and how many replied.

Q. Okay. This is a summary page that you had prepared?

A. Yes. Just for my own reference.

Q. And when did you review that?

A. It would have been late last week. Maybe Friday.

Q. And that was in preparation for today?

A. Yes. Just as a recollection.

MR. McCORMACK: I'll try to remember to make a request for that, and then we can decide --

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MR. ZANG: I'll take it under advisement. Appropriate privileges.

MR. McCORMACK: I wouldn't expect you to do otherwise. That's fine. And that was more for my mental note than anything else.

BY MR. McCORMACK:

Q. I have just a half a dozen to a dozen more questions and then I think we'll be done.

First of all, in the course of your work on Operation False Cures specifically, did you do any consulting with the FDA, anyone from the FDA?

A. Yes.

Q. And describe for me when, where, how, who, what.

MR. ZANG: And just let me say I'm going to let Ms. Colbert answer, but I do want to state the governmental investigative and deliberative process privileges as well as joint law enforcement privilege. I just want to put that on the record to preserve our privileges, but you may go ahead and answer.

THE WITNESS: We spoke with FDA staff off and on during the -- in the duration of the surf. I can't pinpoint any specific dates.

BY MR. McCORMACK:

Q. What was the subject matter of those

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consultations?

A. The nature of the surf, at what stages we were in the surf, when we were going to send out advisory letters.

Q. Okay. Was the purpose of that consultation with the FDA to advise them about the status of the surf or was it to receive feedback and input from the FDA?

A. More just to let them know the status of the surf.

Q. Do you recall -- and specifically yourself, do you recall getting any guidance from the FDA personnel that you were in contact with during Operation False Cures?

MR. ZANG: Again, same objections.

THE WITNESS: Can I ask to confer?

MR. ZANG: Yes.

(Witness and counsel confer.)

THE WITNESS: The FDA was another surf partner, so we were in touch with them about the topics that I just mentioned.

BY MR. McCORMACK:

Q. Sure. Let me try to be more specific.

Did you ever seek guidance from the FDA in making the evaluations about the claims that came up in

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Operation False Cures?
A. No.
Q. Okay. Ms. Colbert, you've used the phrase "surf partner."
What is a surf partner?
A. A participant.
Q. Okay.
A. As in our FTC regional offices were surf partners with our Washington office.
Q. So did the FDA, if you know, craft its own search parameters or did they sort of adopt yours, if you know?
A. I don't know.
Q. Okay.
A. I don't know if they crafted their own. But they did contribute to the list of terms that I mentioned earlier.
Q. The search terms?
A. Yes.
Q. What else did the FDA do, to your knowledge, in the context of Operation False Cures?
They conducted their own surfs?
A. Yes, they conducted their own surfs.
Q. They contributed to the terminology used for the surfs it sounds like.

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A. Yes.
Q. Okay. Do you know, did they supply you with some sites that they deemed -- or that came up for them?
A. Yes.
Q. Do you remember how many the FDA supplied to you?
A. No, I don't.
Q. Do you recall if Daniel Chapter One was one of the sites that FDA supplied to you?
A. Daniel Chapter One was on the FDA list.
Q. Okay. Do you know if Daniel Chapter One came up on any other surfer's list other than the FDA list?
A. Yes.
Q. How many?
A. One.
Q. Just one other?
A. Yes.
Q. Do you remember who it was?
A. The Competition Bureau of Canada.
Q. Okay. Any other FTC surfers that identified Daniel Chapter One, to your recollection?
A. Do you mean did Daniel Chapter One come in as duplicate -- I don't remember.
Q. Okay.

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A. We would have eliminated any duplicates.
Q. Was the Canadian entity you just described a surf partner as well?
A. Yes.
Q. And that was set up before the surf started I presume.
A. Yes.
Q. Okay. All right. Were there any other surf partners?
A. No.
Q. Thanks for bearing with us. This goes with the territory. Thank you.
Are you aware of any press releases that the FTC issued about Operation False Cures and the results of the operation?
A. I believe there was a press release issued. I don't recall the content of it specifically.
Q. Did you have any role in preparing that press release?
A. No. Not that I know of.
Q. Okay. Okay. Do you know who did?
A. Not specifically, but our press office, our public affairs office, most likely would have put it together.
Q. And who -- if you know, who would have directed

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them to do so?
A. Our Division of Consumer and Business Education.
Q. And is there an individual in particular with whom you're familiar that would give that direction?
A. Carolyn Shanoff.
Q. Can you spell her last name if you know it?
A. S-H-A-N, as in Nancy, O-F-F.
And another staffer is Carol Kando, K-A-N-D-O, Pineda, P-I-N-E-D-A.
Q. A few more specifics just to flush out the mechanics of Operation False Cures a little bit further.
I think you've said that in the process of the surfers pulling data off the Web, either the surfers or yourself made a column where claims were identified? Did I understand that right?
A. There's a field.
Q. Okay. A field, a field for claims.
Who filled those fields in?
A. Our interns and myself and a paralegal.
Q. So with respect to the claims that were identified for Daniel Chapter One in that field, do you recall specifically who did it?
A. No, I don't.

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Q. Okay. And when you say interns, yourself and the paralegals, did you all participate or one of those three groups would have done so but hard to discern whom, who specifically?
A. We all worked on the project at different times during the day or during the week. I really couldn't say who filled in the Daniel Chapter One claims field.
Q. Okay. To the best of your recollection, was the instruction to paraphrase the claim or write it word-for-word verbatim? How did that unfold?
MR. ZANG: Objection. Lack of foundation.
THE WITNESS: To take it from the printout that we received.
BY MR. McCORMACK:
Q. Okay. And was it to be taken verbatim from the printout you received?
A. Yes.
Q. Okay. You indicated that there were about a hundred, give or take, sites identified from Operation False Cures and that I think you said about twenty were deemed compliant?
A. Yes.
Q. And then I also asked you how many of the sites shut down, just outright shut down. I think you said some of them did, but you weren't sure how many.

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A. That's right.
Q. Okay. Did you include those sites that shut down within the group that was compliant?
A. Yes.
Q. Okay. So in other words, of those twenty, some shut down, some changed sufficiently to pass muster.
A. That's correct.
Q. Okay. Of those twenty, do you recall how many just outright shut down and how many actually made changes?
A. No, I don't recall.
Q. Is that on the list that you reviewed the other day?
A. It may be. I don't remember specifically each itemized entry. It may be.
Q. Okay. Okay.
Did any -- to the best of your recollection, did any sites make changes or adjustments but did not pass muster?
A. Yes.
Q. Again, do you recall how many?
A. I don't recall how many.
Q. To the extent that you remember either specifically or generally, would there have been an interim step with those folks who made sites -- excuse

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me -- made changes but whose sites still did not pass muster?
A. I would have communicated with them to say that we'd noted the changes that had been made, but there were still -- we still had problems with some other portion that had not been attended to.
Q. And was another -- to the extent you can remember, did the site owner or operator make another effort to make the changes in those cases?
A. Yes.
Q. Were they resolved, generally speaking?
A. Some were; some were not.
Q. Okay. And again, ultimately those that were fell into the twenty or so that were compliant and those that weren't -- never -- were noncompliant obviously.
A. Correct.
Q. Do you know how many, of the sites that were ultimately deemed noncompliant, how many went to complaint, where a complaint was actually issued?
A. No, I don't.
Q. Okay. All right.
And I may have asked you this, and if I did, forgive me, but how many noncompliant sites went to Mr. Cleland?

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A. I don't recall.
Q. However many there were outside the twenty that were either shut down or compliant I presume.
A. Correct.
Q. Okay. All right. And I think I asked you if you know who Michael Marino is.
A. Yes, you did.
Q. Okay. And did you work with him in Operation False Cures?
A. No, I did not.
Q. Do you know if he was one of the surfers through the course of your work on the database?
A. No, I don't know.
Q. And have you ever talked with him?
A. I have not talked with him in connection with this matter. I've talked with him in the past.
Q. But not on this --
A. But not on this matter.
Q. Okay. Okay. Also I think I asked you this, but let me make sure.
Was the word "cancer" one of the target triggers for the database search?
A. I think so. I'm not a hundred percent sure, but I would think it was.
Q. In the course of filling out the fields that

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you've described, was there any column or field for consumer complaints?
A. No.
Q. Were consumer complaints any part of your database search?
A. I did not -- I don't recall searching for consumer complaints in connection with any products.
Q. Or Operation False Cures generally?
A. Correct.
Q. Okay. Okay.
And do you know where the title Operation False Cures came from?
A. No, I don't.
Q. Okay. All right.
And in the course of your work specifically, was part of your job responsibility to help site operators get into compliance?
A. Yes.
Q. Did you ever give site operators specific recommendations or advice about what changes to make?
A. No. I never gave them any language or anything really specific. We don't preapprove the advertising or the claims, so I just made recommendations in the context of FTC advertising law.
Q. Okay. So did you convey FTC advertising law to

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the Web site operator and kind of leave it to them to figure out what worked within those parameters or not?
A. Well, in the advisory letter we provided links to publications. A lot of times it didn't appear that those publications were read, but I tried to break it down and take out some sections that were relevant and applicable to what the Web site operator needed to do.
Q. Okay. In response to any of those advisory letters, did you ever get phone calls, asking for guidance, for instance?
A. They asked for phone numbers, but there were so many Web sites that we just could not talk to everybody.
Q. Okay. Okay.
Okay. Were Web sites considered -- the Web sites overall considered advertising for purposes of Operation False Cures or only specific parts of it?
MR. ZANG: Objection to the extent that calls for a legal conclusion.
You may answer.
THE WITNESS: Is the Web site considered advertising?
Yes.
BY MR. McCORMACK:
Q. Okay. Were there ever instances where, for

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instance, there were portions of the Web site, whether Daniel Chapter One or otherwise, where a portion of the Web site would not be deemed advertising but imparting, let's say, educational information?
MR. ZANG: Objection to the extent that calls for a legal conclusion.
But you may answer if you can.
THE WITNESS: There may have been, yes. I vaguely recollect some essence of that, yes.
BY MR. McCORMACK:
Q. Do you still consider that within the scope of advertising, though, in terms of the discretion you were applying in your role?
A. Yes. That could be implied, implied claims embedded in that.
Q. So in some instances educational information is part of an implied claim in your opinion.
A. Possibly, yes.
MR. ZANG: Objection. This witness -- let me just state the objection. This witness is not qualified --
MR. McCORMACK: Your objection to form is noted. I think that's within the rule. You're certainly welcome to do that. Anything more explanatory I think is out of bounds.

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BY MR. McCORMACK:
Q. And lastly, how about religious information? Would that be part of advertising as well?
MR. ZANG: Same objection.
THE WITNESS: I'm sorry. Could you clarify what you mean by "religious information."
BY MR. McCORMACK:
Q. Daniel Chapter One, the bible verse, for instance.
A. The URL?
Q. Any information about the chapter itself, the bible verse.
MR. ZANG: Objection. Lack of foundation.
BY MR. McCORMACK:
Q. Just as an example.
A. Well, it could imply to the consumer that it has religious connections.
Q. Is that part of your evaluation process?
A. Whether something is religious or has religious connotations?
Q. Correct.
A. Absolutely not.
MR. McCORMACK: Okay.
Thank you.
THE WITNESS: You're welcome.

MR. McCORMACK: I'm finished. You really have been very patient. I appreciate it.

THE WITNESS: No problem.

(Whereupon, the foregoing deposition was concluded at 3:15 p.m.)

CERTIFICATION OF REPORTER

DOCKET/FILE NUMBER: 9329
CASE TITLE: Daniel Chapter One and James Feijo
HEARING DATE: January 22, 2009

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the notes taken by me at the hearing on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

DATED: JANUARY 22, 2009

JOSETT F. WHALEN, RMR

CERTIFICATION OF PROOFREADER

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.

DIANE QUADE

CERTIFICATE OF DEPONENT

I hereby certify that I have read and examined the foregoing transcript, and the same is a true and accurate record of the testimony given by me.

Any additions or corrections that I feel are necessary, I will attach on a separate sheet of paper to the original transcript.

LYNNE J. COLBERT

I hereby certify that the individual representing himself/herself to be the above-named individual, appeared before me this day of , 2009, and executed the above certificate in my presence.

NOTARY PUBLIC IN AND FOR

MY COMMISSION EXPIRES:

WITNESS: LYNNE J. COLBERT
DATE: January 22, 2009
CASE: In the Matter of Daniel Chapter One and James Feijo
Please note any errors and the corrections thereof on this errata sheet. The rules require a reason for any change or correction. It may be general, such as "to correct stenographic error" or "to clarify the record" or "to conform with the facts."

PAGE	LINE	CORRECTION	REASON FOR CHANGE

Exhibit C

In the Matter of:

Daniel Chapter One, et al.

January 22, 2009
Richard L. Cleland

Condensed Transcript with Word Index

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FEDERAL TRADE COMMISSION
I N D E X

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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

Thursday, January 22, 2009

Room 318
Federal Trade Commission
One Bowling Green
New York, New York 10004

The above-entitled matter came on for deposition, pursuant to notice, at 3:40 p.m.

APPEARANCES:

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PROCEEDINGS

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Whereupon --
RICHARD L. CLELAND
a witness, called for examination, having been first duly sworn, was examined and testified as follows:
EXAMINATION
BY MR. McCORMACK:

Q. Mr. Cleland, for the record, my name is Michael McCormack, one of the attorneys for Daniel Chapter One, the respondent in the case that brings us here today.

For the record, could you state your full name and your business address, please.

A. Richard L. Cleland, 601 New Jersey, Northwest, Washington, D.C.

Q. Mr. Cleland, I can presume the answer to this question, but I'm going to ask it anyway.

Have you ever had your deposition taken before?

A. Yes.

Q. How many times?

A. Not a lot. Maybe three or four times.

Q. Okay. I'll dispense with most of the formalities other than to suggest, as you already know, if there's any question you don't understand, that is

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unclear, let me know. I'll do my best to rephrase it. Okay?

A. Yes.

Q. Super.

In preparation for your deposition today, have you reviewed any documents?

A. Yes.

Q. Can you tell me what documents you reviewed?

A. Yes.

I reviewed the commission's policy statements on unfairness, ad substantiation, and deception.

I reviewed a number of FTC cases.

I reviewed the complaint.

I reviewed the notice of deposition.

And that's the documents that I can recall. There may have been some additional ones.

Q. Okay. Do you recall specifically what cases you reviewed?

A. Oh. Among others, Pfizer, Thompson Medical, Kraft.

Those would be the primary cases.

Q. Did you review any cases involving dietary supplement manufacturers?

A. Actually that jogs my memory of some other stuff that I did review.

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The district court decision in the National Urological case. That involved some weight-loss products.

So the answer to your question is yes.

Q. Other than the urological case that you just identified, any others that involved dietary supplements or purported dietary supplements?

And obviously if you don't remember, that's fine.

A. Yeah. I'm not -- I don't recall.

Q. Okay. Before us here on the table, Mr. Cleland, are four documents that have been marked Exhibits DCO 1, 2, 3 and 4.

While I'm having our court reporter mark Exhibit 5, if you'd take a look at those four exhibits and tell me if any of them are documents you reviewed in preparation for today's dep.

(Pause in the proceedings.)

(DCO Deposition Exhibit Number 5, Notice of Deposition Pursuant to 16 CFR 3.33(c), was marked for identification.)

THE WITNESS: The only document that I looked at of Deposition Exhibits 1, 2, 3 and 4 would have been Deposition Exhibit Number 3, which is labeled Complaint Counsel's Answers to Respondents' First Set of

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Interrogatories. And my primary reason for -- and I did not review the whole thing but only those questions that related to issues that were raised in the notice of deposition.

BY MR. McCORMACK:

Q. Prior to reviewing Exhibit Number 3 in preparation for your deposition, had you seen this document, the interrogatory answers?

A. I may have seen a draft of that document.

Q. Okay. Do you recall participating in the preparation of the answers prior to reviewing the document in preparation for this deposition?

A. Yes. I had input into some of the answers.

Q. Okay. Okay. And -- okay.

And forgive me, but I didn't catch your answer if you did.

Did you review document Exhibit Number 4?

A. I did not review Deposition Exhibit Number 4.

Q. Okay. Let me show you now what's been marked Deposition Exhibit Number 5, DCO Number 5, a copy of the notice of deposition that brings you here today. I think you said you reviewed that. Correct?

A. Yes.

Q. And it's my understanding that you are prepared to give testimony in response to the five areas of

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inquiry identified in that deposition notice?

A. Yes.

Q. Is there any area identified in 1 through 5 that you are not prepared to give testimony about?

A. Not that I'm aware of at this time.

Q. Okay. We'll find out, won't we.

With respect to Exhibit Number 5, Mr. Cleland, can you tell me, to the extent that you know, how you were selected to give testimony as opposed to somebody else.

MR. GORDON: Let me object to the form of that, but go ahead, if you know.

THE WITNESS: I volunteered.

BY MR. McCORMACK:

Q. Okay. And was the call yours to make essentially?

MR. GORDON: Objection to form.

Go ahead.

THE WITNESS: Actually had lead counsel objected to it, I think I would have considered an option.

BY MR. McCORMACK:

Q. Okay. Tell me if you would just generally what is your -- well, first, what is your job title with the FTC?

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A. I am assistant director for the Division of Advertising Practices.

Q. And can you give me sort of a Reader's Digest version of what the job responsibilities are for that position?

A. It's primarily a supervisory position. I supervise and manage other attorneys and their casework.

Q. Do you also supervise investigators and paralegals?

A. Well, I would be supervising anybody that was involved in one of my -- one of the cases that I was responsible for, and that would include, depending on the case, investigators or paralegals.

Q. Okay. And when you say -- when you say "cases," are you talking about specific respondents or are you also including operations like Operation False Cures, for instance?

A. It would be both.

Q. Okay. All right.

How long have you been the assistant director of advertising policy?

MR. GORDON: Advertising practices.

MR. McCORMACK: Practices. Thank you.

THE WITNESS: You know, I don't know exactly

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the answer to that question. It seems like a long time.

Probably about roughly eight years.

BY MR. McCORMACK:

Q. And how long have you been with the FTC overall?

A. Since 1991.

Q. And prior to your current role, what was your role?

A. Well, I had bounced back and forth. I was the -- starting -- let me start from 1991 and move forward. It makes more sense going that direction.

Q. Okay. That's fine.

A. From 1991 until about 1994 I was a senior attorney in the Division of Advertising Practices doing litigation.

Then I spent a year and a half to two years, approximately, in the Bureau of Consumer Protection office where I was the coordinator for the regional offices.

Then I spent two years as the assistant director in the Division of Service Industry Practices, where my function actually was pretty much the same as it is now, supervising attorneys in cases and operations.

Q. Could I interrupt you.

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What does "service industry" mean?
A. Well, it was half of the -- half of the division essentially dealt with things like investment frauds, art frauds, things like that, and the other half of the division dealt with medical services, various types of medical services.
Q. As opposed to products or devices?
A. Right.
Q. Okay. Okay.
A. And then that division was dissolved, and I went back to the Division of Advertising Practices where I was a senior attorney for three or four years and then became the assistant attorney -- assistant director for the Division of Advertising Practices.
Q. In that role, just to explore the scope of potential testimony under the dep notice and also taking care, as I will try to do, to stay away from privileged information, can you describe for me the extent to which your role, your current job description, is managerial and administrative versus legal prosecutorial.
MR. GORDON: Objection.
Go ahead.
THE WITNESS: Yeah, I don't know that I can really answer that question because I don't think that

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the job responsibilities divide up that neatly.
I make various decisions on what cases or what the staff recommendation is going to be. I participate in the selection of cases. I participate in and lead others in, you know, management of cases. I've even led a case where it was necessary. It was a big enough case.
So I don't think that -- it doesn't break down squarely in -- at least at my level, it doesn't break down squarely into only supervise, only -- because I do -- the truth is, I do a great deal of all those functions.
BY MR. McCORMACK:
Q. Okay. Do those functions include setting policy for operations like Operation False Cures, for instance?
A. I don't mean to be evasive, but I need a better definition of what you mean by "policies."
Q. Establishing the mechanics of how the investigation or operation will unfold, for instance.
A. I do get involved in that.
Q. And I'll get more specific with my questions.
A. Yeah. Yeah.
Q. I understand.
Do you also participate in what I'll call the

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prosecutorial discretion of which, in the case of Operation False Cures, which supplement manufacturers are going to have complaints filed and prosecuted or not?
MR. GORDON: Objection to form.
THE WITNESS: So I want to make sure. Without conceding that we're talking about supplement manufacturers, the -- I do get -- I do get involved on in terms of recommending cases for further action. I make recommendations with regard to closing cases, the whole gambit of recommendations.
BY MR. McCORMACK:
Q. Okay. With respect to Operation False Cures, did you participate in the prosecutorial discretion that led to a determination of complaints being filed or not?
MR. GORDON: Objection to form.
THE WITNESS: Yes.
BY MR. McCORMACK:
Q. Okay. Was the, if you will, the final authority yours as to who was -- who had complaints filed and who didn't?
A. No.
MR. GORDON: Objection.
THE WITNESS: I'm sorry.

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MR. GORDON: Go ahead. Sorry.
BY MR. McCORMACK:
Q. Was that made by a team?
MR. GORDON: Objection.
THE WITNESS: No. That was made by the commission.
BY MR. McCORMACK:
Q. Okay.
Okay. We, as you may know, just finished taking the deposition of Ms. Colbert, and to help me understand a little bit more about how the policies are implemented, and so forth, let me ask you if I could a few questions about her description of the Operation False Cures mechanism.
First, do you know who came up with the title "Operation False Cures"?
A. Yes.
Q. Who did?
A. I did.
Q. Okay. And do you know who developed the search parameters for the database surf that Ms. Colbert and her team conducted?
MR. GORDON: Objection to form.
You mean Internet surf?
MR. McCORMACK: Yes.

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THE WITNESS: Well, initially I -- my recollection is -- and I'm not sure this is in the scope of the notice, but to the extent my recollection is that Lynne developed the initial list of search terms and that other people, including myself, may have reviewed those and had suggestions as to either some that might not work or some that would be better or -- although I don't have a -- I don't have any recollection of doing any editing in that process, but she would have showed them to me.

BY MR. McCORMACK:

Q. And by "Lynne" you mean Ms. Colbert?

A. I mean Ms. Colbert.

Q. Okay. Okay. In terms of exercising the policies, the FTC policies related to false advertising claims, unfair deceptive claims, and the Operation False Cures project, after, as I understand it, Ms. Colbert submitted to you the list of noncompliant Web sites, in terms of the mechanics, what occurred next?

MR. GORDON: Objection to form.

If you know.

THE WITNESS: Again, my recollection is that I asked another attorney in my office to review that material and make a recommendation to me. And I got

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back a -- those recommendations. Then I reviewed the Web sites and came up with a list of Web sites that I thought were plausible law enforcement targets.

BY MR. McCORMACK:

Q. Okay. Were there specific criteria that you utilized from a policy standpoint to make that, I'll call it, target evaluation?

MR. GORDON: Objection to form.

Go ahead.

THE WITNESS: In general what we were looking for were what we considered to be express or nearly express claims that -- based on what we understood were unlikely to be substantiated or likely to be false.

BY MR. McCORMACK:

Q. Okay. In terms of what -- the phrase you used, "nearly express claims," Ms. Colbert I'll represent to you used the word "implied."

One of the challenges we find in this case is trying to interpret and understand the FTC policies and guidelines as well as regulations if they exist that define what an implied claim is.

A. Uh-huh.

Q. Can you tell me what the criteria is for evaluating what you called the nearly express claims.

MR. GORDON: Objection to form.

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Go ahead.

THE WITNESS: Okay.

I mean, I -- what I can do is refer you to the case law. And in particular I would refer you to cases like Thompson Medical and Kraft. Those cases discuss the different forms, different types of claims in the context of the commission's evaluation of what messages are conveyed in an ad.

In those cases, the commission talks about the claims range from claims that are express, which in which, you know, the meaning of the claim is apparent on its face, to cases or claims that are nearly express, meaning, you know, it's obvious from its face, to implied claims to claims that, you know, all the way on the far end that ultimately that a reasonable consumer might not take or at least the commission couldn't conclude with confidence that a reasonable consumer would take from an ad. And as to those claims, the commission suggested in those decisions that extrinsic evidence might be necessary.

So we're really talking about a range of clarity of a particular claim.

BY MR. McCORMACK:

Q. So it's a range of clarity.

A. Uh-huh.

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Q. So no set definition of what an implied claim or nearly express claim is.

MR. GORDON: Objection to form.

BY MR. McCORMACK:

Q. It's a matter of discretion, is it not?

MR. GORDON: Objection to form.

THE WITNESS: Well, it is a -- you know, the -- with the exception of an express claim. An express claim is it is what it says.

BY MR. McCORMACK:

Q. Right.

A. That essentially all claims that are not express claims are subject to some interpretation.

Q. Okay. From a policy standpoint, Mr. Cleland, once a case is assigned for prosecution, what role do you continue to play, if any, in, say, monitoring the case through its litigation process?

MR. GORDON: Objection to form.

THE WITNESS: If it is a case that is being handled by the Division of Advertising Practices and it was one of my cases, I will continue to manage the litigation, not as lead attorney but as the ultimate decision maker in matters of -- involving the case.

BY MR. McCORMACK:

Q. Sure.

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Is Daniel Chapter One one of your cases, as you just used that phrase?
A. No, it is not.
Q. Okay. To what extent in your role are you involved in crafting what I call the requested remediation that appears in the complaint?
MR. GORDON: Is that in a general matter?
MR. McCORMACK: Let's talk specific to Daniel Chapter One.
Thanks for that clarification.
BY MR. McCORMACK:
Q. Do you know what I mean by "requested remediation"?
A. I think you're talking about the notice order, what I would --
Q. The proposed order?
A. As proposed.
Q. The proposed order.
A. We would call it the notice order.
Q. That's what I'll call it then.
A. I --
MR. GORDON: And what's the question at this point?
MR. McCORMACK: What's his role in crafting that, the language of that notice order.

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THE WITNESS: I think it would be fair to say that because there were multiple cases involved in Operation False Cures, we used what we would refer to as model pleadings for the cases so that the cases would end up with essentially the same type of relief to the extent that we could, given the different forums that were involved in some of the cases.
In terms of developing the model pleadings which ultimately became I think the basis for the notice order in this case, I was active in drafting those model pleadings.
BY MR. McCORMACK:
Q. Okay.
A. And to the extent that I think it -- I can't say that I had the final word on those pleadings because that would have been a matter for ultimately for the Bureau of Consumer Protection staff and the commissioners that voted out the complaint.
Q. In the model pleading process that you just described for Operation False Cures then, do I understand your testimony correctly that you had at least a role in crafting the proposed letter that respondents would have to send in the event --
A. Yes.
Q. -- the ALJ ruled against them?

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MR. GORDON: Objection to form.
Go ahead.
THE WITNESS: Yes.
BY MR. McCORMACK:
Q. Okay. And was that proposed letter -- I call it attachment A to the complaint -- was that proposed letter the same in every complaint that was filed based on Operation False Cures?
MR. GORDON: Objection to the form.
Go ahead.
THE WITNESS: It should have been substantially the same in all cases.
BY MR. McCORMACK:
Q. Okay.
A. Whether or not, because some of these cases were settlements, there may have been some minor variations based on the negotiations in a particular case.
Q. Okay. So in terms of the model pleadings and the notice order that was part of the model pleadings, in every complaint filed under Operation False Cures was there a requirement that the respondent send to consumers a letter that included references to conventional cancer treatments?
MR. GORDON: Objection to the form.

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THE WITNESS: I think that the answer to that question is yes. The one case that I'm not a hundred percent sure is the case that involved a company called Bioque or a product called Bioque. And I'm not a hundred percent sure whether that order contained that provision, my recollection that it is, that it did, but I'm not a hundred percent certain on that.
BY MR. McCORMACK:
Q. Do you remember who the manufacturer or respondent was for that particular product?
Did you call it Biocure?
A. Bioque.
Q. Bioque.
A. No, I don't, but it would have been one of the cases that would have been referred to in the press release announcing the filing of Daniel Chapter One.
Q. Okay. So it was part of Operation False Cures.
A. Yes.
Q. Okay. All right. And just to close this loop, that particular matter did go to an order, an order was entered?
A. Yeah. There was a consent.
Q. Okay. That was my next question. Thank you.
In terms of policy and crafting that notice order, Mr. Cleland, does the FTC give any of

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being violated, and it appears to the commission that the proceeding is in the public interest. The complaint is not a finding or ruling that the defendant or respondent has actually violated the law. The stipulated final order is for settlement purposes only and does not constitute an admission by the defendants of a law violation. A stipulated final order requires approval by the court and has the force of law when signed by the judge."

Q. Okay. So there's a disclaimer in there. Is that what you just read?

MR. GORDON: Objection to the form and beyond the notice.

THE WITNESS: I wouldn't call it a disclaimer. I think it's a pretty clear statement that the commission has not made a determination that the law has been violated.

MR. McCORMACK: Okay.

Mark the next one, please.

(DCO Deposition Exhibit Number 7, FTC-DCO 0747-0766, Self-Regulation and Consumer Protection: A Complement to Federal Law Enforcement, was marked for identification.)

BY MR. McCORMACK:

Q. This is Exhibit 7, Mr. Cleland. I'd ask you to identify that, please.

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A. I don't know what this is.

Q. Okay. I'll represent to you that it was produced by complaint counsel in response to certain requests for production.

A. Okay.

Q. Have you ever seen it before?

A. No.

MR. McCORMACK: Okay.

(DCO Deposition Exhibit Number 8, FTC-DCO 0787-0799, FTC Policy Statement on Deception, was marked for identification.)

BY MR. McCORMACK:

Q. If you would, take a look at Exhibit 8, please. I'd like to know if you can identify this document.

(Pause in the proceedings.)

A. This document appears to be the deception policy -- what's referred to as the deception policy statement.

Q. Is this one of the documents that you reviewed in preparation for your deposition today?

A. Yes, it is.

Q. Okay. Generally speaking, is Exhibit 8 a fair representation of the commission's policy and guidelines with respect to unfair or deceptive practices?

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MR. GORDON: Objection to the form. I think it's beyond the scope of the notice.

Do you want to hear the question again or...

THE WITNESS: I think that this statement fairly reflects the commission's policy on deception.

BY MR. McCORMACK:

Q. That's what I wanted to know. Thank you. Could I direct your attention to the second to last paragraph on the first page, Bates-stamped 0787, please.

MR. GORDON: The second to last page?

MR. McCORMACK: The second to last paragraph of the first page.

MR. GORDON: Sorry.

BY MR. McCORMACK:

Q. It begins with the italicized word "second"?

A. Yes, I see it.

Q. I'm going to go ahead and read it into the record for my own benefit.

"We," I presume meaning the FTC, "examine the practice from the perspective of a consumer acting reasonably in the circumstances. If the representation or practice affects or is directed primarily to a particular group, the commission examines reasonableness from the perspective of that group."

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Do you see that?

A. Yes.

Q. Does that continue to be an accurate statement of FTC policy and procedure?

MR. GORDON: Objection to the form and beyond the scope of the notice.

THE WITNESS: I believe so. Yes.

BY MR. McCORMACK:

Q. Can you tell me what effort, if you know, the FTC made in the DCO case to determine the perspective of a consumer acting reasonably in the circumstances.

MR. GORDON: Objection to the form.

THE WITNESS: Basically what that refers to is ad interpretation of whether or not the commission is analyzing -- is -- it analyzes the ad to determine what claims are conveyed to a reasonable consumer in the target audience for that ad. That's what that refers to.

BY MR. McCORMACK:

Q. And how is the target audience identified?

A. The target audience can be identified from the face of the advertisement.

If you're advertising a product such as shark cartilage for the cure of cancer, then the presumption

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there is that the target audience are people who have -- either have cancer or perceive that they have cancer for that ad, so it is -- you know, it is self-evident in that case.

Q. Okay. In the DCO case, were any cancer patients interviewed, investigated, researched to identify the target audience and their impressions about the DCO statements?

MR. GORDON: Objection to the form and beyond the scope of the notice I believe.

THE WITNESS: The answer is no.

BY MR. McCORMACK:

Q. Okay. Were any efforts made to investigate or interview any users of DCO products in this case?

MR. GORDON: Objection. Beyond the scope of the notice.

THE WITNESS: No. Not by my office.

BY MR. McCORMACK:

Q. Okay. Do you know if that was done by any other office?

MR. GORDON: Same objection.

THE WITNESS: I don't know whether that was done by any other office.

BY MR. McCORMACK:

Q. Okay. Mr. Cleland, did you confer at all with

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any representatives from the FDA with respect to DCO?

A. What do you mean by "confer"?

Q. Did you talk with them, communicate with them in any way?

A. There were communications between the FTC and the FDA involving Daniel Chapter One.

Q. Did you participate in those communications?

MR. GORDON: This is again beyond the scope of the notice.

THE WITNESS: Yes.

BY MR. McCORMACK:

Q. Do you remember who at the FDA you talked with?

MR. GORDON: Same objection.

THE WITNESS: Most likely it was Gary Coody. It could have also been a person by the name of Lisa Romano.

(DCO Deposition Exhibit Number 9, FTC-DCO 0804-0810, FTC Policy Statement on Unfairness, was marked for identification.)

MR. GORDON: Counselor, before we go any further, on Exhibit 7 you've given us a copy that's got I'm assuming your handwriting on it.

MR. McCORMACK: Oh.

MR. GORDON: Because I'm a nice guy, I'm going to give you a chance to fix your exhibit.

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MR. McCORMACK: Thank you. I appreciate it.

(DCO Deposition Exhibit Number 7, FTC-DCO 0747-0766, Self-Regulation and Consumer Protection: A Complement to Federal Law Enforcement, was re-marked for identification.)

BY MR. McCORMACK:

Q. Mr. Cleland, can you identify Exhibit 9, please.

A. Yes.

Q. Please do so.

A. It appears to be a copy of the -- what is referred to as the commission's policy statement on unfairness.

Q. Is this one of the documents you reviewed in preparation for your deposition today?

A. Yes, it is.

Q. If I could direct your attention to the second full paragraph on the first page identified with the Bates number 804.

And the third full sentence I'll quote: "We recognize that the concept of consumer unfairness is one whose precise meaning is not immediately obvious and also recognize that this uncertainty has been honestly troublesome for some businesses and some members of the legal profession."

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Do you see that statement?

A. Yes.

Q. Okay. Do you agree with it or disagree with it today?

MR. GORDON: Objection as to form. It's beyond the scope of the notice.

(Witness and counsel confer.)

THE WITNESS: I agree that that might have been an accurate statement on December 17, 1980. I don't think that it's an accurate statement today.

BY MR. McCORMACK:

Q. And -- fair enough.

What has occurred to bring -- strike that.

Would you say that it's certain today?

A. Would I say -- I think that --

MR. GORDON: Objection as to vagueness and also outside the scope.

THE WITNESS: I think that in part, because of this document, that the commission's exercise of its unfairness jurisdiction is -- it is fairly clear what comes within -- it is clear what comes within the context of unfairness, that there has been an effort to refine the definition of it that -- and to address other issues that were, quote, troublesome to the bar at the time.

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BY MR. McCORMACK:
Q. Have regulations about dietary supplements been promulgated to bring about any of the certainty that you're talking about?
MR. GORDON: Objection. Way beyond the scope of the notice.
THE WITNESS: The -- well, there have been no regulations promulgated by the FDA that deal specifically with the subject of dietary supplements.
BY MR. McCORMACK:
Q. You said FDA. Did you mean to say FDA?
A. By the FTC.
Q. Okay.
A. And by "regulation" I mean trade rule regulations.
Q. Right. Right.
Have there been requests, petitions to make rules along those lines?
A. Yes.
MR. GORDON: Objection. Beyond the scope.
BY MR. McCORMACK:
Q. Okay. The second page of that Exhibit 9, Mr. Cleland, if you could turn to that, and I'd like you to direct your attention to the --
A. Although I need to qualify that in the context

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of this conversation.
Q. Sure.
A. Because it's outside of the scope of this, I'm going to have to say that there have been -- I'm familiar with requests that have -- petitions that have been filed with the FTC regarding rulemaking that would deal with some issues involving dietary supplements.
Whether or not that deals specifically with the commission's unfairness jurisdiction, I'm not prepared to testify on that right now.
Q. Okay. Thank you.
So I'm directing your attention to page 2 of Exhibit 9 and the first full paragraph which appears below the italicized heading "Consumer Injury."
A. Yes.
Q. The first sentence reads: "Unjustified consumer injury is the primary focus of the FTC Act and the most important of the three S&H criteria."
Agree or disagree with that from a policy standpoint?
MR. GORDON: Objection to the form. A, it's beyond the -- and B, it's beyond the scope.
Also are you asking whether he agrees or is he agreeing that that's the FTC policy?
MR. McCORMACK: The latter.

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I'm mindful that the document is 28 years old, so I'm curious to see if the policy has changed.
THE WITNESS: Well, I think that the -- I have no reason to dispute that unjustified consumer injury is the primary focus of the FTC Act.
BY MR. McCORMACK:
Q. You have no reason to dispute that.
A. Right.
Q. Okay.
A. As for whether or not it's the most important of the three criterias in S&H, that was obviously the opinion of the authors of the letter of the commissioners at the time. Whether that continues to be the position of the current commissioners I do not know.
Q. So let's talk about injury in the DCO case.
Are you aware of any physical injury that has occurred to any consumer or user of the DCO products?
A. I am not. I have no knowledge to that effect.
Q. Okay. Do you know if any user of DCO products has complained about them?
MR. GORDON: Objection to the form.
THE WITNESS: Not to my knowledge.
BY MR. McCORMACK:
Q. Okay. Do you know if anyone has been -- is

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claiming an economic injury in fact from their use of DCO products?
MR. GORDON: Objection to the form.
THE WITNESS: Again, I'm not aware of -- given that I just said I wasn't aware of any complaints being filed, it would follow that I'm not aware that anyone is claiming economic injury.
BY MR. McCORMACK:
Q. Well, there may be some investigation done outside the complaint process, which is why I was asking.
But none that you know of.
A. As to specific consumers, no.
Q. Okay. All right.
So the injury component involved in the DCO case is -- what would we call it -- theoretical?
MR. GORDON: Objection.
THE WITNESS: No. I would not call it theoretical.
BY MR. McCORMACK:
Q. Based on presumption of harm?
A. It is --
MR. GORDON: Objection.
THE WITNESS: It is based on the premise that consumers are injured when they are misled and that

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they are misled in this instance because they would make the -- take the implied claim or make the assumption that there was a reasonable basis for the claim. And had they known that there was no reasonable basis for the claim -- that's the allegation -- they may or likely would have made a different decision concerning the product. Therefore, in the view of the FTC, there is consumer injury.

BY MR. McCORMACK:

Q. Okay. How does the FTC make that assumption or arrive at that assumption?

MR. GORDON: Objection to form. I think that's beyond the scope.

But go ahead.

THE WITNESS: Well, I believe that that deduction, that inference, is made based upon both common sense viewing how consumers actually operate in the marketplace as well as the commission's institutional knowledge, having been involved in consumer and consumer behavior for almost a hundred years.

BY MR. McCORMACK:

Q. Okay. So common sense and institutional knowledge.

A. Well, and the observation, as I said, that

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consumers -- that consumers would likely act differently if they knew that there was no basis, no reasonable basis for DCO's claims.

Q. And how -- if there's been no communication with users of DCO products, how does the FTC know how those folks would operate differently?

MR. GORDON: Objection to the form.

THE WITNESS: I think that's a reasonable inference based on the facts.

BY MR. McCORMACK:

Q. And that's an inference that the FTC is making unilaterally.

MR. GORDON: Objection to the form.

THE WITNESS: I don't understand the question.

BY MR. McCORMACK:

Q. Are you presuming, Mr. Cleland, in that case that the statements made by DCO in this case are false?

MR. GORDON: Objection to the form.

THE WITNESS: I am presuming that there is no reasonable basis to support the representations that have been made in the complaint --

BY MR. McCORMACK:

Q. Okay.

A. -- and that consumers either would have a belief that such reasonable basis would exist or take the

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implied claim from those representations that such a reasonable basis existed.

Since they don't have the knowledge that no reasonable basis existed, the likelihood that they would -- the commission's rationale is that a consumer would likely make a different decision if they knew -- a different economic decision if they knew that the DCO or the advertiser had no reasonable basis to make the claim.

Q. On the basis of what information does the FTC make that inference?

A. I've already answered that question.

Q. And has the -- and in the DCO case, has the FTC determined that there was no reasonable basis for the statements that DCO made?

MR. GORDON: Objection to the form.

THE WITNESS: The determination that the commission has made is that there is reason to believe that there is no reasonable basis for the claims, for the representations that are set forth in the complaint.

BY MR. McCORMACK:

Q. If you would, direct your attention to the next page, Bates-stamped 806, specifically the first sentence of the first full paragraph, which reads: "Second, the

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injury must not be outweighed by any offsetting consumer or competitive benefits that the sales practice also produces."

Do you see that?

A. Where is that?

MR. GORDON: This paragraph (indicating).

THE WITNESS: The one that starts "Second, the injury must not" --

BY MR. McCORMACK:

Q. Yes, sir.

A. Okay. I see that.

Q. That is essentially a 1980 iteration of the standard of proof that now appears in 15 U.S.C. 45 subpart (n), is it not?

A. That would be correct.

Q. Can you tell me in the DCO case if any efforts were made to evaluate whether there was offsetting consumer benefits to the users of DCO products.

A. If, as we allege, the claims are unsubstantiated, then there is no offsetting benefit either to competitors or to consumers from those claims.

Q. I'm directing your attention to Exhibit 3, the interrogatories and answers to interrogatories in this case, and specifically, Mr. Cleland, I'd like to direct

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know -- you have looked at the unfairness statement. You have looked at the deception statement. You haven't looked at the substantiation statement yet.

Q. We may get to it yet.

A. Okay.

Q. Assuming it was produced by complaint counsel in response for documents pertaining to FTC policy, though, you would agree with me that at least some portion of it has some weight in reflecting FTC policy.

MR. GORDON: Objection to the form and that it's beyond the scope.

THE WITNESS: And I can't agree with you without reading the document.

BY MR. McCORMACK:

Q. Okay. You have no reason without reading the document to dispute that, though.

MR. GORDON: Same objections.

THE WITNESS: I have no reason either to dispute or agree with you on that statement.

(DCO Deposition Exhibit Number 12, FTC-DCO 0895-0943, was marked for identification.)

BY MR. McCORMACK:

Q. I'm handing you what's been marked Exhibit Number 12.

Can you identify that?

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(Pause in the proceedings.)

A. No.

Q. Okay.

A. I mean, I've not seen this document before. I can read the title of the document.

Q. Sure. Yeah.

And in particular I want to know if it was one of the documents you reviewed in preparation for your deposition.

A. No.

Q. I showed you before Exhibit Number 4. I direct your attention to it again.

And I think you said that this was not one of the documents that you reviewed in preparation for your deposition. Is that right?

A. That's correct.

MR. McCORMACK: Okay. And excuse me just a second.

You know what? Forgive me. I did it again. I had my copy marked by mistake, so let's correct that.

(DCO Deposition Exhibit Number 4, FTC-DCO 1041-1070, Dietary Supplements: An Advertising Guide for Industry, was re-marked for identification.)

BY MR. McCORMACK:

Q. All right. Now that we've corrected that

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error -- and I'm sorry, Mr. Cleland. You said you did not review this document in preparation for your deposition?

A. That's correct.

Q. Are you familiar with it, though, all the same?

A. Yes.

Q. Can you identify it, please?

A. Yes. It appears to be a copy of a document -- I can't read the title of it.

Q. It is hard, isn't it?

A. On this copy.

Q. I'm not sure that's a whole lot better (indicating).

A. Dietary Supplements: An Advertising Guide for Industry.

Q. Okay. Does this document qualify as reflective of FTC policy?

MR. GORDON: Objection. Beyond the scope.

THE WITNESS: This document is -- I would describe it as FTC staff's interpretations of FTC case law and precedence that was provided to industry as for guidance.

BY MR. McCORMACK:

Q. Is that something different than reflecting FTC policy?

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A. Well, you know, to the extent -- has this document been approved as the -- as official FTC policy, no, it hasn't.

Q. Okay. Let me direct your attention to Bates -- within this particular exhibit to Bates number 1050, please.

A. 1050.

Yes.

Q. Okay. And directing your attention to the heading labeled "B. Substantiating Claims" and specifically the -- what I call the five block bullet points that start on the bottom of Bates number 1050 and continue onto the top of Bates number 1051.

A. Yes.

Q. Review those, please.

A. Do what with them?

Q. Review those, please.

A. Yes.

Q. Both pages.

(Pause in the proceedings.)

A. Yes.

Q. Okay. Do those five bullet points -- regardless of whether you hold that this document reflects FTC policy or not, do those five bullet points accurately state FTC policy for substantiation?

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MR. GORDON: Objection. Beyond the scope.
THE WITNESS: I would -- I would have to say that they, at least as to my understanding of Pfizer and Thompson Medical, they -- and subsequent cases, they accurately reflect the FTC's policy.
BY MR. McCORMACK:
Q. Okay. Directing your attention to the first block bullet I call it on Bates page 1051 and the bolded heading that reads "The Benefits of a Truthful Claim and the Cost/Feasibility of Developing Substantiation for the Claim," can you tell me what, if anything, has been done in the DCO case to determine the cost/feasibility of developing substantiation for the statements made --
MR. GORDON: Objection.
BY MR. McCORMACK:
Q. -- or attributed to DCO.
MR. GORDON: Beyond the scope of the notice.
(Pause in the proceedings.)
THE WITNESS: Yeah, I don't think that there was a specific evaluation done in this particular case as to the development -- the cost of development of the -- of the substantiation. I think it's more of a general reference to in general what are the -- can a product be tested, how much does it cost to test this kind of

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claim. And quite frankly, it is only one of five factors, and not all -- all those factors have to be present.
BY MR. McCORMACK:
Q. To your knowledge, has that analysis been done in any case involving health claims made by a purported dietary supplement manufacturer?
MR. GORDON: Objection. Beyond the scope.
THE WITNESS: And I don't know the answer to that.
BY MR. McCORMACK:
Q. Okay. Look at the last block bullet point there on that same page if you would, please, Mr. Cleland, which reads "The Amount of Substantiation that Experts in the Field Believe Is Reasonable."
A. I see that.
Q. Okay. Can you tell me with respect to the DCO case specifically, if you know, what is meant or intended by "experts in the field" -- strike that.
What field are we talking about there with respect to Daniel Chapter One?
MR. GORDON: Objection. Beyond the scope.
THE WITNESS: Well, we're talking about experts in the fields of -- that would be in the field of the representations that were made here. They would be

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experts in -- they could be experts in the field of cancer treatment.
BY MR. McCORMACK:
Q. How about experts in the field of natural healing remedies? Would they qualify?
MR. GORDON: Objection to the form and also beyond the scope.
THE WITNESS: That would depend on their credentials and what they were testifying to.
BY MR. McCORMACK:
Q. Okay. But it's plausible that they would qualify for substantiation under that bullet point.
MR. GORDON: Objection to the form and beyond the scope.
THE WITNESS: Again, it depends on what they're testifying to.
I mean, you know, that's a question of qualifying an expert.
BY MR. McCORMACK:
Q. Okay.
A. And we would look -- when we're looking at experts to -- and I think this particular element is not necessarily meant to be -- you know, we have -- well, let me put it differently.
In terms of consulting experts, our normal

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procedure is to consult experts not only in the disease that we're talking about -- and we are talking about a disease here -- but, you know, experts that would also have some knowledge of what needs -- what would have to be -- from a scientific standpoint, what kind of substantiation would you need for experts in that field of the disease to be -- you know, to be generally accepted as, you know, in terms of its reasonableness.
We have consulted with disease experts. We have consulted with -- and I'm speaking generally -- with experts in alternative medicine. We have consulted with experts in natural products. We have consulted with experts in homeopathic products.
So we're not exclusive in our consultations.
BY MR. McCORMACK:
Q. Are you talking about in the DCO case or in general?
A. No, I'm not talking about the DCO case.
Q. Okay. What if the claims or statements, as is alleged in the DCO case, are not made for scientific purposes but for religious purposes?
MR. GORDON: Objection to the form.
BY MR. McCORMACK:
Q. Does it make a difference?
MR. GORDON: Beyond the scope.

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THE WITNESS: If those statements are made to promote the sale of a product, it doesn't make a difference.
BY MR. McCORMACK:
Q. And if they -- if the products are offered to substantiate the Daniel Chapter One passage from the bible, does that make a difference?
MR. GORDON: Same objection.
THE WITNESS: If the products are being marketed, advertised to the public for purposes represented in those advertisements, that's what the FTC looks at.
BY MR. McCORMACK:
Q. And if -- is there a difference between an advertisement and an offering?
A. The advertisement in this case is any -- it's any document that promotes the product or attempts to induce the consumers to purchase the product.
MR. McCORMACK: Okay. Let's take five.
MR. GORDON: Okay.
MR. McCORMACK: I'll review my notes, confer with counsel. We're twenty minutes from needing to get you out of here anyway.
THE WITNESS: Okay.
(Recess)

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BY MR. McCORMACK:
Q. Mr. Cleland, to your knowledge, has the FTC ever dealt with a case in which health claims for a purported dietary supplement were adequately substantiated?
MR. GORDON: Objection. Beyond the scope.
THE WITNESS: Yes.
BY MR. McCORMACK:
Q. Can you think of how many instances?
MR. GORDON: Same objection.
THE WITNESS: No. I wouldn't have a clue.
BY MR. McCORMACK:
Q. Okay. Fair enough.
A. I mean, I could -- because the FTC is a big organization, number one --
Q. Sure.
A. -- so...
Q. Do you recall what the sources of the substantiation for those cases was?
MR. GORDON: Same objection.
BY MR. McCORMACK:
Q. Or what the sources were?
A. In most of the -- in -- in most of those instances they would have been clinical studies with humans, with control groups randomly assigned to either

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a placebo or a treatment group.
Q. Can you think of any products, generic products themselves that fall under that category?
MR. GORDON: Same objection.
THE WITNESS: Can I think of any.
Where it usually plays out is that there will be substantiation perhaps for a claim as opposed -- you know, one representation as opposed to representations about a whole product or something to that nature.
And I'm trying to think of specific examples, and I'm sure that if I were given adequate notice, I could come up with some, but sitting here I'm not sure.
BY MR. McCORMACK:
Q. And how about the same question, any cases that you're familiar with that the FTC has dealt with where health claims were made by homeopathics that were found to be substantiated?
MR. GORDON: Same objection.
THE WITNESS: I don't recall any of those cases where -- and again -- no. No need to go beyond that. I have no recollection of that event.
MR. McCORMACK: Okay. Great.
Thank you. I have no further questions.
THE WITNESS: Okay.

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MR. GORDON: Why don't we take --
MR. McCORMACK: Yep.
(Pause in the proceedings.)
MR. GORDON: We don't have any questions. That's fine.
THE WITNESS: Thank you.
MR. McCORMACK: Thank you. I appreciate it.
(Whereupon, the foregoing deposition was concluded at 6:09 p.m.)

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CERTIFICATION OF REPORTER

DOCKET/FILE NUMBER: 9329
CASE TITLE: Daniel Chapter One and James Feijo
HEARING DATE: January 22, 2009

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the notes taken by me at the hearing on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

DATED: JANUARY 23, 2009

JOSETT F. WHALEN, RMR

CERTIFICATION OF PROOFREADER

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.

DIANE QUADE

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CERTIFICATE OF DEPONENT

I hereby certify that I have read and examined the foregoing transcript, and the same is a true and accurate record of the testimony given by me.

Any additions or corrections that I feel are necessary, I will attach on a separate sheet of paper to the original transcript.

RICHARD L. CLELAND

I hereby certify that the individual representing himself/herself to be the above-named individual, appeared before me this day of , 2009, and executed the above certificate in my presence.

NOTARY PUBLIC IN AND FOR

MY COMMISSION EXPIRES:

95

WITNESS: RICHARD L. CLELAND
DATE: January 22, 2009
CASE: In the Matter of Daniel Chapter One and James Feijo
Please note any errors and the corrections thereof on this errata sheet. The rules require a reason for any change or correction. It may be general, such as "to correct stenographic error" or "to clarify the record" or "to conform with the facts."

PAGE	LINE	CORRECTION	REASON FOR CHANGE

Exhibit
D

In the Matter of:

Daniel Chapter One, et al.

February 6, 2009
Denis R. Miller

Condensed Transcript with Word Index

For The Record, Inc.
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OFFICIAL TRANSCRIPT PROCEEDING

FEDERAL TRADE COMMISSION

MATTER NO. D09329

TITLE DANIEL CHAPTER ONE

PLACE FEDERAL TRADE COMMISSION
ONE BOWLING GREEN, SUITE 318
NEW YORK, NY 10044

DATE FEBRUARY 6, 2009

PAGES 1 THROUGH 194

TESTIMONY OF DENIS R. MILLER

FOR THE RECORD, INC.
10760 DEMARR ROAD
WHITE PLAINS, MD 20695
(301)870-8025

INDEX

EXHIBITS

UNITED STATES DISTRICT COURT

FEDERAL TRADE COMMISSION

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

Friday, February 6, 2009

Federal Trade Commission
One Bowling Green
New York, New York

The above-entitled matter came on for deposition, pursuant to Agreement, at 9:30 a.m.

Pages 1 - 194

Reported by: Linda A. Schilt

APPEARANCES:

ON BEHALF OF THE FEDERAL TRADE COMMISSION:

THEODORE ZANG, JR., ESQ.

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New York, New York 10004

ON BEHALF OF THE DEFENDANTS:

JAMES S. TURNER, ESQ.

CHRISTOPHER TURNER, ESQ.

BETSY E. LEHRFELD, ESQ.

SWANKIN & TURNER

1499 16th Street, N.W.

Washington, D.C. 20036

DR. D E N I S R. M I L L E R, having first been duly sworn by a Notary Public of the State of New York, was examined and testified as follows:

EXAMINATION BY

MR. S. TURNER:

Q. Good morning.

A. Good morning.

Q. Dr. Miller, could you state your name, address and professional title for the record.

A. Yes. Denis R. Miller, D-E-N-I-S. My address is 36 East Lake Road, Tuxedo Park, New York 10987.

My official title?

Q. Yes, whatever your professional title is.

A. I'm a therapeutic area leader for oncology hematology at Parexel, P-A-R-E-X-E-L, all capital letters, International.

Q. Thank you. Dr. Miller, you met Betsy Lehrfeld who is here, Chris Turner, and I'm Jim Turner, and we are representing the respondent in this case, Daniel Chapter One.

A. Yes.

MR. J. TURNER: What we're planning to do today is go over your expert witness report and talk about that and I want to do three things: One is to talk about how the report was prepared, that's the first

Do you have a background in nutrition?

A. Am I a nutritionist, no. Do I know about nutrition as it relates to cancer patients, yes.

Q. Can you describe your knowledge about nutrition as it relates to cancer patients?

A. Well, I'm very aware of the importance of nutrition in cancer patients. I'm very well aware of the adverse effects of malnutrition. I'm aware of how important it is for cancer patients who are undergoing therapy to make sure that they're well hydrated and not malnourished and, if they are, to treat those deficiencies so they can tolerate their treatment better and have a better quality of life.

I am constantly engaged in working with nutritionists and metabolic colleagues to help support cancer patients that I treated in a comprehensive and full way.

Q. Do you have any training in nutrition?

A. No.

Q. Do you have any certifications in nutrition?

A. No.

Q. I noted in your credentials that you were involved in oncology/hematology. Is that your area of expertise?

A. I'm board certified in oncology and hematology.

there may be other warnings, other side effects and they usually list them all.

Q. Okay. I want to now go to the part of the report "Detailed Discussion of Findings" and begin with Bio*Shark.

A. Yes.

Q. You began that by saying, "The key questions relating to Bio*Shark are: Does Bio*Shark inhibit tumor growth? Is Bio*Shark effective in the treatment of cancer?"

A. Yes.

Q. Who formulated those questions?

A. Well, I formulated the questions in response to the scope of work on page four where I said I had been asked by the FTC to determine whether there is competent and reliable scientific evidence to support or substantiate the following claims, and the first one, does Bio*Shark inhibit tumor growth, and the second, Bio*Shark is effective in the treatment of cancer, and I turned it a -- I asked the question and addressed those questions with the available peer-reviewed literature that addressed whether or not Bio*Shark inhibits tumor growth and whether or not it's effective in the treatment of cancer.

Q. You state that a number of reported

effect of curcumin."

I don't know one by Rao, "Chemoprevention of colon carcinogenesis by dietary curcumin." So all of these papers that I've cited, talk about dietary curcumin. Some of them they may have mentioned where they came from, what the historical background was, but that is where that statement came from. All of these published papers and peer-reviewed literature use the term curcumin, not tumeric.

Q. You make the statement concerning lacking double blind placebo controlled randomized clinical trials of curcumin. Could you summarize your -- the significance of that section in which you talk about the lack of those studies?

A. Before I got to that sentence I described what are the reported studies and what some of the results were of those studies, particularly some of the studies in patients who are at high risk of developing colon cancer, but the ultimate step to demonstrate in a competent and reliable way that curcumin actually does these things would be to do a double blind placebo controlled randomized clinical trial. That's how we do things to show that it really is effective.

Q. Effective?

A. In preventing cancer or treating colon cancer.

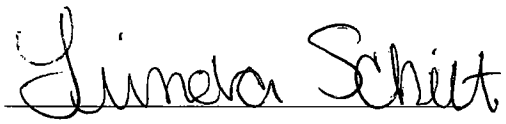
CERTIFICATION OF REPORTER

CASE TITLE: FTC vs. DANIEL CHAPTER ONE

DATE: FEBRUARY 6, 2009

I, HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the notes taken by me in the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

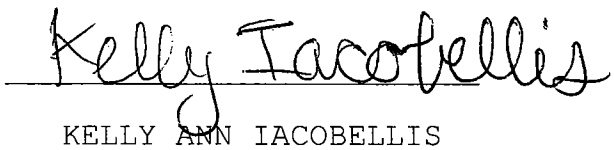
Dated: 2-9-09



LINDA A. SCHILT

CERTIFICATION OF PROOFREADER

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.



KELLY ANN IACOBELLIS

Exhibit
E

In the Matter of:

Daniel Chapter One, et al.

January 22, 2009
Michael W. Marino

Condensed Transcript with Word Index

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Q. Okay.
A. I don't recall seeing Exhibit 3, although that doesn't mean that I didn't see it at one time or another.
Q. Do you recall the circumstances in which you've seen Exhibits 1 and 2 before?
A. Give me one second. I just want to look at some of the --
Q. Take your time.
A. -- pages here.
(Pause in the proceedings.)
I don't recall the specific instances. They just look familiar to me.
Q. Do you recall whether you were asked to help in preparation of answers to the questions that appear in those exhibits?
A. I don't recall if I was asked to help specifically for these legal documents.
MR. McCORMACK: Okay. Great.
I have no further questions. Thank you for your time. You passed your first deposition with flying colors as far as I'm concerned. We appreciate it.
MR. ZANG: Off the record.
(Whereupon, the foregoing deposition was concluded at 10:54 a.m.)

CERTIFICATION OF REPORTER

DOCKET/FILE NUMBER: 9329
CASE TITLE: Daniel Chapter One and James Feijo
HEARING DATE: January 22, 2009

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the notes taken by me at the hearing on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

DATED: JANUARY 22, 2009

JOSETT F. WHALEN, RMR

CERTIFICATION OF PROOFREADER

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.

DIANE QUADE

CERTIFICATE OF DEPONENT

I hereby certify that I have read and examined the foregoing transcript, and the same is a true and accurate record of the testimony given by me.

Any additions or corrections that I feel are necessary, I will attach on a separate sheet of paper to the original transcript.

MICHAEL W. MARINO

I hereby certify that the individual representing himself/herself to be the above-named individual, appeared before me this
day of , 2009, and
executed the above certificate in my presence.

NOTARY PUBLIC IN AND FOR

MY COMMISSION EXPIRES:

WITNESS: MICHAEL W. MARINO
DATE: January 22, 2009
CASE: In the Matter of Daniel Chapter One and James Feijo
Please note any errors and the corrections thereof on this errata sheet. The rules require a reason for any change or correction. It may be general, such as "to correct stenographic error" or "to clarify the record" or "to conform with the facts."

PAGE	LINE	CORRECTION	REASON FOR CHANGE

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notes about that conversation, written notes?
A. I don't recall if I kept written notes.
Q. If you did, I presume they would be in your file.
A. Yes.
Q. Okay. Did you make any kind of e-mail report about that conversation to anyone that you recall?
A. Yes.
Q. Okay. I presume a copy of that would also be within your file.
A. Yes.
Q. I should ask, do you keep written copies of your e-mails on particular cases?
A. It depends.
Q. Okay. On what?
A. In the initial stage of the investigation I may or may not, depending on its importance, whether or not I think I'll need it in the future. Later on, if there's a litigation hold, then I'll keep those documents.
Q. Do you keep electronic copies of your e-mails in any case?
A. The same rule applies.
Q. In this case did you -- have you kept copies of everything you produced?

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Let me rephrase it actually.
Have you destroyed or deleted anything in the Daniel Chapter One case?
A. During the course -- the course of the entire investigation?
Q. Correct.
A. I'm sure I might have thrown out some things. Yes.
Q. Do you know what?
A. I can't remember specific items.
Q. Do you generally recall what you tossed out or deleted?
A. No. Not -- no.
Q. Anything exculpatory, for instance?
A. No, no. Absolutely not.
Q. Okay.
A. No. The only reason I would throw something out is if I felt I didn't need it anymore, you know, for my own knowledge.
Q. Can you tell me why the purchases you made of DCO products was done undercover as opposed to aboveboard?
A. I was merely told to make an undercover purchase. I don't know why that decision was made.
Q. Do you know generally if there's a policy

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reason that things like that are done undercover or not?
A. I don't know if there's a policy reason.
Q. How about a strategic reason that you're aware of?
A. There may be a reason that we don't want the company that we're looking at to know that we're looking at them.
They may, for example, shut down the Web site.
They may, for example, change something on their Web site.
They may not send us the products --
Q. Okay.
A. -- if they knew that we were with the FTC.
Q. Do you know who Ms. Colbert is, C-O-L-B-E-R-T?
A. Yes.
Q. Who is she?
A. She's an investigator with the FTC.
Q. Does she work -- where does she work?
A. She works in headquarters.
Q. Which is where?
A. Washington, D.C.
Q. Do you know what -- strike that.
Did she play a role in the investigation of DCO, to your knowledge?

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A. I have a general recollection that she did.
Q. And what's your general recollection about the role she played?
A. I don't know specifically. I just remember the name.
Q. Have you had any conversations with her about DCO?
A. Not that I could recall.
Q. And lastly --
A. And if I could just go back.
Q. Yep.
A. Just to clarify my one answer, I think she's an investigator. She may be an attorney, but I think she's an investigator.
Q. Okay. And if you would, Mr. Marino, take a look at what I'll hand you that has been marked Exhibits 1, 2 and 3, marked specifically DCO 1, DCO 2 and DCO 3. Just peruse those and tell me if you've ever seen those documents before.
(Pause in the proceedings.)
A. Okay. I briefly looked at these.
Q. And have you seen these documents before?
A. I may have seen these two before (indicating).
Q. And you're referring to Exhibits 1 and 2 only?
A. That's correct.

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"consumer injury."
THE WITNESS: Could you rephrase that or -- could you rephrase that.
BY MR. McCORMACK:
Q. What is it about the question you didn't understand?
A. I don't understand the question.
Q. Is there any particular part you don't understand?
A. Yeah. Could you just ask it again then or just --
Q. Sure.
Is investigation of consumer injury within the scope of your job responsibilities?
A. Generally, no.
MR. ZANG: And again I just want to note the objection, even though you answered very quickly, to the extent that that's calling for a legal conclusion.
BY MR. McCORMACK:
Q. In the course of your job responsibilities, Mr. Marino, do you ever evaluate the phrase "net overall impression of health claims"?
A. No.
Q. Do you have an understanding of what that phrase means?

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A. No.
Q. Have you ever investigated what you understand to be conventional cancer treatments or products?
A. I have a general recollection. Yes.
MR. ZANG: Again, I would just caution you not to go into the specifics of any company that has not publicly been identified.
BY MR. McCORMACK:
Q. Yes. At this point I don't want to -- no names.
Do you recall how many instances you've investigated?
A. Just one or two.
Q. I'm sorry. One or two?
A. One or two.
Q. Did either of those go to a phase of a public complaint being filed? If you know.
A. I don't know.
Q. All right. Do you recall specifically, again without naming names, the product or treatment that was at issue in either of those?
A. No.
Q. Can you give me a time frame?
A. Again, these were the similar products we were talking about earlier. I vaguely remember there were --

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now that I'm thinking about it, I vaguely remember there were cancer claims associated with those investigations, but again I think it was like five years ago or something like that.
Q. And to clarify, were those dietary supplement cases, if you remember, or were they something else?
MR. ZANG: Objection.
I don't think we've ever established the meaning of "dietary supplement," so if you want to lay a foundation or ask Mr. Marino if he has an understanding of "dietary supplement" --
BY MR. McCORMACK:
Q. Do you understand what I mean by "dietary supplement"?
A. I have an understanding of it.
Q. Okay. Then I'll re-ask the question.
Were those dietary supplement cases, the other ones that you're referring to?
A. I think they were.
Q. Okay.
A. But again it was five or six years ago, so I don't remember specifically.
Q. I understand.
It's a yes-or-no question. Do you know if conventional cancer treatments, claims about

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conventional cancer treatments have ever been evaluated by the FTC?
A. I don't know.
Q. Through the course of your investigation on Daniel Chapter One specifically, did you interview or research -- strike that. It's compound.
In the course of your investigation of Daniel Chapter One, did you interview anyone with cancer who used dietary supplements?
A. No.
Q. And in the course of your investigation of Daniel Chapter One did you do any research, separate from interviewing people, did you do any research about conventional cancer treatments, their safety and efficacy?
A. Not that I can remember, no.
MR. McCORMACK: I want to take a two-minute break, make sure that I've exhausted my questions, and then we'll wrap.
(Recess)
BY MR. McCORMACK:
Q. We are back on the record following our break.
Just a few follow-up questions, Mr. Marino, and then we'll let you go, with thanks.
When you spoke with Ms. Oppie, did you keep

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companies were targeted in Operation False Cures?
A. Oh, I don't know.
Q. Independent of what you received from DCO Web site or with the products, did you do any investigation about the products themselves from other sources?
A. You mean the efficacy -- what is it -- efficacy?
Q. Efficacy?
A. No.
Q. Apart from the efficacy, did you do any research about just the elements of the products?
A. You mean the ingredients?
Q. Yes.
A. No.
Q. Okay. Did you do any research or investigation about complaints that any user of DCO products had ever made?
A. Yes.
Q. Okay. Tell me what steps you took in that regard.
A. I mentioned before that I went to the BBB's Web site to see if they had any complaints.
Q. What did you find?
A. I could not find any complaints.

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Q. Other than the BBB's Web site --
A. Well, let me back up.
Q. Yep.
A. I'm sorry.
Q. That's okay.
A. But the reason I couldn't find any complaints was because the BBB -- the search was inconclusive. The BBB didn't have a listing for Daniel Chapter One at the time that I could find, so therefore I couldn't identify any complaints for Daniel Chapter One.
Q. Is there a reason --
(Pause in the proceedings.)
Do you have an understanding about why the BBB wouldn't have a listing for Daniel Chapter One?
A. No.
Q. Do you know if the BBB only opens a file if they receive a complaint?
A. I don't know.
Q. Would it be your understanding that the reason there was no listing with the BBB of DCO is that they had not received a complaint?
A. I don't know why it's not listed.
Q. Okay. Any other sources besides the BBB that you investigated or researched to determine complaints about DCO?

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A. Yes. I conducted a Consumer Sentinel search.
Q. A Consumer Sentinel?
A. A Consumer Sentinel search.
Q. Tell me generally what Consumer Sentinel is.
A. Consumer Sentinel is a database that the FTC maintains to keep a record of consumer complaints.
Q. And what did the result of your Consumer Sentinel search turn up about DCO?
A. There was only one complaint that was listed, and that complaint was entered by Lynlea Givens Oppie.
Q. And the complaint was what you'd already described from your conversation?
A. Very similar.
Q. So in other words, to the best of your recollection, Ms. Oppie's complaint as revealed by the Consumer Sentinel search was not about the product but was about her father's testimonial.
A. I don't remember the specifics of it, but it was substantially similar to what she told me over the phone.
Q. Okay. Was a written record kept of your Consumer Sentinel search?
A. Not a written record by me. I did not make hand notes. However, I did print up a summary of the complaint. Yes.

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MR. McCORMACK: For the record, I'll follow up with you separately. I think we requested that, but I think the response we got is that there is nothing available on that.
MR. ZANG: I think the request, if it's the one I'm recalling, was regarding consumer complaints against DCO, and Ms. Givens, if that's her name, was not a direct consumer herself.
MR. McCORMACK: Could be. We'll double-check.
BY MR. McCORMACK:
Q. Mr. Marino, are you aware of any specific injuries that DCO or its products have caused to consumers?
A. I wouldn't know that.
Q. You would not know that?
A. I would not know that.
Q. That was not within the scope of your investigation then; is that right?
A. That's correct. That was -- yes, that's correct.
Q. Okay. Apart from the DCO case specifically, is the investigation of specific consumer injury ever within the scope of your job responsibilities?
MR. ZANG: I just want to object in terms of lack of foundation with respect to the term

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list.
A. Yes.
Q. Did you ever contact any of the people that were on that list?
A. I never contacted anyone from that list as a result of reviewing that list.
Q. How about -- did you contact anyone on that list for some other reason or prompted by some other direction?
A. I never contacted anyone on that list.
Q. Okay. All right.
With respect to DCO, have you contacted anyone, whether on the list of testimonials, anyone who's purchased a product or who is a follower of DCO's ministry, for any purpose related to this case in your investigation?
A. Could you repeat that.
Q. Sure.
Have you contacted anyone who is a DCO follower, who's used their products --
MR. ZANG: Objection.
BY MR. McCORMACK:
Q. -- related to the investigation?
MR. ZANG: Objection with respect to the terminology of "follower." Lack of foundation there.

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BY MR. McCORMACK:
Q. Do you understand what I mean?
A. I understand what you mean.
And based on what you asked me so far, the answer is no, I haven't contacted anyone, based on what you just asked me.
Q. Okay. Have you contacted any third party related to the DCO investigation?
A. Yes.
Q. Who?
A. I was asked by an attorney to contact Lynlea Givens --
Q. Oppie?
A. Oppie, that's it.
Q. O-P-P-I-E?
A. I'm not sure of the spelling, but that's the name.
Q. I think that's what it is.
And did you succeed?
A. Yes.
Q. And when did you do that?
When did you contact her?
A. It was in October or November of the previous year, 2008.
Q. Do you have an understanding what the purpose of

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your contact with Ms. Oppie was?
A. Yes.
Q. What's that understanding?
A. I was to interview her and see what her story was.
Q. And did you do so?
A. Yes.
Q. What's her story?
A. Her story was that she was doing some research on her father, she was on the Internet, she came across Daniel Chapter One's Web site, she saw that her father's -- her father's name appeared along with a testimonial purportedly by him in which he endorsed Daniel Chapter One's products, and she was upset about that because he had been dead for several years.
Q. Anything else that she imparted to you?
A. She said that she was very upset, she contacted the company.
Q. Is that it as far as you can recall?
A. Those are the general points that come to mind now.
Q. To your knowledge and recollection, did she contradict anything in the testimonial itself?
A. I never read the testimonial word for word, so I couldn't say.

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Q. But did she share anything that indicated she disputed what was in the testimonial?
A. Not that I recall at this point.
Q. Okay. Did she give you any indication that you recall that she felt the testimonial was inauthentic?
A. I don't remember.
Q. Okay. Mr. Marino, I've got a few more questions and I also want to be sensitive to our time schedule, so I'm going to perhaps bounce around a bit. Bear with me.
You used the word I think in specific reference to your purchase of DCO products as an undercover purchase.
What did you mean by "undercover"?
A. I used an undercover name and some other undercover information.
Q. Do you recall the name you used?
MR. ZANG: Objection. That would be investigatory privilege.
MR. McCORMACK: Okay. I won't press that one right now, but I understand.
BY MR. McCORMACK:
Q. Do you know the identity of any of the -- strike that.
Do you know if other dietary supplement

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Q. Sure. Go ahead.
A. We -- I'm just thinking how I could frame this.
I'm not quite sure I understand.
If your question is have we ever gone out and at the outset investigated nonprofits -- is that what you're asking, or are you asking me have you ever in the course investigated companies that turned out to be nonprofits or...
Q. Well, first of all I'm asking for what you've done.
A. Okay.
Q. And let's parse it out in the ways you've just described.
So first, have you ever investigated companies who you knew going into the investigation were nonprofits?
A. Not that I could recall.
Q. And the part two of that question I guess would be: Have you ever investigated companies that through the course of your investigation you learned were nonprofits?
A. Yes.
Q. Okay. Do you recall if those investigations of nonprofits related to claims that were made by those nonprofits?

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A. I don't remember.
Q. Okay. What do you remember about the investigation of those nonprofits? What was the reason for the investigation?
MR. ZANG: And here just let me pause and direct you, Mr. Marino, not to disclose the names of any companies that you might have investigated in the past unrelated to Daniel Chapter One that have not been publicly disclosed.
MR. McCORMACK: Agreed. I'm not looking for names.
THE WITNESS: I don't remember.
BY MR. McCORMACK:
Q. Okay. All right.
In the course of issuing reports to your supervisors -- I'm talking generally now -- are there times when you include in your reports recommendations or conclusions?
A. Generally speaking?
Q. Yes.
A. Yes, sometimes I do.
Q. Okay. In the Daniel Chapter One matter did you do so?
A. I don't recall specific instances. No.
Q. If you did so, I presume they would have been

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communicated verbally or by e-mail.
A. Correct.
Q. Okay. And is that something that you would keep notes on in your file?
A. Not necessarily.
Q. Through the course of your work for the FTC, Mr. Marino, have you had any training about what constitutes a health claim?
MR. ZANG: Objection. Lack of foundation.
MR. McCORMACK: Objection noted.
THE WITNESS: If you're talking about formal training like classroom training, the answer is no.
BY MR. McCORMACK:
Q. Okay. How about informal training?
A. Professional reading on my own. Yes.
Q. Okay. Do you understand what is meant by the phrase "structure/function claim" in the context of health claims, for instance?
A. No.
Q. Through the course of your investigation of DCO, did you ever feel that you needed to have an understanding of what health claims are?
A. No.
Q. How about structure/function claims?
A. No.

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Q. Okay. At any time during your investigation of Daniel Chapter One did you focus specifically on media other than the Web site?
A. What do you mean, "focus"?
Q. Did you gather information about Daniel Chapter One from media other than the Web site?
A. Not that I recall at this point.
Q. Okay. Okay. Did you gather information in the course of your investigation of Daniel Chapter One on testimonials?
A. Yes, I did.
Q. Describe that process for me, please.
A. Going back to the Web site preservation, we captured some testimonials in that Web site preservation.
Q. So there wasn't, I gather from your answer -- and correct me if my impression is wrong -- there wasn't a specific direction to focus on testimonials; it was just part of the general Web site capture?
A. Not necessarily. I was just giving that one instance.
At a later point, I was asked to make a list of individuals who appeared on Daniel Chapter One's Web site as providing testimonials.
Q. Okay. Did you -- and I presume you created that

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Q. Who's "we"?
A. The team collectively.
Q. The attorneys you've mentioned and yourself.
A. And myself, right.
Q. Okay. All right. Can you frame for me the time when you made the purchases of the products relative to downloading the Web site? Days? Weeks? Months?
A. Well, I purchased the products on January 3, 2008. I purchased the radio shows July -- I guess July of 2008.
Q. Actually your memory is pretty good, so thank you. I'm impressed.
Okay. At any time during the course of your investigation did you talk with anyone, by phone or in person or even by e-mail I suppose, with anyone who you knew or understood to be affiliated with Daniel Chapter One?
A. Not that I recall, no.
Q. How about with Accent Radio?
A. Yes, I did.
Q. Share that with me, please, the circumstances.
A. I had to contact Accent Radio Network because we -- at the time we didn't receive the CDs that we ordered.
Q. You received different CDs?

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A. No. We didn't receive any.
Q. Oh, okay. All right.
A. So I spoke to the person and said, We haven't received the CDs. They -- I forget what they said. I waited another period of time. I called them again and said, Hey, we still haven't received the CDs. They said, Oh, it was an oversight, we're sending them now, and then received the CDs.
Q. Do you happen to recall who you spoke with by any chance?
A. No, I don't.
Q. Okay. So we've identified the download and capture of the Web site. We've identified an undercover purchase of four products. Right?
A. Right.
Q. And we've identified the purchase of two specific radio programs; right?
A. Correct.
Q. Any other tasks that you undertook in your investigation of DCO?
A. Yes.
I conducted a BBB search.
I did a Whois search.
I did a Lexis search.
I did a D&B search.

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Did I say that already?
Q. I think you did, but that's okay.
A. Oh, I'm sorry.
And that's all I could remember offhand right now.
Q. Do you recall what, if anything, was revealed by the Lexis search?
A. I conducted a search for the company. It revealed the company's -- the usual information that a Lexis search would reveal: the company's addresses, the company's telephone numbers, you know, telephone numbers that are associated with the company, addresses that are associated with the company, corporate officers who are associated with the company, that sort of information.
Q. Okay. Did you do any investigation into the organizational status of Daniel Chapter One as a nonprofit organization, for instance?
A. I was asked to obtain copies from the Washington Secretary of State for their articles of incorporation.
Q. And did you do so?
A. Yes, I did.
Q. And how did you do that?
A. I wrote a letter to Washington Secretary of

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State requesting the articles of incorporation.
Q. Did you do any investigation into the status of DCO as a religious organization?
A. Not specifically as a religious organization, no.
Q. In the course of your work over the last ten years with the FTC, have you investigated other nonprofit organizations for any reason?
MR. ZANG: Objection. Foundation.
BY MR. McCORMACK:
Q. You can go ahead and answer.
A. That threw me off a little bit.
Q. That's okay.
A. Could you repeat the question.
Q. Sure.
Over the course of your investigatory work for the FTC over the last ten years, to the extent you can recall, have you investigated other nonprofit organizations?
MR. ZANG: And again, same objection.
MR. McCORMACK: Noted.
THE WITNESS: No.
BY MR. McCORMACK:
Q. Okay. I presume that you haven't --
A. Let me qualify that if I could.

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A. Correct.
Q. Okay. All right.
In the course of learning about that reference, did you deem that significant to your investigation or not?
A. It had no impact whatsoever.
Q. On your investigation.
A. Correct.
Q. Okay. All right.
We've talked about task one I think in its entirety.
Can you tell me -- if I'm wrong about that, let me know -- what was the next task you undertook in the investigation of DCO?
A. I don't recall the exact chronology. There were several tasks I had to do, but I can't give you a chronological order for each of those tasks.
Q. Okay. Why don't you describe to the best of your recollection what the next task was, and if it's out of order, I'll forgive you.
A. Again, I can't -- I can't tell you every task -- well, maybe I didn't make this clear. I don't remember every task also.
I mean, I would have to look at my investigative file.

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The next major task I did, if that's acceptable to you --
Q. Start there?
A. Okay -- was an undercover purchase for Daniel Chapter One products.
Q. And is that the -- remember I described that DVD earlier?
A. Correct.
Q. Is that DVD of that undercover purchase?
A. That's correct.
Q. Did you make more than one purchase?
A. I made one -- there was one purchase for four products.
Q. Describe for me what you did there, please, as best you can recall.
A. Okay. I went to Daniel Chapter One's Web site and I chose four products that were identified for me and I purchased those products.
Q. When you say that were identified for you, by your supervisors I presume.
A. By one of the attorneys in charge of the matter.
Q. It wasn't the Web site that identified them for you.
A. No. Absolutely not.

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Q. And it was just four products?
A. Just four products.
Q. And I'm sorry. I think I interrupted you.
But you followed through with the purchase online?
A. I think I was done with my answer.
Q. And I may have missed it.
Did you follow through with the purchase online?
A. Oh, I'm sorry. Yes. Yes.
Q. And actually took delivery of the products?
A. Yes, I did.
Q. Okay. Next task or major task that you can recall.
A. The next major task I can recall is purchasing two radio shows -- or recordings of two radio shows that were broadcast by Daniel Chapter One or their principals.
Q. And you purchased those how?
A. I went online to Accent Radio Network -- I'm sorry. Let me back up.
I went online to Daniel Chapter One's Web site that had a link to Accent Radio Network's Web site and then made a purchase from Accent Radio Network's Web site.

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Q. Of the?
A. Two recordings.
Q. Downloaded radio shows?
A. I'm not saying downloaded. Of the two radio shows. When I made the purchase, they sent me CDs of the shows.
Q. Okay. How did you pick the two shows that you purchased?
A. I was told to pick those two shows.
Q. I see. Okay.
Do you have any understanding why those two particular shows were selected --
A. No.
Q. -- your understanding?
A. No.
Q. Okay. Did you investigate what, if any, relationship existed at the time between DCO and Accent Radio Network?
A. Not specifically.
Q. Okay. How about unspecifically?
A. There was a point in the investigation when we identified Accent Radio Network and then -- then I think collectively we tried to determine whether there was a connection between them. That's the extent of what I remember.

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A. No.
Q. Okay.
A. Not specific products.
Q. I'm sorry?
A. Not specific products or specific companies I don't recall.
Q. Okay. It certainly would have been some type of claim, though, I presume.
A. Yes.
Q. And were they health claims, if you remember or know?
A. They were dietary supplement claims.
Q. Okay. Okay. Do you remember the specific claims that were at issue in those cases?
A. No.
Q. When you receive instructions to investigate any of these small handful of dietary supplement companies, are you looking for the specific claims or are you just kind of following general protocols of downloading information, gathering information, printing information?
A. I'm not sure if I understand the question.
If you're asking me -- if you're asking me if someone will come up to me and say, Hey, investigate this matter and follow a certain set formula and do

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that -- is that what you're asking me?
Q. Yes.
A. For this type of case?
Q. Right.
A. Or for Daniel Chapter One in particular?
Q. Let's talk first about this type of case.
A. Okay.
No, that's not what happens.
Q. Okay. And was it any different for Daniel Chapter One?
A. No.
Q. How does it happen?
A. Generally an attorney will approach me and an attorney will tell me, Mr. Marino, could you do this, for example, preserve a Web site, and then I'll preserve the Web site.
Q. Okay. So it's not within your job responsibilities -- through the course of your job responsibilities, you're not exercising discretion about what's important within the Web site versus what's not important in the Web site, for instance.
A. Are you talking about Daniel Chapter One in particular?
Q. Let's talk about Daniel Chapter One in particular.

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A. I don't decide what's an important claim and what's not an important claim.
Q. Okay. And how about outside of the claims per se? Do you use your discretion in deciding what's important information and what's not important information?
A. You'll have to be more specific than that.
Q. The name Daniel Chapter One, for instance.
A. Would I think that's an -- are you asking me if I would think that's an important what?
Q. For instance, do you exercise or did you in this case exercise discretion in deciding that the name Daniel Chapter One was relevant to the investigation or not?
A. As a target or as a possible target?
Q. As a concept.
A. No.
Q. Do you know what Daniel Chapter One means or refers to?
A. I think it's a biblical reference.
Q. Are you familiar with the biblical reference by any chance?
A. That particular one?
Q. Yes.
A. Not very familiar, no, just in a very broad

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sense.
Q. Tell me what your broad sense is.
MR. ZANG: Mr. McCormack, here I'm going to object on the grounds of relevance.
But go ahead. You can answer.
MR. McCORMACK: Objection noted.
BY MR. McCORMACK:
Q. You can go ahead and answer.
A. I understand that -- oh, boy.
Q. And I don't want you to guess. If you don't know, that's fine. I'm just curious.
A. Yeah. I understand it's a biblical reference having to do with nature or God being able to help people maybe cure themselves or help themselves or something like that. That's the extent of my understanding.
Q. Sure.
Where did you gain that understanding?
A. Through general conversation. I don't recall the exact source.
Q. Do you recall if you gained that understanding from the DCO Web site at all?
A. No. Absolutely not.
Q. Okay. So you're certain that you didn't gain that understanding from the Web site.

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A. Okay. Hypothetically what I wait for is a prompt from the computer saying it's finished.
Q. Okay. So again, you're relying on the computer to tell you that it's downloaded all the relevant information.
A. Correct.
Q. Now let's talk about Daniel Chapter One specifically.
Did you do any manual exercise in reviewing the Daniel Chapter One Web site?
A. I don't understand the question.
Are you talking about while it's saving the information?
Q. Or even afterwards.
I guess what I'm interested in knowing is, during the course of this task one, if you downloaded, captured every single page from the Daniel Chapter One Web site with information about Daniel Chapter One and what it does.
A. Okay. As I alluded to earlier, not every program that's designed to capture Web sites would capture every single thing.
For example, Teleport Pro in some instances can't capture pop-ups, can't capture streaming videos, so for example, those are things that program won't be

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able to capture.
Q. Okay.
A. So in general, that's a factor to be considered when dealing with Teleport Pro, if I answered your question correctly.
Q. Okay. So anything that was a still shot of text or graphic from the Daniel Chapter One Web site you believe was captured during the course of this task one?
A. Not necessarily.
Q. Can you explain?
A. Yes. Teleport Pro is designed to capture all of the files in a particular -- or at a particular Web site or in a particular Web site.
In Daniel Chapter One's Web site case -- and this tends to happen in a lot of Web sites that have a lot of catalogs or large catalogs -- the program tends to run on and on and on.
Additionally, Teleport Pro is also designed to seek out other Web sites that are linked to the Web site you're trying to preserve, so it will also start preserving those Web sites as well, so it could tend to run on and on.
So at some point with Daniel Chapter One I had to make a decision to stop the program; otherwise, it

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would just keep going.
Q. So at some point you made that decision and saved the disk and handed it to Mr. Waldman.
A. Yes. At some -- well, let me go back.
At that point when I realized that it was just going on and on, I stopped the Web site preservation, the Teleport Pro. I preserved it to the computer. I preserved it to a CD. I gave it to Mr. Waldman. I explained to Mr. Waldman what happened. I suggested that he review it to make sure it had all the information that he wanted preserved.
Q. Okay. Did you take notes during your performance of the task one you just described?
A. I don't recall. I'd have to check.
Q. Okay. Prior to being assigned this investigation of Daniel Chapter One, do you recall having investigated any dietary supplement manufacturer before?
A. Yes.
Q. Can you tell me how many times?
A. I think about two times before.
Q. Can you give me a general time frame, window of time, when those investigations took place?
A. I would say approximately four to five years ago.

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Q. Okay.
A. But let me qualify that --
Q. Sure.
A. -- in saying give or take a year or so.
Q. Sure. That's fair.
Do you know if those investigations were part of Operation False Cures?
A. Oh, I have no idea.
Q. Okay.
A. I don't think so.
Q. Okay. Were the investigations similar in the sense that you were investigating companies that were making claims that the FTC was adverse to?
A. I'm sorry. Could you say that again.
Q. Yes. I'll try.
Were you, in those previous cases -- I think you said one or two or maybe two or three --
A. Right.
Q. -- when you investigated dietary supplement companies, were those investigations prompted by alleged claims that those manufacturers had made contrary to FTC policies and guidelines?
A. I don't know.
Q. Okay. Do you recall what you were investigating?

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Mr. Waldman for him to review.
Q. Okay. Let me stop you.
For the record, I'll represent to you that we have received a disk I'm going to call it. I'm not a tech guy, so bear with me. I think it's a DVD. And I put it in the computer and it plays what appears to be a screen shot of a navigation through at least part of the DCO Web site. I can see the cursor move. I can see it click on certain links, new pages load, so on and so forth.
Does that sound familiar?
A. It sounds familiar, but that's not the program I'm talking about.
Q. Okay. What is it that I've just described, if you know?
A. That's a Camtasia recording of an undercover purchase I made.
Q. Can you spell "Camtasia"?
A. C-A-M-T-A-S-I-A.
Q. Back to the preserving the Web site.
Maybe explain to me how that's different.
Is that just sort of taking still shots of the various pages?
A. What Teleport Pro does is it creates an off-line replication of the Web site.

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Q. Okay.
A. So once you preserve that Web site and then either preserve it on a computer or a CD, then you're able to navigate that Web site just as if you were online at the real Web site.
Q. You can navigate it from the CD, for instance.
A. Correct.
Q. All right. We're still on task one now, and that is preserving the Web site.
Did you capture, preserve, the entirety of the DCO Web site?
A. No.
Q. Why?
A. Because no program that I'm aware of could capture everything on every Web site.
Q. Okay. Is this a case, Mr. Marino, where you essentially hit the "start" button and let the program run its course of capturing the Web site, or do you navigate page by page as part of your interaction with the Teleporter (sic)?
A. If you're asking me do I just press a button and it records rather than me kind of helping it record by prompting it and stuff like that --
Q. That is what I'm asking.
A. It's the former. I press a button. I say

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record. I step back. I watch it record.
"Record" is a bad word to use. I let it save the data.
Q. Okay. How, if at all, do you satisfy yourself that you have captured all of the relevant portions of the DCO Web site in that particular case then?
A. Generally you'll wait for a prompt from the computer from the program saying, you know, something to the effect that, you know, the program is finished -- I'm sorry -- Teleport Pro is finished, and then when that happens, you hit "okay."
Q. But you're relying on the technology to capture all of the Web site that it deems relevant?
That was a question.
A. Okay. And my answer is this. I rely on the program to capture all of the information that it can capture.
Q. Okay. All right. Does the -- and have I got the name right? Is it Teleporter?
A. Teleport Pro.
Q. Teleport Pro. Thank you.
Does the Teleport Pro require any kind of loading of data into it, particular search engines or particular words?
A. Yes. At the initial stage there is some

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information I have to put into it.
Q. Can you give me an example?
A. Yes. The most important thing you have to put in is the Web site address.
Q. Okay. Anything else?
A. My recollection for Daniel Chapter One alone --
Q. Right.
A. -- is that that's the only information I put in.
Q. So in other words, you're not also conditioning your search by putting in the word, for instance, "cancer" as part of the Teleport Pro search engine.
A. Yeah. Absolutely not, no.
Q. Okay. All right.
Hypothetically speaking -- and I appreciate your patience because I'm trying to figure out how this works -- how do you satisfy yourself, if at all, that you've downloaded from the Daniel Chapter One Web site all of the relevant information, including perhaps a disclaimer page, for instance?
A. Okay.
Q. Hypothetically speaking.
A. If we're talking hypothetically and we're not talking specifically to Daniel Chapter One --
Q. I'll go there next.

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Q. With the FTC?
A. No. With I think the Social Security Administration.
Q. Do you know when he left the FTC?
A. Last year sometime.
Q. 2008.
A. Correct.
Q. Okay. All right. Do you recall what instructions, if any, Mr. -- was it Mr. Waldman?
A. Yes.
Q. -- what instructions, if any, that Mr. Waldman gave you insofar as conducting your investigation of Daniel Chapter One?
MR. ZANG: And here I would just caution you, Mr. Marino, to not discuss the substance of those instructions because for that we will claim a privilege but rather you can certainly start with whether or not he gave you instructions, if you want to ask that question, Mr. McCormack.
BY MR. McCORMACK:
Q. Did he give you instructions?
A. From time to time he gave me instructions.
Q. Did you follow those instructions?
A. Yes, I did.
Q. So why don't you tell me what your very first

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step was after speaking with Mr. Waldman for the first time about DCO.
A. The first time Mr. Waldman approached me, he asked me to preserve Daniel Chapter One's Web site.
Q. Do you recall when that was?
A. That was December 20, '07.
Q. Did you have --
A. I'm sorry. Let me go back.
That's -- it was on or about December 20.
Q. Fair enough.
What was your understanding, assuming you had one, about the purpose for your investigation or, more specifically, why was DCO being investigated?
A. Mr. Waldman briefly explained to me that --
MR. ZANG: I just again want to caution you, Mr. Marino, not to go into the substance of any legal theories or case theories that you might have discussed with Mr. Waldman.
And Mr. McCormack, I would ask that you focus your questioning on the concrete tasks that Mr. Marino carried out either under the direction of Mr. Waldman or not.
MR. McCORMACK: I'll rephrase the question, although I think if we go back and look at it again, we'll see that my question was what his understanding

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was, and certainly I think his understanding bears on how he shaped the concrete tasks.
BY MR. McCORMACK:
Q. So it's challenging waters we're sailing here and I think we're doing well, but let me ask you again, Mr. Marino, what was your understanding of the purpose of your tasks?
MR. ZANG: And again let me just interject, Mr. Marino. If you can distinguish your understanding from what might have been conveyed to you in terms of any legal theories or investigatory theories, then you should testify as to that, but that only.
THE WITNESS: Okay.
Mr. Waldman expressed to me that there were some cancer -- some claims relating to cancer -- some cancer claims that Daniel Chapter One was making and that we wanted to -- that he wanted to preserve the Web site.
BY MR. McCORMACK:
Q. So your understanding was that you were investigating cancer claims that DCO was making on its Web site; true?
A. And possibly other claims. Yes.
Q. Other than cancer you mean.
A. I think so. Yes.

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Q. So not claims about Oriental tea but claims about specific disease conditions?
A. I remember him specifically saying cancer claims at the time.
Q. Okay. So task one was to preserve the Web site.
A. Yes.
Q. All right. And what did you do? As best you can recall, walk me through step by step what you did to preserve the Web site.
A. Well, first, I went to the computer and I opened a program called Teleport Pro. I opened the program. I placed Daniel Chapter One's Web site address into the program, and then I started preserving the program.
Q. How did you get Daniel Chapter One's Web site address?
A. It was provided to me by Mr. Waldman.
Q. Okay. Thank you.
Go ahead.
A. When the computer -- when the computer was preserving the Web site, I was monitoring its progress, and then when I was satisfied that I got all the information that I could get, I saved the Web site, the program Web site, I copied it to a CD and I handed it to

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privilege on that.
MR. McCORMACK: Right. And so far I'm -- right now I'm trying to find the parameters of that. Indeed, I think you and I are on the same page in that regard at least so far, which isn't to say we may not collide a little bit. But yeah, I certainly understand that and will try to do my best -- in fact, let me make note of that, Mr. Marino.
At times -- and we're doing great so far, mindful that it's early, but you might take just a brief moment following each of my questions to give Mr. Zang an opportunity to jump in as he may need to do.
THE WITNESS: Have I been talking too fast?
MR. McCORMACK: No. Actually I think you're doing great. Believe me, I've had plenty of witnesses who were on top of each other, and we're not having that trouble right now.
BY MR. McCORMACK:
Q. Okay. In terms of -- you've used the word -- we've both used the word "reporting" to Mr. Zang or others through the course of the Daniel Chapter One investigation, and I may refer to the respondent here as DCO as well, the initials "DCO." You referred to reports.

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Can you share with us what form those reports took?
A. Mostly verbal and e-mail.
Q. Were there exceptions?
In other words, you say mostly verbal and e-mail, suggesting that maybe not exclusively verbal and e-mail.
A. That's all I could recall at this time.
Q. Okay. But there were reports that you made by e-mail to your -- I'll call them your superiors in this case.
A. Yes.
MR. McCORMACK: Just for the record, Mr. Zang, we've requested his full file, haven't -- Mr. Marino's full file, haven't received copies of those e-mails.
I'm going to guess, though I prefer not to, that the e-mails to which Mr. Marino just referred are probably going to be claimed as privileged, but we don't have a privilege log either to evaluate those, so when the opportunity presents itself, if we can get that log, that would be helpful.
MR. ZANG: I'll certainly take that under advisement.
I, by the same token, remind you and your co-counsel that there is a lot of outstanding discovery

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much more so on your end, including a privilege log that we're still waiting for from you.
MR. McCORMACK: I understand that. And my job right now is to get as much as I can in the way of proper discovery from the FTC, and that's all I'm going to worry about for today, but thank you.
BY MR. McCORMACK:
Q. Still on the record, Mr. Marino, how about notes?
Now, did you take any notes through the course of your investigation regardless of whether or not they were conveyed to FTC counsel in the DCO matter?
A. Yes.
Q. Do you know if those notes have been produced?
A. I have no idea.
Q. Okay. Are you aware that a request for your file was made by DCO counsel?
A. No, I was not aware.
Q. Okay. Do you recall anytime in the past two or three weeks being asked to prepare your file for copying or production, for instance?
A. I don't recall that.
Q. Okay. All right. Can you give me a sense of -- strike that.
How often did you take notes in the DCO case?

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I'm talking precomplaint phase.
A. Periodically.
Q. Okay. All right. Let's attack it this way.
Are you familiar with Operation False Cures?
A. I've heard the name.
Q. What do you understand that operation to be, if you have one?
A. My understanding of that is that it was a project to identify certain companies that were making misleading claims dealing with dietary supplements.
Q. And to the best of your recollection, can you describe -- strike that.
Were you asked or instructed to get involved in Operation False Cures as a general matter or were you assigned a specific task to investigate DCO?
A. I was only asked to investigate DCO.
Q. Okay. Do you have any knowledge or understanding how DCO was identified as a subject for your investigation?
A. No. Absolutely not.
Q. Who directed you to investigate DCO?
A. The attorney in charge of the case at the time was Ron Waldman. He approached me.
Q. Do you know what Mr. Waldman is doing today?
A. He's an administrative judge.

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adequate answer.
Was the training on investigative techniques as opposed to FTC policies and law do you remember?
A. The one -- I'm sorry. The one portion of it that I do remember distinctly was an interview -- it was techniques in interviewing.
Q. Okay.
A. So that's the one class I remember.
Q. Right. Fair enough.
Next let's turn to the organizational structure as you understand it within your department.
Can you give me a sense of to whom you report in your job as an investigator?
A. Generally I'll report directly to the attorney in charge of the case.
Q. Okay. In this particular matter for Daniel Chapter One, who is that?
A. Currently I think it's Ted Zang and I think he's the lead attorney.
Q. Are you not certain?
A. The reason I'm not certain is because we've had several changes. Recently we had several other attorneys assigned to the matter.
But that's my understanding, Ted is in charge.
Q. Okay. In the Daniel Chapter One case, are

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there other attorneys on the case to whom you also report?
A. Yes.
Q. And who are those?
A. David Dulabon, Carole Paynter, and that's who I've reported to in the past, directly to.
Q. All right. And you're located here in the New York office?
A. Yes, I am.
Q. Do you -- again in the Daniel Chapter One case, have you reported to anyone with the FTC in Washington, D.C.?
A. Not directly, no.
Q. Okay. Tell me a little bit -- strike that.
Do you have reports yourself; that is, do you have people who report to you in the course of your work on any particular case?
A. Are you talking specifically for this case?
Q. I'm talking generally right now.
A. In an informal way I'll have interns conduct assign -- do assignments for me, and they'll report back to me, but that's on an informal basis.
Q. How about in this Daniel Chapter One case specifically?
A. I've asked one intern to do an assignment for me

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that I can recall at this point.
Q. And who was the intern?
A. I think her name is -- she's new, so I think her name is Jeanine.
Q. Do you know her last name?
A. No.
Q. Is Jeanine still an intern with the FTC?
A. Yes, she is.
Q. And what was the task? Do you recall?
A. Yes. She's -- she is doing some work for us on looking at backgrounds for several witnesses for this case.
Q. So she's working -- she's presently working on the case.
A. Yes.
Q. All right. How long has she been working on the Daniel Chapter One case?
A. She has been working for -- I can answer how long she's been working for me. She's been working for me probably for the past week or week and a half.
Q. On Daniel Chapter One.
A. Yes.
Q. Okay. Fair enough.
So she didn't participate in any way in the investigation -- I'll call it the precomplaint

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investigation phase.
A. No.
Q. To your knowledge, who other than yourself did participate in, I'll call it, the precomplaint investigation stage, if anyone, on Daniel Chapter One?
A. From what I recall, I worked on the case, Ted Zang worked on the case, another attorney, Ron Waldman, worked on the case. And that was precomplaint.
The only reason I'm hesitating is I'm not quite sure when David Dulabon, another attorney here, started working on it. I'm not sure if it was precomplaint or post-complaint.
MR. ZANG: Mr. McCormack, let me just interject at this point because I'm not sure where your line of questioning is going, but while for the purposes of this deposition I want to try to allow you to ask as many questions as are appropriate, I do want to preserve for the record the governmental deliberative process privilege, and so, you know, at some points I may interject an objection.
And to the extent that Mr. Marino gives the who, what, where of the investigative process here, I probably will not interrupt him, but if he starts to go into the substance of the investigation, we do claim

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A. Yes.
My name is Michael W. Marino. That's M-A-R-I-N-O. My business address is One Bowling Green, Suite 318, New York, New York 10004.
Q. Have you ever had your deposition taken before?
A. No.
Q. Okay. Lucky you.
Let me give you just a little overview of what we're going to do and maybe agree upon some ground rules to help the process go a little more efficiently, particularly since we're kind of pressed for time this morning.
Obviously we have a court reporter who is transcribing everything that we're all going to say so long as we're on the record for purposes potentially anyway of transcribing a written record of this deposition which can be used in administrative hearing proceedings, court proceedings and any other public purposes.
I'll be asking you a series of questions and obviously asking you to do your best to answer those questions. And if at any time you don't understand my question, let me know. I'll do my best to clarify.
Also, nods and shakes of the head and uh-huhs and huh-uhs, even though perfectly fine for casual

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conversation, don't transcribe very well so that you may find that I may prompt you to answer yes or no. Don't take that as a sign of disrespect. It's simply to make sure that we've got the record clear. Indeed, transcribed depositions really don't go as smoothly as casual conversation, so you may find I'll try to negotiate us through that.
Okay?
A. Okay.
Q. Super. Thank you.
First of all, can you tell me what, if anything, you did to prepare for today's deposition?
A. I looked over my investigative file and I met with Ted Zang yesterday.
Q. Can you tell me what is in your investigative file? Just give me for now a Reader's Digest version of what that file consists of.
A. The file consists of pages that I printed up from my undercover purchase of Daniel Chapter One's products.
It includes pages that I printed up from the computer from my undercover purchase of Accent Radio Network's two recordings of Daniel Chapter One's radio broadcasts.
It has I think a BBB report, a D&B report, a

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Whois report.
That's all I could recall offhand.
Q. Can you describe for me what a Whois report is?
A. Yes. There are several entities or companies that keep track of domain names, and if for some reason you want to see what company owns a domain name or what company is associated with a domain name, you can do a search to find out what that company is.
Q. Okay. Great. Thank you. We may come back to that in a minute.
For now, though, tell me what is your current job description with the FTC.
A. I'm a Federal Trade investigator.
Q. Can you tell me what the job duties of an investigator with the FTC are as you understand them?
A. Investigators assist attorneys in collecting facts, collecting evidence, to assist them in building cases.
Q. And how long have you been in that role with the FTC?
A. About ten years.
Q. Have you been an investigator for that entire ten-year period?
A. Before that, I was an investigator for the Department of Labor for one year.

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Q. Okay. All right.
Is there a particular focus that you have in your responsibilities as investigator?
In other words, are there specific cases or do you investigate cases of all types for the FTC?
A. I focus on consumer protection cases.
Q. Tell me a little bit about the training that you've had, if any, to help you in your job duties as an investigator.
A. When I was with the Department of Labor, I went to several trainings, both on-site and off-site, basic investigative procedures, investigative accounting, and pension and welfare plan training. That was for the Department of Labor.
For the Federal Trade Commission, I attended one training in Washington, D.C. several years ago, and I think that was a three-day training, and then I attended several law enforcement conferences.
Q. Do you remember the substance of the training in D.C. during that three-day period you just described?
A. It was about six or seven years ago, so I don't remember.
Q. Okay. Let me just explore that further, mindful, if you don't remember, that's a perfectly

FEDERAL TRADE COMMISSION
I N D E X

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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

Thursday, January 22, 2009

Room 318
Federal Trade Commission
One Bowling Green
New York, New York 10004

The above-entitled matter came on for deposition, pursuant to notice, at 9:33 a.m.

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P R O C E E D I N G S
- - - - -

Whereupon --
MICHAEL W. MARINO
a witness, called for examination, having been first duly sworn, was examined and testified as follows:

(DCO Deposition Exhibit Number 1, Complaint Counsel's Responses to Respondents' First Request for Production of Documentary Materials and Tangible Things, was marked for identification.)

(DCO Deposition Exhibit Number 2, Complaint Counsel's Responses to Respondents' First Request for Admissions, was marked for identification.)

(DCO Deposition Exhibit Number 3, Complaint Counsel's Answers to Respondents' First Set of Interrogatories, was marked for identification.)

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EXAMINATION

BY MR. McCORMACK:

Q. Good morning, Mr. Marino.

For the record, my name is Michael McCormack. I am co-counsel for the respondent in this case, Daniel Chapter One and Jim Feijo, F-E-I-J-O.

For the record, could you state your name and business address, please.

Exhibit
F

REPORT OF EXPERT WITNESS SALLY LaMONT
In the Matter of Daniel Chapter One
FTC Docket #9329

I. QUALIFICATIONS

As you will see in my curriculum vitae, I am dually licensed in California as naturopathic doctor and acupuncturist. I graduated from the National College of Naturopathic Medicine in Portland, Oregon in 1981 and have been licensed in both Oregon and California to practice naturopathic medicine. I graduated from Emperor's College of Oriental Medicine in 1986 and have been licensed in both California and Oregon to practice acupuncture. I am a member of the American Association of Naturopathic Physicians and the California Naturopathic Doctors Association and the California Society of Oriental Medicine and Acupuncture.

I have practiced naturopathic medicine since 1981, working with diet, nutritional supplements, botanical medicine, and mind-body treatments. Since being licensed as an acupuncturist in California in 1986, I have integrated acupuncture and Chinese herbal medicine into my work. My practice focuses on helping people identify the root causes of their condition, removing the obstacles to cure, and developing personalized natural treatment protocols to resolve symptoms and promote health. I evaluate patients through a variety of state-of-the-art laboratory tests and integrate nutritional medicine with herbal medicine and acupuncture.

Since 2005, I have been on the faculty of San Francisco State University's "Institute for Holistic Healing Studies" within their Department of Health Education. Over the past 4 years, her popular classes include "Naturopathic Medicine and Personal Wellness", "Nutrition and Herbal Medicine" and "The Holistic Health Speakers Series".

In 1998, I joined the board of directors of the California Naturopathic Doctors Association (CNDA). I took a brief sabbatical from my practice in May of 2000 to serve as Executive Director of the CNDA and lead the successful legislative campaign to

license NDs in California. Passage of the Naturopathic Doctors Practice Act resulted in the creation of the Bureau of Naturopathic Medicine within California's Department of Consumer Affairs. Licensure of NDs provides Californians legal access to the care of licensed naturopathic doctors. The established scope of practice in California allows licensed NDs to serve as primary health care providers who treat acute and chronic conditions, in a prevention-oriented approach to healthcare.

For the last 22 years, I have witnessed the tremendous value that changes in lifestyle, diet and the correct use of the nutritional and herbal supplements can provide. During this time in practice I have had the opportunity to provide adjunctive care to patients undergoing conventional cancer treatment, utilizing a range of dietary supplements and botanical medicines that were compatible with their conventional regimen. The body has immense self-healing capacities, which when properly supported can respond and heal from even serious diseases. In my experience, people receiving chemotherapy and radiation fare better, in both the short and long term, when they concurrently use natural therapies and lifestyle to mitigate the side effects and support their overall health.

An additional note: I have had the unusual experience of supporting my first husband, John LaMont, M.D., a family practitioner, through his death from non-Hodgkins lymphoma in 1992. John lived for 16 years with this cancer and as one of the first medical doctors interested in nutrition and natural therapies, he pursued virtually all known conventional and alternative treatment modalities. Together we explored a variety of nutritional interventions including the use of high dose intravenous vitamins, traditional Chinese medical options including acupuncture and variety of Chinese herbal medicine, Ayurvedic medicine including working with Dr. Deepak Chopra in 1991, Dr. Stanislaus Burzynski's antineoplastic therapies and well as 4 rounds of conventional chemotherapy, radiation, monoclonal antibody therapies at Stanford and a bone marrow transplant.

Together, my education and these experiences give me a unique perspective as an expert witness in this case.

II. SCOPE OF WORK

I have been asked by the attorneys representing Daniel Chapter One to provide a opinions on the use of nutritional supplements and botanical medicines in the prevention and treatment of illness, including but not limited to cancer. In addition, I was asked to review the evidence that exists regarding the mechanisms of action of the major constituents of DCO's cited products and to provide an opinion of that evidence for:

- "GDU"
- "7 Herb Formula"
- "BioMixx"
- "BioShark"

Compensation: $175/hour
Prior expert testimony: see prior disclosures.

III. MATERIALS CONSIDERED

To form my opinion, I have conducted literature searches on PubMed, that includes over 18 million citations from MEDLINE and other life science journals for biomedical articles back to 1948. PubMed includes links to full text articles and other related resources. I also utilized Google, and numerous websites including the website of the Memorial Sloan-Kettering Cancer Center, Dr. Duke's Ethnobotanical and Phytochemical Database and the database of the American Botanical Council. I have utilized several books, including Medicinal Plants of the World (Van Wyk and Wink). In addition, I have drawn from my experience as a practicing naturopathic doctor and acupuncturist who utilizes dietary supplements and botanical medicines in daily practice.

I have also reviewed the information provided to me by Daniel Chapter One, including the Daniel Chapter One Product Labels, Literature provided by Daniel Chapter

One, and the Summary of Medical Evidence provided Daniel Chapter One, all of which I understand have been provided to the FTC by Daniel Chapter One and/or its counsel.

IV. SUMMARY OF OPINIONS ON THE EVIDENCE PRESENTED

Hippocrates, the Father of Medicine, advised his patients to "Let your food be your medicine and your medicine be your food." Traditional and indigenous cultures naturally understood the connection between plants as both their food and their medicine. Today, there is a growing body of scientific evidence to substantiate the fact that the natural compounds present in plants act in multiple ways to support our innate homeostatic mechanisms, improve physiological function and reduce the expression of disease. "Epidemiological studies consistently indicate that consumption of fruits and vegetables lowers cancer risk in humans and suggest that certain dietary constituents may be effective in preventing (colon) cancer. Plant-derived phenolic compounds manifest many beneficial effects and can potentially inhibit several stages of carcinogenesis in vivo." Carcinogenesis 2000 May; 21(5): 921-7. Many population studies have demonstrated lower incidences of several chronic degenerative diseases in cultures that eat a plant-based diet compared to the Western diet. Campbell, TC, *The China Study* (Dallas, TX: Ben Bella Books 2005); Cordain, L., "Origins an Evolution of the Western Diet: Health Implications for the 21st Century," American Journal of Clinical Nutrition 81, no.2 (2005): 341-54.

Humans have co-evolved with plants and we survive and thrive today because our bodies utilize plants for sustenance. The macronutrients, micronutrients and phytonutrients in food and phytochemicals in plants are biologically active compounds that influence our metabolism. A wealth of information on potential treatments for cancer and other conditions dwells in the clinical knowledge of traditional and indigenous cultures and their Material Medica. Herbalists have long known that herbs are an extension of food and have used the plants of this earth as medicines. They have prepared teas and concentrated extracts to potentiate the therapeutic effects of these phytomedicines. More recently, ethnobotanists and pharmocognocists have worked to identify and catalogue these plants and their bioactive constituents. International researchers have begun the laborious process of isolating the biologically active

compounds and examining their mechanisms of action in order to determine their effect on various aspects of disease, especially carcinogenesis (i.e. the production of cancer or carcinoma).

The biologically active compounds in plant medicines have been termed "secondary metabolites". Interestingly, the compounds produced by one species to protect them from their environment actually influence the metabolism of another species, and mimic the structure of our hormones, neurotransmitters and other aspects of our metabolism. These biologically active compounds have interacted with and shaped our physiological processes over millennia in a process termed "evolutionary molecular modeling". One of the advantages of using the phytonutrients present in food and the phytochemicals present in plants is that they exert their influences on multiple molecular targets. "Secondary metabolites usually are multifunctional compounds because most of them carry more than one pharmacologically active chemical group. In addition, secondary metabolites usually occur in complex mixtures. In consequence, the extract of a medicinal plant affects more than one molecular target and it is likely that several targets are affected concomitantly when taking phytomedicines. In complex disorders, the application of such extracts increases the chances of "hitting" one or several relevant targets". Van Wyk and Wink, *Medicinal Plants of the World*, Timber Press, Portland, Oregon 2003.

In his recent book "Anticancer -- A Way of Life", oncologist David Servan-Schreiber, M.D., Ph.D., who is himself a two-time cancer survivor, suggests we can approach cancer in this way: "There are certain circumstances under which these savage bands are disrupted and lose their virulence: (1) when the immune system mobilizes against them, (2) when the body refuses to create the inflammation without which they can neither grow nor invade new territories, or (3) when blood vessels refuse to reproduce and provide the supplies the cells need to grow. These are the mechanisms that can be reinforced to prevent the disease from taking hold. Once a tumor is installed, none of these natural defenses can replace chemotherapy—or radiotherapy. But they can be exploited, accompanying conventional treatments, to fully mobilize the body's resistance to cancer". Dr. Servan-Schreiber goes on to elucidate the growing body of evidence that a

diet rich in chemoprotective plants can assist us in multiple ways in our fight to prevent and support the treatment of cancer. (Servan-Schreiber, D., *Anticancer—A Way of Life,* Viking Penguin Press, New York, New York, 2008).

Scientific research, a selection of which follows in this report, demonstrates that the phytonutrients and phytochemicals present in plants have the capability to act at the precise molecular targets that scientists are seeking to affect with the new generation of biological response modifiers:

- Immunostimulatory effect: astragalus and medicinal mushrooms
- Anti-inflammatory effect: curcumin and bromelain
- Anti-angiogenic effect: green tea and ginseng

Some examples of how plant phytochemicals act as "biological response modifiers" to affect our physiological process are detailed here in this report:

- Watercress: rich in glucosinolates that inhibit carcinogenesis and induce apoptosis
- Turmeric rich in curcuminoids that inhibit COX2
- Bromelain: proteolytic and anti-inflammatory effect
- Quercitin (ubiquitous in plants): inhibits tumor growth, alters cell cycle regulation
- Green tea (EGCG): signal transduction, inhibits COX2 and induces apoptosis,

Knowledge of this kind of information should empower us to use these compounds as our food and as our medicine. The awareness of the powerful chemoprotective effects of plant foods and medicines should not influence patients with cancer and other serious diseases to abandon using the most effective methods that modern medicine has to offer. Furthermore, such knowledge does not diminish the need for further research but instead should hasten its pace.

"Phytomedicines often contain a mixture of substances that have additive or even synergistic effects, so that the health benefits are difficult to test or verify. Plant medicine

or phytochemicals may have subtle effects of several different biochemical pathways and receptors in the mind-body continuum that may all contribute directly and indirectly to restore equilibrium and balance. It is hard to dismiss medical claims of safety and efficacy when a plant medicine has been used in traditional cultures for centuries without evidence of serious side effects. Research results generated over the last few decades have given us a much better understanding of the scientific rationale behind many natural remedies." Van Wyk and Wink, *Medicinal Plants of the World*, Timber Press, Portland, Oregon 2003.

Without a doubt, research is urgently needed to elucidate the mechanisms of action of phytonutrients and phytochemicals in the prevention and treatment of disease. The very complexity of these compounds presents immense challenges for research since they do not occur, nor do they act in isolation. One challenge with this approach is that it reduces the naturally occurring agent, which contains multiple compounds affecting multiple targets, to a single agent affecting a single target. While it is urgent that we understand the secondary metabolites and their actions, developing a new drug from that information is not the only worthwhile path. Adding to the challenge is the fact that research dollars are limited when natural agents can't be patented and their sale will never recover the cost of the research. As pharmaceutical scientific research works to identify new potential drugs from natural agents, it tends to diminish or dismiss the therapeutic value of the former.

Traditional use evidence does not replace human clinical trials. There are real limits to our current understanding of plant-based medicines that rests mostly on cultured cell lines and animal models. But many would argue that it is not essential that we wait to recommend the use of the original plant compound until all the evidence has been collected. The current situation is that cancer patients in particular are denied the opportunity to utilize natural therapies in a clinical setting until they have failed conventional therapies. In our rush to identify and utilize the most biologically active components of food and botanical medicines, we must respect the fact that for millennia mankind has used these foods and plants without evidence of serious harm.

V. ANAYLSIS AND FINDINGS

A. GDU

The four main ingredients in GDU are reviewed in this document.

1) Bromelain
2) Turmeric
3) Feverfew
4) Quercetin

SCIENTIFIC NAME: ANANAS COMOSUS (BROMELIACEAE)

Common name: Bromelain

Historical use: Bromelain belongs to a group of plant-derived proteolytic enzymes isolated from the stem and core of the pineapple. It has been used in the Chinese Materia Medica, other Asian cultures and by Western herbalists for a wide range of applications including but not limited to traumatic injury and arthritis and cancer.

Clinical Summary:

Bromelain has many in vitro and in vivo studies and its properties include: 1) the ability to interfere with growth of malignant cells; 2) inhibit platelet aggregation; 3) fibrinolytic activity; 4) anti-inflammatory action; 5) skin debridement properties. These biological functions of bromelain, a non-toxic compound, have therapeutic values in modulating a) tumor growth; b) blood coagulation; c) inflammatory changes; d) debridement of third degree burns; 3) enhancement of absorption of drugs. J Ethnopharmacol. 1988 Feb-Mar; 22(2):191-203.

Biochemically active constituents and known mechanisms of action:

Chemical constituent: Sulphydryl proteolytic enzyme, cysteine-proteinase. Bromelain also contains a peroxidase, acid phosphatases, several proteases inhibitors and organically bound calcium. Alt Med Rev 1: 243-257.

In addition, CCS and CCZ are two novel constituents (proteases) that and bind the growth of a broad range of tumor cells including breast, colon, lung, ovarian and melanoma. Med Res News 2005; http://www.qimr.edu.au

Bromelain has been demonstrated to:

- Reduce platelet aggregation and adhesion of platelets to blood vessel endothelial cells.
  Cell Mol Life Sci 2001;58:1234-45.

- Act as anti-inflammatory agents in various forms of arthritis and inflammatory states via reduction in PGE2 and TXA2. Ethnopharmacology 22:191-203

- Down-regulate immunosuppressive cytokine TGF-beta, inhibits tumor cell growth, modulation of immune cell function, modulation of cell adhesion molecules and the effects on platelet aggregation and thrombosis. Cancer Chemother Pharmacol 2001; 47: S10-5 & Cell Mol Life Sci. 2001 Aug:58(9):1234-45

- Systemic enzyme therapy (including bromelain) significantly decreased tumor–induced and therapy-induced side effects and complaints such as nausea, gastrointestinal complaints, fatigue, weight loss, and restlessness and obviously stabilized the quality of life.
  Integr Cancer Ther. 2008 Dec; 7(4):311-6

- The anti-metastatic effect of bromelain occurs with or without its proteolytic and anticoagulant activity: Journal of Can Res Clin Onc. 1998; 114: 507-508

- Bromelain treatment alters leukocyte expression of cell surface molecules involved in cellular adhesion and activation. Clin Immunol. 2002; 104:183-190

- Pretreatment with bromelain of human T cells cleaves CD44 surface adhesion molecules and markedly enhances CD2-mediated T cell activation. J Immonol 1992; 149:3809-16

- In addition, in vitro studies have shown that bromelain can:
  - inhibit the cytokines IL 4, IL2, gamma interferon
  - reduce cell surface receptors CD44 which is associated with leukocyte migration and induction of proinflammatory mediators
  - reduce CD4 lymphocytes (primary effectors in animal models of inflammation)
  - block growth of a broad range of tumor cells including breast, lung, colon, ovarian and melanoma via two proteins, CCS and CCZ discovered in 2005 by researchers at Queensland Institute for Medical Research.

    Pakistani Journal of Nutrition Review 7 (4); 513-520, **2008**

- Inhibit the first step of metastasis by diminishing the expression of intracellular compounds that degrade the intracellular matrix and allow migration of metastatic cells through tissues. Cell Mol Life Sci. 2001 Aug:58(9):1234-45

- Bromelain reversibly inhibits invasive effects on glioma cells; These results indicate that bromelain exerts its anti-invasive effects by proteolysis, signaling cascades, and translational attenuation.

  Neoplasia. 2001 Nov-Dec;3(6):469-79

Adverse reactions: diarrhea, GI disturbance, allergic reactions (to pineapple). Cell Mol Life Sci. 2001 Aug:58(9):1234-45

Herb/Drug Interactions:

Bromelain may increase blood and urine levels of antibiotics.

Bromelain may change the effect of drugs such as 5-FU and vincristine.

Bromelain may increase the risk of bleeding due to its antithrombotic effects.

http://www.mskcc.org/mskcc/html/69152.cfm

SCIENTIFIC NAME: RHIZOMA CURCUMA LONGA (ZINGIBERACAE)

Common Name: Turmeric, Indian saffron

History of use: Turmeric is a yellow-pigmented spice with a long history of use in Asian cooking and as Traditional Chinese and Ayurvedic medicine. It is part of the ginger family and has been used as an anti-inflammatory. It has been used for centuries in the Asian countries without any toxic effects. Curr Pharm Des. 2002; 8(19):1695-706

Clinical summary: A growing body of research suggests that curcumin has a potential for the prevention and treatment of cancer. Preclinical trials have shown that curcumin can both inhibit the formation of tumors in animal models and act on a variety of molecular targets involved in cancer development. In vitro studies have shown that curcumin induces apoptosis and some degree of selectivity of cancer cells. Clinical trials have revealed that curcumin is well tolerated and may produce antitumor effects in people with precancerous lesions or who are at high risk for developing cancer. This seems to indicate that curcumin is a pharmacologically safe agent that may be used in cancer chemoprevention and therapy. Both in vitro and in vivo studies have shown, however, that curcumin *may* produce toxic and carcinogenic effects under certain circumstances and specific conditions and may alter the effectiveness of chemotherapy and radiotherapy.

Mol Nutr Food Res. 2008 Jun; 52 Suppl 1:S103-27

Human clinical trial: Oral curcumin is well tolerated and, despite its limited absorption, has biological activity in some patients with pancreatic cancer. Clin Can Res. 2008: 14(14): 4491-4499.

Turmeric has demonstrated anticarcinogenic effect in cultured cell lines and animal models, at all phases of cancer growth including initiation, post-initiation, promotion, and progression, allowing it to be useful in secondary prevention. Cancer Research. 1999 Feb 1 (59): 597-601

The current science indicates multiple mechanisms of action to support the intake of such a level of turmeric along with other dietary sources of flavonoids (quercitin) as a reasonable suggestion for individuals who are fighting cancer.

Biochemically active constituents and known mechanisms of action:

To date, at least 94 biologically active compounds have been isolated from turmeric (Dr. Duke's Phytochemical and Ethnobotanical Database (accessed 1/09).

The plant derived phenolic compound curcumin (diferuloylmethane) is the most active constituent.

Curcumin functions as a potent COX 2 inhibitor with anti-inflammatory, anti-oxidant and multiple anticancer activities in dozens of vitro studies and some human clinical trials, a selection of which follows:

Mol Nutr Food Res. 2008 Jun;52 Suppl 1:S103-27

- Curcumin induces apoptosis (programmed cell death) in both androgen-dependent and androgen-independent prostate cancers. Prostate Cancer and Prostatic Diseases. 2000 Aug; 3(2):84-93 PMID: 12497104

- Curcumin has a chemoprotective and growth inhibitory action against a variety of cancer cell lines. Curcumin works in concert with TNF-related inducing ligand (TRAIL) and sensitizes androgen sensitive human prostate cancer cells lines to trigger apoptosis. Mol Cancer Ther. 2003 Jan;2(1): 95-103

- Curcumin inhibits:
  - Lipoxygenase activity and the leukotrienes the follow
  - COX 2 expression and the proinflammatory prostaglandins that follow.
  - The initiation of carcinogenesis by inhibiting cytochrome p450 enzymes and increases glutathione S-transferase
  - The promotion and progression of carcinogenesis (S,G2/M cell cycle phase and induction of apoptosis)
  - The growth of DNA mismatch repair of defective colon cancer cells.

Curr Pharm Des. 2002; 8(19): 1695-706

- Curcumin exerts its anti-carcinogenic properties by inducing modulation of the cell cycle and apoptosis by inhibiting proliferation and inducing apoptosis in specific gastric and colon cancer cell lines. Anticancer Research. 2001 Mar-Apr; 21(2A):873-8

- Curcumin inhibits human colon carcinoma (Lovo) cell proliferation in a dose dependent manner, and induces apoptosis in colon cancer cells and arrests the cell cycle in S, G2/M phase. Anticancer Res. 1999 Sep-Oct;19(5A):3675-80.

- Curcumin decreases the number (and size) of AOM-induced tumors in mice, as well as the percent of mice that get tumors; decreases the numbers of papillomas and squamous cell cancers of forestomach and adenomas and adenocarcinomas of the duodenum and colon
  Cancer Research. 1994 Nov 15; 54(22): 5841-7

- Curcumin has a chemoprotective effect in mice with AOM induced colon cancer in various stages of turmorigenesis. Cancer Res. 1999 Feb 1; 59(3):597-601

- Curcumin suppresses Apc (gene mutation) that causes intestinal adenomas in animal models Carcinogenesis, 2000 May;21(5): 921-7

- Curcumin is known to down regulate Cyclin-D1 expression through activation of both transcriptional and post-transcriptional mechanisms in various prostate, breast and squamous cell lines. Oncogene. 2002 Dec 12;21(57):8852-61

- Curcumin can suppress tumor initiation, promotion and metastasis-found to be safe, with no toxicity up in human clinical trials at a dose of up to 10 grams per day.
  Anticancer Research 2003 Jan-Feb; 23(1A):363-98

Adverse effects: none known. http://www.mskcc.org/mskcc/html/69401.cfm

Herb Drug Interactions:

Anticoagulants / Antiplatelets: Turmeric *may* increase risk of bleeding

Brinker F. Herbal Contraindications and Drug Interactions, 2nd ed. Sandy (OR): Eclectic Medical Publications; 1998

Camptothecin: Turmeric inhibits camptothecin-induced apoptosis of breast cancer cell lines in vitro. Cancer Res 2002;62:3868-75.

Mechlorethamine: Turmeric inhibits mechlorethamine-induced apoptosis of breast cancer cell lines in vitro. Cancer Res 2002;62:3868-75.

Doxorubicin: Turmeric inhibits doxorubicin-induced apoptosis of breast cancer cell lines in vitro. Cancer Res 2002;62:3868-75.

Cyclophosphamide: Dietary turmeric inhibits cyclophosphamide-induced tumor regression in animal studies. Cancer Res 2002;62:3868-75.

SCIENTIFIC NAME: TANACETUM PARTHENIUM (COMPOSITAE)

(PREVIOUSLY IT WAS KNOWN AS CHYRSANTHEMUM PARTHENIUM)

(ASTERACEAE)

Common name: Feverfew, Bachelor's button, wild chamomile

Historical use: Feverfew has been used for centuries as a febrifuge and for the treatment of migraines and arthritis. Other historical uses have been in the treatment of anemia, earache, dysmenorrheal, dyspepsia, trauma and intestinal parasites. More recently, it has been used in gardens to control noxious pests (its pyrethrin component is an effective insecticide and herbicide). Duke JA, Handbook of Medicinal Herbs. CRC Press, Boca Raton, FL, 1985 p.118

Clinical summary: Derivatives from the leaves of the plant have been used primarily to treat migraine headaches. Parthenolide extract has been shown to reduce the frequency of migraine attacks. Another constituent of feverfew has antioxidant activities. A few in

vitro studies have shown that feverfew exhibits anticancer effects. See http://www.mskcc.org/mskcc/html/69219.cfm and below.

Biochemically active constituents and known mechanisms of action:

To date, 46 biologically active constituents have been isolated from Chrysanthemum parthenium.

(Dr. Duke's Phytochemical and Ethnobotanical Databases (accessed 1/09 but dated 1992. Since this time, the botanical name has evolved to be listed as Tanacetum parthenium).

Parthenolide, a sesquiterpine lactone, has been isolated from the leaf of Tanacetum and has been the most studied constituent for its anti-inflammatory action. Additional constituents include

Parthenolide has demonstrated effectiveness against cancer by inhibiting NF Kappa B activity:

- Parthenolide has been used in conjunction with Sulindac, an NSAID, in the treatment of pancreatic cancers, demonstrating decreased NFkappaB DNA binding and transcriptional activities in cells treated with the combination compared with the single agents, demonstrating cooperative targeting of the NF-KB pathway. These data provide preclinical support for a combined chemotherapeutic approach with NF-KB inhibitors and NSAIDs for the treatment of pancreatic adenocarcinoma. Mol Cancer Ther. Apr 2005;4(4):587-594

- Transcription factors such as NF-KB provide powerful targets for drugs to use in the treatment of cancer. In this report parthenolide (PT), a sesquiterpene lactone of herbal remedies such as feverfew *{Tanacetum parthenium)* with NF-kB inhibitory activity, markedly increased the degree of human leukemia HL-60 cell differentiation when simultaneously combined with 5 nM 1D:,25-dihydroxyvitamin Di (I,25-(OH)2D3). PT by itself did not induce HL-60 cell differentiation. In addition, These results indicate that PT strongly potentiates the 1,25-(OH)2D3-induced HL-60 cell differentiation into monocytes *via* the inhibition of NF-KB activity and provide evidence that inhibition of NF-KB activation can be a pre-requisite to the efficient entry of promyelocytic leukemia cells into a

differentiation pathway. British Journal of Pharmacology (2002) 135, 1235-1244

- Parthenolide is a major sesquiterpene lactone derived from feverfew (Tanacetum parthenium) with known anti-inflammatory activity. Moreover, the anticancer potential of this compound was suggested. In this study, we determined the effect of parthenolide on proliferation of three human cancer cell lines: human lung carcinoma (A549), human medulloblastoma (TE671), human colon adenocarcinoma (HT-29) and human umbilical vein endothelial cells (HUVEC) in vitro. Parthenolide inhibited proliferation of all three types of cancer cells (A549, TE671, HT-29) and HUVEC with the following IC(50) values (in muM): 4.3, 6.5, 7.0 and 2.8, respectively. Thus, the antiproliferative potential of parthenolide was confirmed. Pharmacol Rep. 2007 Mar-Apr; 59(2): 233-7

- Parthenolide is an active sesquiterpene lactone present in a variety of medicinal herbs and is well known for its anti-inflammatory activity. The antimicrotubular and antiproliferative effects of parthenolide, well-known microtubule-stabilizing anticancer agent, may influence paclitaxel activity. The tubulin/microtubule system may represent a novel molecular target for parthenolide, to be utilized in developing new combinational anticancer strategies. Chemico-Biological Interactions 149 (2004) 165–173

- Parthenolide, an active ingredient of herbal remedies such as feverfew (Tanacetum parthenium) mimicked the effects of IkBa by inhibiting NF-kB DNA biding activity and Mn-SOD expression, and increasing paclitaxel-induced apoptosis of breast cancer cells. These results suggest that active ingredients of herbs with anti-inflammatory properties may be useful in increasing the sensitivity of cancers with constitutively active NF-kB to chemotherapeutic drugs. Oncogene 2000 (19) 4159-4169

Adverse reactions: Patients allergic to ragweed, chrysanthemum, marigold or other members of the Compositae family may have cross-reactivity to feverfew. Minor GI distress may occur. Mouth ulcerations have been reported from chewing fresh feverfew

leaves. Cases of airborne contact dermatitis have also been reported. http://www.mskcc.org/mskcc/html/69219.cfm

Withdrawal: Muscle stiffness, anxiety, and moderate pain usually occur following cessation of long-term feverfew use (post-feverfew syndrome). Br Med J (Clin Res Ed). 1985 Aug 31; 291(6495): 569–573 and Br J Dermatol. 2007 Mar;156(3):510-5

Herb/Drug interactions: Theoretically, feverfew may have additive effect with anticoagulants and antiplatelet drugs. http://www.mskcc.org/mskcc/html/69219.cfm

SCIENTIFIC NAME: QUERCETIN (3,3',4',5,7-pentapentahydroxyflavone)

Common name: Quercetin

Clinical summary: Quercetin is a phytonutrient that is a member of the polyphenolic flavonoid family, constituting the major bioflavonoids in the human diet. The glycoside form is readily available in dietary plants such as ***onions, apple, buckwheat, red wine and teas.*** Quercetin has a number of biological activities such as antioxidant, anti-inflammatory, and anti-allergy. Quercetin is being used for the treatment of allergic rhinitis, cardiovascular disease, inflammation, cancer prevention and treatment. http://www.mskcc.org/mskcc/html/69346.cfm

Biological activities and known mechanism of action:

Quercetin is a flavonoid molecule ubiquitous in nature. A number of its actions make it a potential anti-cancer agent, including cell cycle regulation, interaction with type II estrogen binding sites, and tyrosine kinase inhibition. Quercetin appears to be associated with little toxicity when administered orally or intravenously. Much in vitro and some preliminary human data indicate quercitin inhibits tumor growth. Altern Med Rev. 2000 Jun; 5(3): 196-200

What follows is an overview of the research on quercetin and cancer from Alternative Medicine Review 2000 Jun; 5(3): 196-200:

- Quercetin was found to down regulate expression of mutant p53 protein to nearly undetectable levels in human breast cancer cell lines. Lower concentrations gave less reduction. The inhibition of expression of p53 was found to arrest the cells in the G2-M phase of the cell cycle.

- Quercetin has been found to inhibit the expression of the p21-ras oncogene in cultured colon cancer cell lines. Mutations of ras proto-oncogenes are found in over 50% of colon cancers, as well as many other tumor types.

- Radiotherapy: Quercetin showed a significant but mild enhancement of the cytotoxic effect of radiation on rat hepatoma cells when added to the medium. A human study showed topical and oral administration of quercetin to reduce skin damage during radiotherapy in patients with head and neck cancers.

- Chemotherapy: Quercetin has been shown to increase the therapeutic efficacy of cisplatin both in vitro and in vivo in mice. An in vitro study using human ovarian and endometrial cancer cell lines found that addition of quercetin to cisplatin caused a potentiation of the cytotoxic effect of cisplatin
- Quercetin has been shown in vitro to protect normal renal tubular cells from cisplatin toxicity.

Adverse reactions: Human studies have not shown any adverse effects associated with oral administration of quercetin in a single dose of up to 4,000 mg (Eur J Clin Pharmacol 1975; 9:229-234)
or after one month of 500 mg. twice daily. (Urology 1999; 54: 960-963)

Herb/Drug interactions:
Chemotherapeutic agents: See above for chemotherapeutic agents
Papain and Bromelain: May assist the absorption of Quercetin in the intestine. Herr, SM. Herb-Drug Interaction Handbook. Chuch Street books. 2nd ed. Nassau NY 2002
Quinolone antibiotic: Quercetin may compete for DNA gyrase binding sites on bacteria. Urology 1999;54:960-3.

B. 7 HERB FORMULA

Ingredients of Daniel Chapter One's "7 Herb Formula" are listed and a selection of the scientific evidence of the activity of their constituents is presented.

SCIENTIFIC NAME: ARCTIUM LAPPA (Asteraceae):

Common Names: Burdock, Greater Burdock, Gobo and Nui bang zi (pin yin)

Historical use: Burdock has a long history of use dating from the Chinese Materia Medica, Native Americans, and Eclectic herbalists as an alterative, anti-inflammatory, antimicrobial, cholegogue, diuretic, diaphoretic, hypoglycemic, and a "blood purifier." Arctium lappa was an original herb in Renne Caisse's "Essiac Tea", which has been used to support the immunity of those with cancer. According to the Journal of Ethnopharmacology, Essiac tea possesses potent antioxidant and DNA-protective activity, properties that are common to natural anti-cancer agents. J Ethnopharmacology. 2006 Jan 16;103(2); 288-96.

Biologically active constituents and proposed mechanisms of action: To date, at least 119 secondary metabolites have been isolated from Arctium lappa (Duke's Phytochemical and Ethnobotanical Database) accessed 1/09. Arctium lappa contains many polyphenolic acids and flavonoids with potential chemoprotective effects. Below is a list of five of Arctium lappa's most active constituents:

- Arctigenin: extract of Arctium lappa showed potent antiproliferative activity against B cell hybridoma cell, MH 60 through apoptosis Planta Medica. 2006 Feb; 72(3):276-8 Arctigenin potently inhibits the activity of MKK1 in vitro, thus inhibiting phosphorylation of MAP kinases http://www.proteinkinase.de/html/map_kinase_inhibitors.html#arctigenin
- Chlorogenic acid: this study found chlorogenic acid to have anticancer properties via inhibition of microsomal G6P transferase in glioma cells. Cancer Cell International, 2006, 6: 7:dol.10.1186/1475-2867-6-7
- Inulin: a plant fiber/sugar that reduced carcinogenesis in rats Carcinogenesis. 2002 Nov. 23 (11): 1953-60

Clinical summary: Arctium lappa contains numerous compounds that possess antipyretic, antimicrobial, antimutagenic, anti-oxidant, antitumor, cholegogue and desmutagenic activities. Chemoprevention of Cancer, CRC Press, 1995 Nixon D

Adverse effects: hypoglycemia. Some potential for allergic reaction/contact dermatitis if sensitive to chrysanthemum; it should be avoided by pregnant and lactating women because it may cause uterine stimulation. JAMA 1978; 239: 2157

Herb/drug interactions: none discovered

SCIENTIFIC NAME: RHEUM PALMATUM (Polygonaceae)

Common name: Chinese rhubarb (da huang), Turkey Rhubarb

Historical use: Rhubarb has been used in the Chinese Materia Medica for centuries for the treatment of inflammatory diseases; as a purgative/laxative in both Chinese, Western, European herbal medicine; Rheum palatum was an original herb in Renne Caisse's "Essiac Tea", which has been used to support the immunity of those with cancer. According to the Journal of Ethnopharmacology, Essiac tea possesses potent antioxidant and DNA-protective activity, properties that are common to natural anti-cancer agents. J Ethnopharmacology. 2006 Jan 16;103(2): 288-96.

Biologically active constituents and proposed mechanisms of action::

Contains 30 biologically active chemicals (Dr. Duke's Phytochemical and Ethnobotanical Databases) accessed 1/09

- Anthroquinone derivatives are its major active constituents and it is derivatives of these compounds that that play a substantial role in inhibiting angiogenesis. Journal of Ethnopharmacology. 2009 Jan 21: 121 (2): 313-7
- Aloe-emodin: (anthroquinone) possesses anti-tumor properties Med Research Review. 2007 Sept; 27(5): 609-30
- Emodin: is the most abundant anthroquinone in Rheum. It is capable of inhibiting cellular proliferation, induction of apoptosis, prevention of metastasis...through induction of protein kinases, phosphoinositol 3 kinase (P13K), protein kinase C (PKC), NF-Kappa B (NF-KappaB), and mitogen-activated protein kinase (MAPK) signaling cascades. Its anti-proliferative properties are through the p53 and p21 pathways.

  Med Res. Review. 2007 Sept; 27(5): 609-30

- Emodin: inhibits protein kinasep651ck; acts on a number of molecular targets within the cell; Inhibits mammalian cell cycle modulation in specific oncogene over expressed cells; induces apoptosis; is used in combination with chemotherapy to reduce toxicity and enhance efficacy; inhibitory effects on angiogenic and metastatic properties make it a sensible candidate as a specific blocker of tumor-associated events. Medical Research Review. 2007 Sep; 27 (5): 591-608
- Quercitin: is the flavonoid molecule that is ubiquitous in nature, although no research on its action in Rheum is available.
- Rhein: (anthroquinone) inhibits the proliferation of various human cancer cells; this study demonstrated that rhein induced cell cycle S-phase arrest on human hepatocellular carcinoma BEL-7402 cells, via downregulation of oncogene c-Myc and apoptosis through the caspase-dependent pathway. American Journal of Chinese Medicine. 2008; 36(4):805-13

Clinical Summary: Rhubarb has been used for a variety of conditions including cancer, immunosuppression, constipation, diarrhea, ulcers, hypertension and chronic renal fatigue. The anthroquinone and tannins are thought responsible for the laxative and constipating effects, respectively. Although animal studies have confirmed antitumor effects, limited human clinical data is available. Memorial Sloan-Kettering Cancer Center http://www.mskcc.org/mskcc/html/69357.cfm

Adverse reactions: Intestinal cramps, nausea, vomiting and diarrhea have been reported due to the laxative effect. Long-term use can result in potassium loss due to diarrhea. Do not use long term. Memorial Sloan-Kettering Cancer Center http://www.mskcc.org/mskcc/html/69357.cfm

Herb/Drug Interactions: Diuretics: Potassium loss due to the stimulant laxative effect can increase potential risk for hypokalemia. Digoxin: stimulant laxative effect can increase potential risk for hypokalemia. Brinker F. Herb Contraindications and Drug Reactions, 3rd edition.

SCIENTIFIC NAME: RUMEX ACETOSELLA (Polygonaceae)

Common name: Sheep sorrel

Historical use: Sheep sorrel historically has been used as a salad green and spring tonic. Rumex acetosella was an original herb in Renne Caisse's "Essiac Tea", which has been used to support the immunity of those with cancer. According to the Journal of Ethnopharmacology, Essiac tea possesses potent antioxidant and DNA-protective activity, properties that are common to natural anti-cancer agents. J Ethnopharmacology. 2006 Jan 16;103(2); 288-96.

Biologically active constituents and proposed mechanisms of action:

Contains 33 biologically active chemicals (Dr. Duke's Phytochemical and Ethnobotanical Databases) accessed 1/09.

- Glycosides: Hyperoside, quercitin
- Anthroquinones: emodin, aloe-emodin, rhein, physcion (Memorial Sloan-Kettering Cancer Center Database (http://www.mskcc.org/mskcc/html/69375.cfm)

Clinical summary: Sheep sorrel is extremely nutrient-rich, containing high levels of calcium, iron, magnesium, silicon, sulfur, copper, iodine, manganese, zinc and vitamin C in addition to vitamins A, B complex, D, E, K, P and U. It also contains rutin, the flavones glycosides hyperin and hyperoside, carotenoids, organic acids and Anthroquinones. Sheep sorrel tea has been used traditionally to treat inflammation, fevers and cancer. Though anthraquinones are known to have antioxidant and antitumor activity, the anthraquinones in sheep sorrel have not been tested for these effects beyond anecdotal reports. American Botanical Council HerbClip ™

Adverse effects: Sorrel contains oxalate (oxalic acid), which may be toxic in large doses. Reports of organ damage and one report of death following ingestion of a concentrated sorrel soup have been published. Sorrel may also cause kidney stones, precipitation of drugs taken concomitantly, and malabsorption of minerals, such as calcium, iron, or zinc. http://www.naturalstandard.com/index-abstract.asp?create

Herb/Drug interactions: none known

SCIENTIFIC NAME: ULMUS RUBRA (Ulmuceae)

Common Name: Slippery Elm, Red elm, Indian elm

History of use: Ulmus rubra has been historically used for gastrointestinal disorders, skin ulcers or abscesses, cancers, coughs, fevers and inflammation. Its primary constituent is mucilage, which is responsible for the demulcent, emollient and antititussive properties, which form a viscous material following oral administration or for topical use. (Memorial Sloan-Kettering Cancer Center database: http://www.mskcc.org/mskcc/html/69381.cfm.

Ulmus rubra was an original herb in Renne Caisse's "Essiac Tea", which has been used to support the immunity of those with cancer. According to the Journal of Ethnopharmacology, Essiac tea possesses potent antioxidant and DNA-protective activity, properties that are common to natural anti-cancer agents. J Ethnopharmacology. 2006 Jan 16;103(2); 288-96.

Biologically active constituents and proposed mechanisms of action:

Contains 50 biologically active chemicals (Dr. Duke's Phytochemical and Ethnobotanical Databases) accessed 1/09. It is comprised mainly of mucilage, phytosterols, fatty acids and tannins, none of which have been studied for cancer.

Adverse reactions: none known

Herb/drug interactions: Theoretically, the mucilage and fiber content may slow the absorption of concomitantly administered oral medications, though no interactions have been reported. No human or animal studies have been performed to evaluate the efficacy of any proposed claims.

SCIENTIFIC NAME: UNCARIA TOMENTOSA (Pedaliaceae)

Common name: Cat's Claw, Garabato amarillo, Una de Gato

Historical use: Cat's Claw is a vine native to South America, specifically the Peruvian rainforest, where it has been a traditional medicine. It is a very popular immune-enhancing supplement and is known to help digestive complaints, arthritis and is considered to have an anti-inflammatory effect and anti-tumor effects.

http://www.mskcc.org/mskcc/html/69166.cfm

Biologically active constituents and proposed mechanisms of action:

Contains 29 biologically active chemicals (Dr. Duke's Phytochemical and Ethnobotanical Databases) accessed 1/09

The most biologically active compounds in Uncaria tomentosa are:

- Oxyindole alkaloids: isorhyncholophylline, rhynchophylline and protect against glutamate cell death in cultured cerebellar cells in rats. Journal Pharm Pharmacol. 1999 Jun;51 (6): 715-22
- Oleanolic acid and ursolic acid: a synthetic triterpenoid based on naturally occurring ursolic and Oleanolic acids induces apoptosis induced by TNF and chemotherapeutic agents through downregulation of expression of NF-Kappa B in human leukemic cells.
  Clin Cancer Res. 2006 Mar 15;12(6): 1828-38
- The primary mechanism for cat's claw anti-inflammatory actions appears to be immunomodulation via suppression of TNF synthesis. Free Radical Biology and Medicine. 2000 29(1) pp. 71-28
- An aqueous extract of cat's claw induced apoptosis, inhibited liopolysaccharide induced iNOS expression, cell death and inhibited the activity of NF-Kappa B, providing mechanistic evidence that cat's claw is an effective anti-inflammatory agent. Alimen Pharmacol Ther 1998 Dec; 12(12):1279-89
- Another aqueous extract of Uncaria tomentosa (C-Med-100) demonstrated a suppressive effect on tumor cell growth through induction of apoptosis. Anticancer Research 1998 Sep-Oct; 18(5A):3363-8
- Uncaria tomentosa (C-Med-100) demonstrated in a human trial to decrease DNA damage and increase DNA repair. Phytomedicine 8(4) pp. 275-282

Clinical Summary: In vitro studies show that the alkaloids from Cat's claw enhance phagocytosis, display immunomodulatory properties, alleviate inflammation, and possess anti-viral activity. Cat's claw is also thought to have anticancer activities and lab results demonstrated growth inhibitory effects on glioma and neuroblastoma cells as well as promyelocytic cells. http://www.mskcc.org/mskcc/html/69166.cfm

Adverse reactions: hypotension and diarrhea. http://www.mskcc.org/mskcc/html/69166.cfm

Herb/Drug interactions: an additive effect with anti-coagulants or hypotensives is possible but has not been reported. http://www.mskcc.org/mskcc/html/69166.cfm

SCIENTIFIC NAME: ELEUTHEROCOCCUS SENTICOSUS (Araliaceae):

Common Names: Siberian ginseng, Eleuthero ginseng, Ci Wu Jia (pin yin); Acanthopanax senticosus

Historical use: Eleutherococcus senticosus has been used for thousands of years in the Traditional Chinese Materia Medica as a kidney tonic to increase longevity, improve general health and appetite. In 1958, the Russian scientist Brekhman coined the term "adaptogen" as a substances that 1) must be innocuous and cause minimal disorders in the physiological functions of an organism, 2) must have a non-specific action (i.e., it should increase the resistance to adverse influences by a wide range of physical, chemical and biochemical factors), and 3) usually has a normalizing action irrespective of the direction of the pathological state (alterative action). The Healing Power of Herbs, Murray; Three Rivers Press, New York, 1995, pp.315-20)

Farnsworth and colleagues reviewed data on an Eleutherococcus senticosus root extract administered to over 2,100 human subjects to assess the adaptogenic effects of ginseng and concluded that it:

1. Increased ability of humans to withstand adverse physical conditions (heat, noise, motion, workload increase, exercise and decompression), and
2. Increase mental alertness and work output, and
3. Improved quality of work produced under stressful conditions, and athletic performance.

Farnsworth and colleagues reviewed data on an Eleutherococcus senticosus root extract administered to over 2,200 human subjects to assess its adaptogenic effect in disease states and concluded that it appears to be effective in:

1. Atherosclerotic conditions in that it can lower serum cholesterol levels, reduce blood pressure and eliminate angina symptoms in human subjects;
2. Improving kidney function and regulating blood pressure in patients with acute kidney infection
3. Improved sense of well-being of psychological complaints (insomnia, hypochondriasis, neuroses) possibly through regulation of biogenic amine content in the brain.

Economic and Medical Plant Research 1, 156-215. Farnsworth, 1985
The Healing Power of Herbs, Murray: Three Rivers Press, New York. 1995, pp.315-20)

Biologically active constituents and proposed mechanisms of action:

To date, at least 51 biologically active constituents in Eleutherococcus have been identified (Dr. Duke's Phytochemical and Ethnobotanical Database) accessed 1/09. The main active constituents are the eleutherosides, though very little current research is available. Below are some of the highlights:

- Eleutherococcus senticosus demonstrated immunomodulatory properties (enhanced the cellular response of the mouse immunological system (chemokinetic activity of mice spleen cells, GvH reaction), as well as a stimulatory effect of Eleutherococcus on the humoral response (antibody production) in mice. Pol Journal Vet Science 2003;6(3 Suppl):37-9.

- Eleutherococcus senticosus, as part of a formula (AdMax) was evaluated for its effect on ovarian cancer patients. In patients who took AdMax, the mean numbers of 4 T cell subclasses were increased, the mean amounts of IgG andIgM were incrased and the results suggest that the combination of extracts from adaptogenic plants may boost the suppressed immunity in ovarian cancer patients who are subject to chemotherapy. Phytotherapy Res. 2006 May; 20(5): 424-5

- Standardized extracts of Eleutherococcus senticosus at generally recommended doses for over-the-counter use are unlikely to alter the disposition of co-administered medications primarily dependent of CY2D6 or CYP3A4 pathways for elimination. Drug Metab Disp. 2003 5(31): 519-22

- Eleutherococcus senticosus extract was applied to cells in culture resulting in a slight radioprotective effect. American Journal Chinese Medicine. 1981 (9) 48-56

- Eleutherococcus senticosus provided anti-proliferative effects against L1210 murine leukemia cells and suggests that it may be useful for reducing the concentration of conventional anti-metabolites used for their anti-proliferative effects on tumor cells. Journal Pharmacological Science. 1984 Feb; 73(2): 270-2

- Eleutherococcus senticosus aqueous extract of eleutheroside E may have contributed to the anti-fatigue action, recovery of the reduction of NK activity and inhibition of corticosterone elevation induced by swimming stress. Journal of Ethnopharmacology. 2004 Dec;95(203):447-53

Clinical summary: Although initial reports from the Soviet Union and reviews of that literature by Farnsworth suggested therapeutic value of Eleutherococcus senticosus as an adaptogen, very little current research has been done to substantiate those findings. It is now being recommended that the term "adaptogen" be discontinued and further research be done on this plant to confirm potential therapeutic value in these areas: Anti-oxidant, anti-cancer, immunostimulatory, anti-inflammatory, hypocholesterolemic, cholorectic, anti-pyretic and anti-bacterial actions.

Journal of Ethnopharmacology. 2004 Dec;95(203):447-53

Adverse effects: toxicity studies in animals demonstrated that 33% ethanol extract of E. senticosus is virtually non-toxic; it is very well-tolerated in humans and side-effects are quite minimal; very high doses may produce insomnia, irritability, melancholy and anxiety. Economic and Medical Plant Research 1, 156-215, Farnsworth, 1985The Healing Power of Herbs, Murray; Three Rivers Press, New York, 1995, pp.315-20)

Herb/drug interactions: none discovered

SCIENTIFIC NAME: NASTURTIUM OFFICINALE (BRASSICACEAE)

Common name: Watercress, Berro

Historical use: Like sorrel, watercress has been used historically as a salad green and spring tonic.

Biologically active constituents and proposed mechanisms of action:

Contains 47 biologically active chemicals (Dr. Duke's Phytochemical and Ethnobotanical Databases) accessed 1/09. The most biologically active constituent of watercress for cancer is phenethyl isothiocyanate (PEITC). Watercress may have exceptionally good anticarcinogenic potential as it combines a potent inhibitor of Phase 1 enzymes (PEITC) with at least three inducers of phase II enzymes (PEITC, 7-methylsulfinylheptyl ITC and

8-methylsulfinyloctyl ITC. These compounds act at three stages of carcinogenesis in that they:

1. Inhibit carcinogen activation
2. Induce phase II enzymes and enhance excretion of the potential carcinogens and
3. Induce apoptosis via activation of protein kinase pathway.

The putative anticarcinogenic activity of ITC is consistent with the results of epidemiological studies, which have suggested a reduction in cancer risk through the consumption of cruciferous vegetables. Carcinogenesis. 2000 21(11) pp. 1983-88

- PEITC: PEITC selectively affects xenobiotic-metabolizing enzymes in the liver, lung and nasal mucosa and is especially effective in inhibiting the cytochrome p450 dependent oxidation of NNK in the lung and NDMA in the liver of rats. Carcinogenesis. 1992 13(12) pp.2205-2210
- PEITC: PEITC was found to be a very potent inhibitor of N-nitrosobenzylmethylamine-induced rat esophageal carcinogenesis. Cancer Research. 1991 51, pp. 2063-2068.

Clinical summary: Watercress contains high levels of the glucosinolate, *gluconasturtiin*, which is hydrolyzed to phenethylisothiocyanate (PEITC) upon pulverization of the leaves. It is also a rich source of vitamins A and C, sulfur, iodine, calcium and manganese. Several animal and human studies have demonstrated that PEITC inhibits lung tumors induced by NNK (from tobacco smoke). It also activates detoxification enzymes in cancerous cells. Indoles present in watercress are antiestrogenic and dispose of excess estrogen, which may help prevent hormone related cancers.

American Botanical Council HerbClip ™

Adverse reactions: none discovered

Drug/herb interactions: none discovered

C. "BioMixx"

Four of the main ingredients of Daniel Chapter One's "BioMixx" formula, Whey protein, Astragalus membranaceus, Camellia sinensis and Eleutherococcus senticosus are listed, and a brief selection of the scientific evidence of the activity of their constituents is presented.

WHEY PROTEIN

Whey Protein: Whey is a co-product of cow's milk in the manufacture of cheese and in recent years has become a functional food. The two primary sources of protein in milk are the caseins and whey. After processing occurs, the caseins are the proteins responsible for making curds, while the whey remains in an aqueous environment. The components of whey include:
Beta-lactoglobulin, alpha-lactalbumin, bovine serum albumin, lactoferrin, immunoglobulins, lactoperoxidase, enzymes, glycomacropeptides, lactose, and minerals. Today whey is a popular dietary protein supplement purported to provide antimicrobial activity, immune modulation, improved muscle strength and body composition, and prevention of cardiovascular disease and osteoporosis. Alt Med Rev. 2008 Dec; 4(13); 341-7

Whey Protein Constituents:

Whey protein contains all the essential amino acids in higher concentrations than vegetable protein sources. They are efficiently absorbed and utilized relative to free amino acid solutions.
Whey proteins have a high concentration of Branched chain amino acids (BCAA): isoleucine, leucine, valine, which are important factors in tissue growth and repair. Whey proteins are also rich in the sulfur-containing amino acids cysteine and methionine, which enhance immune function through intracellular conversion to glutathione, one of the most important antioxidants in the cell. Crit Food RevSci Nutr 2002;42: 353-75

Mechanisms of Action:

Whey has potent antioxidant activity, likely by contributing cysteine-rich proteins that aid in the synthesis of glutathione (GSH), a potent intracellular antioxidant. Crit Food Rev Sci Nutr 2002;42: 353-75

Detoxification:

Practitioners use whey protein as a source of cystein to increase intracellular glutathione levels. As a detoxifying agent, glutathione peroxidase (GSHPx), which is derived from selenium and cysteine, is an endogenous antioxidant enzyme that converts lipid peroxides into less harmful hydroxy acids. In addition to the above mentioned properties, the alpha-lactalbumin component of whey chelates heavy metals and reduces oxidative stress because of its iron chelating properties. Toxicology 1999; 137:169-184 and J Nutr Biochem 2003: 14:251-8

Immune enhancement:

An *in vitro* study demonstrated that bovine-milk derived IgG suppresses human lymphocyte proliferative response to T cells and conclude that it is likely to confer immunity that could be carried to humans. Int Arch Allergy Appl Immuno 1993:4:231-9

Alpha-lactalbumin also has direct effect on B-lymphocyte function, as well as suppressing T-cell dependent and independent responses. J Nutr 1985;114:1403-8

Clinical indications:

Whey's amino acid profile makes it useful for enhancing body composition, supporting protein synthesis and building lean body mass. For these reasons it has been used in patients with diabetes, obesity, cardiovascular disease, to support pediatric bowel health, and to improve glutathione levels

in individuals infected with HIV and in cancer. Alt Med Rev. 2008 Dec; 4(13); 341-7

- Whey protein concentrates have been researched extensively with respect to cancer prevention and treatment, and glutathione stimulation is thought to be the primary immune-modulating mechanism. Alt Med Rev. 2008 Dec; 4(13); 341-7

- The amino acid precursors to glutathione in why might increase glutathione levels in tissues, stimulate immunity and detoxify potential carcinogens. Anticancer Res 2000; 20:4785-92
- Several animal studies have been assessed the effect whey's immune enhancing components, especially lactoferrin and beta-lactoglobulin. In an animal model of colon cancer, animals given whey components demonstrated significantly lower incidence of tumors and fewer aberrant crypts. Cancer Epidemiol Biomarkers Prev 2000;9: 113-7 Cancer Epidemiol Biomarkers Prev 2001: 10:555-8 Jpn J Cancer Res 1997: 88:523-6
- Fractionated whey had the ability to reduce oral mucositis in hamsters via induction of TGF-beta. Oral Oncol 2002; 38: 478-85

Side Effects and Toxicity:

- Individuals with known allergy to milk may not tolerate why, but many dairy sensitive individuals find that casein is the culprit and not whey, especially if it is hydrolyzed and therefore less allergenic. Most whey proteins have been processed to remove lactose and so those who are lactose intolerant may tolerate hydrolyzed whey protein. Alt Med Rev. 2008 Dec; 4(13); 341-7

SCIENTIFIC NAME: ASTRAGALUS MEMBRANACEUS (FABACEAE)

Common name: Yellow root, huang qi (pin yin)

Historical use: Astragalus has been used in Traditional Chinese Medicine for thousands of years as an immune stimulant and qi tonic (adaptogen).

Clinical Summary: Astragalus has been used to support and enhance immune function and is still widely used in China and by acupuncturists for chronic immune conditions like chronic hepatitis and as an adjunctive therapy in cancer. Astragalus extracts have been shown to possess cytostatic properties, inhibit tumor growth and in vitro, animal and anecdotal human data show that astragalus reduces immune suppression resulting from chemotherapy. Astragalus-based herb formulas may enhace the effect of platinum-based chemotherapy. http://www.mskcc.org/mskcc/html/69128.cfm

Biochemically active constituents and known mechanisms of action:

To date, 38 biologically active constituents of Astragalus membranaceus have been isolated. The most biologically active compounds in Astragalus are the triterpene saponins (astragalosides I-X), polysaccharides and isoflavones.

- Because Astragalus memebranaceus is used as immunomodulating agent in treating immunodeficiency diseases and to alleviate the adverse effects of chemotherapeutic drugs, the anti-carcinogenic effects of Astragalus saponin extract were investigated in HT-29 human colon cancer cells and tumor xenograft. Our findings have shown that Astragalus saponins (AST):
    - inhibits cell proliferation through accumulation in S phase and G2/M arrest, with concomitant suppression of p21 expression and inhibition of cyclin-dependent kinase activity.
    - promotes apoptosis in HT-29 cells through caspase 3 activation and poly(ADP-ribose) polymerase cleavage, which is indicated by DNA fragmentation and nuclear chromatin condensation.
    - demonstrates an anti-tumorigenic effects in vivo, of which the reduction of tumor volume as well as pro-apoptotic and anti-proliferative effects in HT-29 nude mice xenograft are comparable with that produced by the conventional chemotherapeutic drug 5-fluorouracil (5-FU).
    - reduced the side effects (body weight drop and mortality) associated with the drug combo 5-FU and oxaliplatin are not induced by AST.
    - These results indicate that AST could be an effective chemotherapeutic agent in colon cancer treatment, which might also be used as an adjuvant in combination with other orthodox chemotherapeutic drugs to reduce the side effects of the latter compounds. Carcinogenesis 2007 28(6):1347-1355; doi:10.1093/carcin/bgl238

- A partially purified fraction (F3) with an estimated molecular weight of 20,000 to 25,000 derived from the traditional Chinese medicinal herb Astragalus membranaceus, was found to possess a potent immunorestorative activity in vitro.

These data indicate that F3 administration markedly enhances the rats' ability to reject the xenogeneic graft and therefore possesses a strong immune potentiating activity in vivo. These preclinical data also provide the rational basis for the use of extracts of Astragalus membranaceus in phase I clinical trials among patients suffering from iatrogenic or inherent immune deficiency states. J Clin Lab Immunol. 1988 Mar;25(3):125-9.

- Meta-analysis: Astragalus has been shown to have immunologic benefits by stimulating macrophage and natural killer cell activity and inhibiting T-helper cell type 2 cytokines. Many published studies have assessed the use of Astragalus and other Chinese herbal medicines in combination with chemotherapy. We sought to evaluate evidence from randomized trials that Astragalus-based Chinese herbal medicine combined with platinum-based chemotherapy (versus platinum-based chemotherapy alone) improves survival, increases tumor response, improves performance status, or reduces chemotherapy toxicity.
  Results: Of 1,305 potentially relevant publications, 34 randomized studies representing 2,815 patients met inclusion criteria. Twelve studies (n = 940 patients) reported reduced risk of death at 12 months (risk ratio [RR] = 0.67; 95% CI, 0.52 to 0.87). Thirty studies (n = 2,472) reported improved tumor response data (RR = 1.34; 95% CI, 1.24 to 1.46). In subgroup analyses, Jin Fu Kang in two studies (n = 221 patients) reduced risk of death at 24 months (RR = 0.58; 95% CI, 0.49 to 0.68) and in three studies (n = 411) increased tumor response (RR = 1.76; 95% CI, 1.23 to 2.53). Ai Di injection (four studies; n = 257) stabilized or improved Karnofsky performance status (RR = 1.28; 95% CI, 1.12 to 1.46).
  Conclusion: Astragalus-based Chinese herbal medicine may increase effectiveness of platinum-based chemotherapy when combined with chemotherapy. These results require confirmation with rigorously controlled trials.
  Journal of Clinical Oncology, Vol 24, No 3 (January 20), 2006: pp. 419-430

Adverse reactions: none known

Herb/Drug Interactions:

- Immunosuppresants: Astragalus may antagonize the effects of immunosuppressants such as tacrolimus and cyclosporine.
- Aldesleukin: Concomitant treatment with astragalus has resulted in a 10-fold potentiation of tumor-cidal activity with decreased side effects.
- Cyclophosphamide: Astragalus may decrease immunosuppression following treatment.

http://www.mskcc.org/mskcc/html/69128.cfm (1) (14) (15)

SCIENTIFIC NAME: CAMELLIA SINENSIS (Theaceae)

Common name: Green tea

Historical use: Green tea has been a preferred beverage throughout Asia for millennia. It has a small amount of theophylline that provides a slight stimulatory effect. Its mild flavor allows it to be blended with other components (jasmine flowers) or toasted rice, soy or corn to create a variety of pleasant flavors.

Clinical Summary: Because green tea contains numerous polyphenols, it has potent antioxidant actions its use is associated with cardioprotective, neuroprotective and chemoprotective effects. It has been used to lower cholesterol, lipids, Epidemiologic studies show an inverse relationship between consumption of tea, especially green tea, and development of cancers. Numerous in vivo and in vitro studies indicate strong chemopreventive effects for green tea and its constituents against cancers of various organs.

Biochemically active constituent and proposed mechanisms of action:

The polyphenolic flavonoids are the major biologically active constituents: catechin, epicatechin, epicatechin gallate, epigallocatechin 3-gallate (EGCG), sinecatechin, and proanthocyanadins.

Recent studies demonstrate the following clinical outcomes:

- Epigallocatechin 3-gallate (EGCG) is a well-known chemoprevention factor that triggers apoptosis in cells going through the p53 dependent pathway. Cancer Res 2008;68(11);4150-62

- EGCG and EGC are capable of altering AhR transcription and are responsible for most, if not all, of the AhR antagonist activity of GTE, thus offering an insight to how it prevents tobacco related carcinogenesis. Chem Res Toxicol. 2003;16(7);865-872
- ECGC inhibits the growth of human squamous carcinoma, breast carcinoma and colon carcinoma cells and is associated with rapid inhibition of activation of RTKs,EGRF, HERR2 and HER3 inhibition of activation or the expression of several downstream signaling molecules involved in cell proliferation and survival. Therefore, ECGC or Poly E may be useful when used alone or in combination with other agents in the prevention and treatment of colon and other types of human cancer. AACR Conf Front Canc Res Prevent. Nov 12-15, 2006
- ECGC inhibits cancer cell growth through the inhibition of IGF-1and VEGF receptors, inhibits the Ras/MAPK and P13K/Akt signaling pathways, thereby modulating the expression of target genes, which are associated with induction of apoptosis and cell cycle arrest in cancer cells. Int. J. Mol. Sci. 2008, Volume 9(6), Page 1034-1049

Adverse reactions: Nausea and GI upset have been reported

Herb/Drug Interactions: theoretically, large amounts of green tea may inhibit Vitamin K absorption, thus antagonizing the effects of anticoagulants; may reduce absorption of atropine; may reduce bioavailability of iron and codeine.

http://www.mskcc.org/mskcc/html/69247.cfm

SCIENTIFIC NAME: ELEUTHEROCOCCUS SENTICOSUS (Araliaceae):

Common Names: Siberian ginseng, Eleuthero ginseng, Ci Wu Jia (pin yin); Acanthopanax senticosus

Historical use: Eleutherococcus senticosus has been used for thousands of years in the Traditional Chinese Materia Medica as a kidney tonic to increase longevity, improve general health and appetite. In 1958, the Russian scientist Brekhman coined the term "adaptogen" as a substances that 1) must be innocuous and cause minimal disorders in the physiological functions of an organism, 2) must have a non-specific action (i.e., it

should increase the resistance to adverse influences by a wide range of physical, chemical and biochemical factors), and 3) usually has a normalizing action irrespective of the direction of the pathological state (alterative action). The Healing Power of Herbs, Murray; Three Rivers Press, New York, 1995, pp.315-20)

Farnsworth and colleagues reviewed data on an Eleutherococcus senticosus root extract administered to over 2,100 human subjects to assess the adaptogenic effects of ginseng and concluded that it:

1. Increased ability of humans to withstand adverse physical conditions (heat, noise, motion, workload increase, exercise and decompression), and
2. Increase mental alertness and work output, and
3. Improved quality of work produced under stressful conditions, and athletic performance.

Farnsworth and colleagues reviewed data on an Eleutherococcus senticosus root extract administered to over 2,200 human subjects to assess its adaptogenic effect in disease states and concluded that it appears to be effective in:

1. Atherosclerotic conditions in that it can lower serum cholesterol levels, reduce blood pressure and eliminate angina symptoms in human subjects;
2. Improving kidney function and regulating blood pressure in patients with acute kidney infection
3. Improved sense of well-being of psychological complaints (insomnia, hypochondriasis, neuroses) possibly through regulation of biogenic amine content in the brain.

Economic and Medical Plant Research 1, 156-215, Farnsworth, 1985
The Healing Power of Herbs, Murray; Three Rivers Press, New York, 1995, pp.315-20)

Biologically active constituents and proposed mechanisms of action:

To date, at least 51 biologically active constituents in Eleutherococcus have been identified (Dr. Duke's Phytochemical and Ethnobotanical Database) accessed 1/09. The main active constituents are the eleutherosides, though very little current research is available. Below are some of the highlights:

- Eleutherococcus senticosus demonstrated immunomodulatory properties (enhanced

the cellular response of the mouse immunological system (chemokinetic activity of mice spleen cells, GvH reaction), as well as a stimulatory effect of Eleutherococcus on the humoral response (antibody production) in mice. Pol Journal Vet Science 2003;6(3 Suppl):37-9.

- Eleutherococcus senticosus, as part of a formula (AdMax) was evaluated for its effect on ovarian cancer patients. In patients who took AdMax, the mean numbers of 4 T cell subclasses were increased, the mean amounts of IgG andIgM were incrased and the results suggest that the combination of extracts from adaptogenic plants may boost the suppressed immunity in ovarian cancer patients who are subject to chemotherapy. Phytotherapy Res. 2006 May; 20(5): 424-5

- Standardized extracts of Eleutherococcus senticosus at generally recommended doses for over-the-counter use are unlikely to alter the disposition of co-administered medications primarily dependent of CY2D6 or CYP3A4 pathways for elimination. Drug Metab Disp. 2003 5(31): 519-22

- Eleutherococcus senticosus extract was applied to cells in culture resulting in a slight radioprotective effect. American Journal Chinese Medicine. 1981 (9) 48-56

- Eleutherococcus senticosus provided anti-proliferative effects against L1210 murine leukemia cells and suggests that it may be useful for reducing the concentration of conventional anti-metabolites used for their anti-proliferative effects on tumor cells. Journal Pharmacological Science. 1984 Feb; 73(2): 270-2

- Eleutherococcus senticosus aqueous extract of eleutheroside E may have contributed to the anti-fatigue action, recovery of the reduction of NK activity and inhibition of corticosterone elevation induced by swimming stress. Journal of Ethnopharmacology. 2004 Dec;95(203):447-53

Clinical summary: Although initial reports from the Soviet Union and reviews of that literature by Farnsworth suggested therapeutic value of Eleutherococcus senticosus as an adaptogen, very little current research has been done to substantiate those findings. It is now being recommended that the term "adaptogen" be discontinued and further research

be done on this plant to confirm potential therapeutic value in these areas: Anti-oxidant, anti-cancer, immunostimulatory, anti-inflammatory, hypocholesterolemic, cholorectic, anti-pyretic and anti-bacterial actions.

Journal of Ethnopharmacology. 2004 Dec;95(203):447-53

Adverse effects: toxicity studies in animals demonstrated that 33% ethanol extract of E. senticosus is virtually non-toxic; it is very well-tolerated in humans and side-effects are quite minimal; very high doses may produce insomnia, irritability, melancholy and anxiety. Economic and Medical Plant Research 1, 156-215. Farnsworth, 1985The Healing Power of Herbs, Murray; Three Rivers Press, New York, 1995, pp.315-20)

Herb/drug interactions: none discovered

D. "BioShark"

History of use: In 1971, Judah Folkman, MD published his work on angiogenesis and cancer in the New England Journal of Medicine. Robert Langer, PhD at MIT followed with the observation that bovine cartilage could inhibit neovascularization of solid tumors. Dr. John Prudden demonstrated that bovine cartilage could inhibit the in vitro growth of osteosarcoma and human myeloma cultured cells. Dr. Prudden developed Catrix, a bovine tracheal cartilage, and began treating end-stage cancer patients in 1972. This therapy exerted a major inhibitory effect on a variety of cancers but did not eliminate them completely. In 1983, Langer began work comparing shark cartilage to bovine cartilage, reporting the same amount of shark cartilage contained 1000 times the quantity of anti-angiogenic factor as did bovine cartilage.

Initial studies in mice by William Lane, PhD showed dramatic results of a decrease in tumor weight of 40% in the treated animals compared to a 2.5 fold increase in tumor weight of the untreated group. Dr. Lane outlined a case report of 8 humans in stage III and IV cancer utilizing 30 grams/day of shark cartilage taken as enemas, which produced very encouraging results. A human clinical trial of 29 patients suffering from stage IV and V cancers that had failed conventional therapies was begun. At the end of 16 weeks

of rectal enemas at a dose of one gram of powdered shark cartilage per 2 pounds of body weight, some patients had marked reduction in tumor size and reduced vascularization of the tumor tissue and tissue adjacent to the tumor. Many patients reported a reduction in pain and an improved sense of well-being.
Townsend Letter for Doctors: Review article Aug/Sept. 1994

In 1994, a Phase 2 human clinical controlled trial was sanctioned by the FDA and conducted by Dennis Miller, MD et al at Cancer Treatment Centers of America. The results of this 60 patient study concluded that under the specific conditions of this study, shark cartilage as a single agent was inactive in patients with advanced-stage cancer and had no salutary effect on the quality of life. J Clin Oncol. 1998 Nov;16(11):3649-55.

The challenge with this and other human clinical trials in cancer patients is that the only candidates for therapy are those who are end-stage and have failed conventional treatments. This obviously eliminates candidates who have a strong and functional immune system.

In 2008, researchers isolated two partially purified anti-angiogenesis proteins from shark cartilage that were demonstrated to block microvessel sprouting in the collagen-embedded rat aortic ring assay in vitro and inhibition of capillary sprouting in the CAM assay in vivo. Bioscience Reports (2008) 28, (15–21)

Cartilage in general, and shark cartilage in particular, have demonstrated inhibition of angiogenesis in cell cultures and animal studies. The shark cartilage that has been used in most studies was a highly purified protein derivative. The particularly high doses used, distinct fishy flavor and difficulty with routes of administration present unique challenges with this therapy in humans.

VI. SUMMARY AND CONCLUSIONS

Based on my experience and expertise, as well as the research cited above, I hold the following opinions:

A. There is a reasonable basis to claim that the ingredients of GDU contain bromelain, a source of natural proteolytic enzymes from the pineapple, which helps digest unwanted proteins. GDU also contains turmeric, feverfew and quercitin, which help to reduce inflammation and relieve pain. Next, it is reasonable to claim that these ingredients as a whole may be used as an adjunct to cancer therapy, and that the ingredients possess a wide range of actions as anti-inflammatory agents.

B. There is a reasonable basis to claim that the ingredients of 7 Herb Formula fight tumor formation, and fight pathogenic bacteria.

C. There is a reasonable basis to claim that the ingredients of BioMixx boost the immune system, build lean body mass and support healing. It is also reasonable to claim that these ingredients assist the body in fighting cancer, cachexia and in healing the destructive effects of radiation and chemotherapy treatments."

D. There is a reasonable basis for the claims that pure skeletal tissue of sharks provides a protein that inhibits angiogenesis – the formation of new blood vessels. It is also reasonable to claim that angiogenesis has been demonstrated to inhibit tumor growth in some studies.

February 4, 2009

Sally LaMont ND, LAc

Sally LaMont, N.D. L.Ac.

Exhibit G

REPORT OF EXPERT WITNESS JAMES DUKE
James A. Duke, PhD, Botany
Economic Botanist, US Department of Agriculture (retired)
In the Matter of Daniel Chapter One
FTC Docket #9329

I. QUALIFICATIONS

See attached CV.

II. SCOPE OF WORK

Review and offer opinion supported by evidence and experience on the ingredients of the challenged products; to review the science of herbal efficacy; and to clarify the complex nature of herbal science versus the relatively simple science of pharmaceuticals.

Compensation: $350.00 per hour or $2500.00 per day, plus expenses

Prior Expert Testimony: No expert testimony in the last four years.

III. MATERIALS CONSIDERED

A. James Duke Biblical Publications:

Duke, JA. 1983. *Medicinal Plants of the Bible*. Conch Publications. NY. 233 pp.

Duke, JA. 1999. *Herbs of the Bible: 2,000 Years of Plant Healing*. Interweave Press, Loveland, CO. 256 pp.

Duke, JA. 1999. *Herbs of the Bible: 2,000 Years of Plant Healing*. Interweave Press, Loveland, CO. 256 pp. Reprinted Whitman Publications, Duke, Jim. 2000. Herbs of the Bible. *New Living* (June), p. 7.

Duke, JA. 2000. PARACELSUS: Wild Lettuce: A Bitter Herb of Biblical Proportions. *J. Med. Food* 3(3):153-4.

Duke, JA. 2002. Food Farmacy Forum. Some Biblical Herbs. *The Wild Foods Forum* 13(1):8-9.

Duke, JA. 2006. Food Farmacy: Biblical Herbs vs. Pharmaceuticals (Keynote), pp. 51-52 in Medicines from the Earth 2006. (Jun 2-Jun 6, 2006). Official Proceedings Gaia Herbal Research Institute. Brevard NC. 199 pp.

Duke, JA, duCellier, J, and Duke, PA. 2008. *Duke's Handbook of Medicinal Plants of the Bible*. CRC Press, Boca Raton, FL.

Duke, J. A. 1983. *Medicinal Plants of the Bible*. 233 pp. TradoMedic Books, Buffalo, NY. Treats over 100 Biblical species, with illustrations mostly by Peggy K. Duke. Apparently out of print.

Duke, J.A. 1999. *Herbs of the Bible - 2000 Years of Plant Medicine*. Interweave Press, Loveland CO. 241 pp.. $34.95. ISBN 1-883010-66-7

B. Other James Duke Herbal Publications:

Duke, J. A. 1997. *The Green Pharmacy*. Rodale Press, Emmaus, PA 18098-0099. 507 pp. ISBN 0-87596-316--1(hardcover)ISBN-57954-124-0 (paperback)

Duke, J. A. 1999. *Dr. Duke's Essential Herbs* (13 Vital Herbs You Need to Disease-proof your Body - Boost your energy - Lengthen your Life). Rodale Press. Emmaus, PA 18098. 240 pp. $24.95 ISBN- 1-57954-183-6 (Hard Cover)

Duke, J. A. 2000. *The Green Pharmacy Herbal Handbook*. Rodale Press. 282 pp. $19.95 ISBN- 1-57954-184-4

Duke, J. A. 2001. With Michael Castleman. The Green Pharmacy Antiaging Prescriptions - Herbs, Foods, and Natural Formulas to Keep you Young. Rodale Press, 560 pages. Emaus, Pa. $29.95. ISBN 1-57954-198-4(Hardcover)

Duke, JA, Bogenschutz-Godwin, MJ, DuCellier, J and Duke, PA. 2002. *CRC Handbook of Medicinal Plants*. 2nd. Ed. CRC Press, Boca Raton, FL. 936 pp

Duke, JA, Bogenschutz-Godwin, MJ, DuCellier, J and Duke, PA. 2002. *CRC Handbook of Medicinal Spices*. CRC Press, Boca Raton, FL. 348 pp. $119.95. ISBN-0-8493-1279-5

Phytochemical Database: http://www.ars-grin.gov/duke

The Green Pharmacy at: http://www.mothernature.com/Library/Bookshelf/index.cfm

C. See Appendix I for additional materials relied on.

IV. SUMMARY OF OPINION

1. There is a reasonable basis for the claims that the ingredients of 7 Herb Formula "..., fights tumor formation, and fights pathogenic bacteria."

2. There is a reasonable basis for the claims that the ingredients of GDU "contains natural proteolytic enzymes (from pineapple source bromelain) to help digest protein -- even that of unwanted tumors and cysts. This formula also helps to relieve pain and heal inflammation. . GDU is also used for. . .and as an adjunct to cancer therapy. GDU possesses a wide range of actions including anti-inflammatory and antispasmodic activity. . ."

3. There is a reasonable basis for the claims that the ingredients of BioMixx "boosts the immune system, ...to allow for natural healing. It is used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatments."

V. ANALYSIS AND FINDINGS

I base my conclusions, from my experience and knowledge, on three analytical points:

First, herbal based and nutritional food information can be drawn from the Bible.

Second, herbs, including those from the Bible provide help to the health of people that can be as good as or superior to help provided by pharmaceuticals.

Third, significant science, as set out below, supports herbal use, and a system – which I call a third arm to a standard pharmaceutical study—could establish the value of herbs to the scientific gold standard urged by conventional science.. Without an approach like the third arm approach, it will never be possible to find sufficient resources to run classical pharmaceutical studies on whole herbs, let alone to evaluate the hundreds of single chemical entities in each herb.

In the meantime the public should not be denied access to the information available that certain herbs have credible evidence that they contribute to healing, even for conditions such as cancer. In the absence of resources for massive studies we have to rely on the less expensive science set out below.

1. The Science of Herbs:

I begin with the third point first. Here are three ways I use to establish the efficacy of an herb: one is the Multiple Activities Menu's (MAM's), the second is Indications Evaluations (IE's), and the third is 60 abstracts in PubMed. I am only presenting ways one and two here.

A. The MAM is a listing, recognized worldwide, which I have created and maintained for over 20 years on the United States Department of Agriculture (USDA) website. Information is put into the website about the relationship between an herb and a condition.—in this case cancer. Then the information is drawn out for a review of the current scientific status of the herb in question.

The following are Multiple Activities Menu's (MAM's) for 16 DCO herbs and their relation to cancer as recorded in the USDA website. These can be done online at my USDA website.

DANIEL CHAPTER ONE HERBS MAM's:

MAM: *Actaea (Cimicifuga) racemosa* (Black cohosh) for Cancer (15/14=1.07)
MAM: *Allium sativum* (Garlic) for Cancer (347/147=2.36)
MAM: *Ananas comosus* (Pineapple) for Cancer (73/79=0.92)
MAM: *Arctium lappa* (Burdock) for Cancer (98/61=1.61)
MAM: *Astragalus membranaceus* (Huang qi) for Cancer (110/26=4.23)
MAM: *Camellia sinensis* (Green Tea) for Cancer (483/457=1.06)
MAM: *Curcuma longa* (Turmeric) for Cancer (213/66=3.28)
MAM: *Eleutherococcus senticosus* (Eleuthero) for Cancer (163/43=3.79)
MAM: *Glycine max* (Soybean) for Cancer (483/457=1.06
MAM: *Nasturtium officinale* (Watercress) for Cancer (3/5=0.6)

MAM: *Rheum palmatum* (Chinese Rhubarb) for Cancer (85/21=4.05)
MAM: *Rumex acetosella* (Sheep sorrel) for Cancer (11/27=0.41)
MAM: *Smilax sarsaparilla* (Sarsparilla) for Cancer (0/13=0)
MAM: *Tanacetum parthenium* (Feverfew) for Cancer (88/19=4.63)
MAM: *Ulmus rubra* (Slippery Elm) for Cancer (4/17=0.24)
MAM: *Uncaria tomentosa* (Cat's Claw) for Cancer (79/31=2.55)

The number on the right hand side of the "/" is the number of cancer affecting aspects of the herb being evaluated.

See Appendix II for detailed presentation of the MAM's for DCO herbs, such as the following one for Turmeric, presented as an example. (Turmeric, one of the 16 DCO herbs, would certainly be in my meals were I subject to cancer, and I am genetically targeted for colon cancer. Turmeric's curcumin is probably better than Celebrex, which like other synthetic COX-2-I's was once touted off-label for the prevention of colon cancer. There are 66 indications of Turmeric affecting cancer in this MAM. Some are bolded.)

Curcuma longa (Turmeric)
(One of the top 5 medicinal spices, with some anticancer activities, proven to my satisfaction)

INDICATIONS (TURMERIC): Abscess (f1; FNF; TRA); `Achlorohydria (1; KHA); `Adenocarcinoma (1; `HOS; MES); Adenoma (1; `HOS; MES; X7954412); Adenopathy (1; DAD; JLH; X16737669 X7954412); `Alcoholism (1; `TEU; X16691314); Allergy (f1; TUR; WAM; X17569221); X17211725); Alzheimer's (1; COX; FNF); Amenorrhea (f1; BGB; PH2; `TEU; WHO); `Anemia (f; TUR); **Anorexia (f12;** BGB; BIB; BRU; PHR; PH2; TUR; X17569218); Arthrosis (f1; COX; KAP; MAB; WAM; WHO; X16781571); Asthma (f1; FAJ; MAB; TUR; WHO; `X17569221); X17211725); Atherosclerosis (1; MAB; SKY; VAD; JMF8:246; `X18602074; X17211725); Athlete's Foot (1; FAJ; FNF); `Atony (f; DEP); \Bacillus (1; X10552805); \Bacteria (1; X10552805); `Biliouness (f1; KAB; TUR; VAD); Bite (f; BIB; `DEP; PH2); Bleeding (f; PH2); Boils (f1; DAD; WHO); \Bowen's Disease (1; X11712783); Bronchosis (f; BIB; `DEP; PH2); Bruise (f; DAV; `DEP; IHB; PED; PH2; TUR; WHO); `Burlitt's Lymphoma (1; X18852135); Bursitis (1; SKY); Cancer (f1; JLH; MAB; X17211725); **Cancer, abdomen (1; COX; FNF; JLH); \Cancer, bladder (f1; X18342436; X16596191; X11712783); Cancer, breast (f1; COX; FNF; MAB; MES; TUR; `X19138983; X17448598; X16781571); \Cancer, cervix (f1; TUR; X17448598;**

X11712783); Cancer, colon (f1; COX; FNF; JLH; JNU; MES; `X X18794115; X18423603; 17448598; X17201158; X17044774; X16820928; X16781571; X16737669; X16712454); Cancer, duodenum (f1; `TEU; X7954412); `Cancer, epithelium (1; X17448598); \Cancer, esophagus (f1; JAC7:405; `TEU; TUR); `Cancer, intestine (f1; JLH; `TEU; TUR); Cancer, joint (f1; JLH; MAB); Cancer, kidney (f1; JLH; TUR); \Cancer, liver (f1; `TEU; JAC7:405); \Cancer, lung (f1; TUR; X16521985); Cancer, mouth (f1; COX; FNF; JLH; TUR; `X 17448598;); Cancer, nose (f1; COX; FNF; JLH); Cancer, ovary (f1; JLH; X17174384; X163765850); `Cancer, pancreas (1;18347134 `X 17448598; X17440100) Cancer, prostate (f1; JLH; MES; TUR; `X 17448598; X17332930); Cancer, rectum (1; X17044774); Cancer, sinew (f1; COX; FNF; JLH); \Cancer, skin (f1; MES; `TEU; X16781571 X16712454; X7954412); \Cancer, stomach (f1; TUR; JAC7:405; X17448598; X16712454); \Cancer, uterus (f1; `TEU; X11712783);` Candida (f1; TUR); `Carcinoma (1; TUR); Cardiopathy (f1; AKT; MAB; TUR; `X15622377; `X19153099); Cataracts (f1; MAB; `TEU); Catarrh(f; `DEP; UPW); `Cerebrosis (1; `TEU); `Cervical Dysplasia (1; WAF); Chestache (f; PH2); `Chickenpox (f; TUR); Childbirth (f; DAD); **Cholecocystosis (12;** APA; KOM; PHR; SHT; TUR; VAD; WHO; `JAF51:6802); `Cholera (f; SKJ); \Circulosis (f; BOW); Cold (f; `DEP; KAP; NPM; PH2); Colic (f; APA; PED; PH2; TUR); `Colitis (1; X17429738; X17276891 ); Coma (f; DAD); Congestion (f; APA; BIB;`DEP); Conjunctivosis (f; KAB; MAB; PH2; SKJ; SUW; `TEU), Constipation (f; PH2; `X18484280;); `Convulsion (f; IHB); `COPD (1; X17569221) Coryza (f; `DEP; KAB); `Cough (f; NPM); Cramp (f1; AKT; BIB; DAD); `Crohn's (1; X16387689);`Cystic Fibrosis (1; X16239599); Cystosis (f; PH2); `Depression (f 1; X18420184;` X17955367; X16504000; X17134862; X17022948; X16651723; X16171853); `Dermatomycosis (1; `TEU); Dermatosis (f1; AKT; `DEP; MAB; PH2; SUW; `TEU; WHO; WOI; `X18484280; ); \Diabetes (f1; BOW; JMF8:251; `X18484280; X17226069); Diarrhea (f1; APA; `DEP; IHB; WHO; `X18484280;); `Dipsomania (1; (X16691314); Dropsy (f; DAD); Duodenosis (1; X7954412); `Dysentery (f; IHB); Dysgeusia (f; `HOS; KAB); `Dyskinesia (f`1; VAD; X18022680 ); `Dyslactea (f; SKJ); Dysmenorrhea (f1; AKT; APA; DLZ; FAJ; PED; WHO; 17569218); **Dyspepsia (f12;** KOM; MAB; PH2; SKJ; WHO; `X18484280); Dysuria (f; ADP; DAD); `EBV (1; `HOS; TUR); Eczema (f1; BGB; FAJ; KAP; MAB; `TEU); Edema (f1; KAP; PH2; `TEU); Elephantiasis (f; DAD); `Embolism (X18611416; X18826584)`Encephalomyelitis (1; TUR); Enterosis (f1; AKT; DAD; PH2; `TEU; WHO); Epilepsy (f; WHO; X16028990); Epistaxis (f; DAD; PH2); `Epithelioma (1; X17448598); `Escherichia (1; TUR); \Esophagosis (1; JAC7:405); Fever (f1; APA; BIB;`DEP; COX; `TEU; TUR); Fibrosis (1; BGB; MAB; X17569221; X19152370); `Fistula (f; SKJ);`Fit (f; DEP); Fungus (f; BIB; PH2); Gallstones (f1; APA; MAB; `TEU); Gas (f1; APA; IHB; PH2; TUR); Gastrosis (f1; PH2; VAD); `Gingivosis (1; X18929638); Glioma (1; X17562168 ;X17395690); Gonorrhea (f; BIB; KAB); Grey Hair (f; HAD); \Fungus (1; LIB); Headache (f; PH2); `Helicobacter (1; TUR); `Heartburn (f; TUR); Hematemesis (f; DAD; PH2); Hematuria (f; DAD); Hemorrhage (f; PED); Hemorrhoid (f; FAJ; MAB); **Hepatosis (f12;** AKT; APA; DAD; DEP; `HOS; MAB; MD2; PED; PHR; PH2; PNC;`TEU; TRA; `X19152370; `X19069843 ; `X18484280; X17569218`X16691314); `Herpes (f; EGG); High Blood Pressure (1; KAP; MAM); High Cholesterol (1; AKT; APA; KHA; MAB; TRA; VAD; JMF8:246); High

Triglycerides (1; KHA; MAB; TRA); `HIV (1; `HOS); `Hyperacidity (f; ADP); `Hyperemesis (f; `TEU); `Hyperhomocysteinemia (1; X15622377); `Hyperkinesi`s (1; X18022680); **Hyperlipidemia (12;** MAB; PHR; JMF8:256); `Hypoacidity (1; KHA); `Hypothermia (f; SKJ); Hysteria (f; DAD; `DEP); `IBD (1; TUR; X17569223); IBS (1; PED); **Infection (f12;** MAB; MPI; PH2); **Inflammation (f12;** APA; `DEP; `HOS; KOM; PHR; PH2; `TEU; TRA; WAM; WHO); `Ischemic (1; X17955367 ;X16504000); Itch (f; APA; KAP; PH2; TUR); Jaundice (f1; `ADP; DEP; MAB; `TEU; TRA; TUR; X17569218); Laryngitis (f1; BIB; COX); \Leishman`ia (1; `TEU; X10865470); Leprosy (f; PH2; TUR); Leukemia (f1; AKT; `HOS; TUR; X18396784; X17448598; X17201156; X16521985; X16364242); Leukoderma (f; DAD; `X18484280); \Leukoplakia (1; X11712783); Lichen Planus (f; X17604143); Lymphoma (1; BIB; COX; `HOS; X17182546); Malaria (f; KAB;KAP; PH2; WOI; `X18484280); `Measles (f; TUR); `Melanoma (1; `HOS; TUR); `Metastasis (1; `HOS); Morning Sickness (f1; FAJ; MAB); Mucososis (f; PH2; TUR); `Multiple Sclerosis (1; X17569223); `Mycobacteria (1; TUR); Mycosis (f1; `DEP; FAJ;PH2; X8824742); `Multiple Sclerosis (1; X17569223); `Mycobacteria (1; TUR); Mycosis (f1; `DEP; FAJ;PH2; X8824742); `Myelodysplasty(1; `X18324353) `Myeloma (1; `X18324353 ; X17404048); `Nausea (1; `HOS); \Nematode (1; X8221978); \Nematode (1; X8221978); Nephrosis (f1; AKT; PH2; X17002671); `Nicotinism (1; (X16691314); `Nyctalopia (f; SKJ); Ophthalmia (f1; AKT; DAD; `DEP; IHB; PH2); Orbital Pseudotumor (1; PR14:443); **Osteoarthrosis (f12**; KHA; MAB; `TEU; X12723628); Osteoporosis (1; X17182546); `Otorrhea (f; DEP); Ozoena (f; KAB); Pain (f1; ADP;BIB; `DEP; COX; FAJ; `TEU; TUR; WHO; X16028990); Pancreatitis (1; TUR; X17900536); `Papilloma (1; `TEU;);Parasite (f; BIB; DAD; KAP LIB); `Parkinson's (1; X17900536); `Periodontosis (1; X18929638); \Plasmodicide (1; X10865470); Polyp (f1; COX; JLH; JNU; MES); `Proctosis (f; SKJ); `Pseudomonas (1; TUR); Psoriasis (1; FAJ; FNF; MAB; `TEU; `X18484280; `X17569223; X16387689); Puerperium (f; FAJ; MAB; `TEU); `Pulmonosis (1; X17569221); `Respirosis (1; X17569221); Radiation (1; AKT); Restenosis (1; MAB); Rheumatism (f1: BIB; COX; SKY; `TEU); Rhinosis (f1; COX; JLH); Ringworm (f; APA; BIB; `DEP; KAP; PH2); `Salmonella (1; TUR); `Sarcoma (1; `HOS); **Scabies (f12;** BGB; `DEP; KHA; TUR); `Schistosoma (1; `X19143127; X17948736; X 17907745); `Shock (1; TUR); `Sinusitis (f; ADP; TUR); Smallpox (f; DAD; TUR); `Snakebite (1; JAF51:6802); **Sore (f12;** KHA; PH2); Sore Throat (f; PH2); `Sortase-A-Inhibitor (1; X16277395);`Spasm (f; IHB); Sprain (f1; DEP; IHB; MAB; SUW); Staphylococcus (1; FAJ; MPI; TUR; UPW); `Sting (f; DEP); `Stomatosis (f; X17604143); Stone (f1; HHB; MAB); `Stress (1; `HOS; TUR; X17022948); Stroke (f`1; BOW; PH2; X18611416); Swelling (f1; AKT; COX; NPM; PH2; TUR); Syphilis (f; DAD); `Thalassemia (1; X17897073); `Thrombosis (f1; TUR; VAD; X18611416; X18826584); `Thrush (f1; TUR); `Tonsilosis (f; NPM); Trauma (f; AKT; X16028990); ``Tuberculosis (1; X15203565; X11591115); `Tumor (1; `HOS); Ulcer (f1; BIB; COX; FAJ; `HOS; PED; WHO; X16327153); `Unconsciousness (f; SKJ); **Uveosis (12;** AKT; `TEU; X18421073); VD (f; BIB; DAD); Vertigo (f; BIB; `DEP; DAD; FAJ); \Virus (1; `HOS; X10389986); Vomiting (f; PH2); Wart (f; JLH); Whitlow (f; JLH); \Worm (f1; `DEP; X8221978); Wound (f1; APA; BGB; IHB; PH2; SUW; WAM; `X18929638; `X18655004; X17900536; X16286372); Yeast (f1; PED; TUR).

B. Indications Evaluations (IE's) Summary: Review of Indications of 16 DCO Herbs. (See Appendix III for comparison of herb indications to pharmaceutical indications)

Actaea (Cimicifuga) racemosa (Black Cohosh). Widely sold and respected for menopausal difficulties.

*Allium sativum (Garlic): My most important herbal medicine, useful at preventing all the major killers and sepses.

Ananas comosus (Pineapple); Bromelain, the proteolytic enzyme, has many proven activities.

Arctium lappa (Burdock); Contains antilymphomic lignans.

Astragalus membranaceus (Huang Qi/ Yellow Root): Widely sold in America and China as an anticancer immunomodulator.

Camellia sinensis (Green Tea): Food farmacy item widely and scientifically promoted for many indications.

*Curcuma longa (Turmeric): One of the top 5 medicinal spices, with some anticancer activities, proven to my satisfaction.

Eleutherococcus senticosus (Eleuthero) Sold widely as an alternative to ginseng, adaptogenic tonic.

Glycine max (Soybean): Studied by the late Judah Folkman and widely sold as a food farmacy item, in part for its mix of antiangiogenic isoflavones and quercetin.

*Nasturtium officinale (Watercress): Like most crucifers (members of the Brassicaceae), this nutritious edible species is properly touted as a cancer preventive.

Rheum palmatum (Chinese Rhubarb); Sold as laxative and in Essiac formula, touted for cancer.

Rumex acetosella (Sheep sorrel) Sold in Essiac formula, touted for cancer.

Smilax aristolochiifolia (Sarsaparilla) Widely sold, e.g., for Lyme Disease; contains compounds which can be converted to hormones.

Tanacetum parthenium (Feverfew) I think it's about as good for migraine as pharmaceutical sumatriptan.

Ulmus rubra (Slippery Elm) Sold in Essiac formula, touted for cancer.

Uncaria tomentosa (Cat's Claw) Famed immunomodulator from Latin America; proofs possibly more promotional than scientific.

Half of the new pharmaceuticals will be relabeled (with stronger warnings) or partially or completely recalled within a decade. Meanwhile, more expensive pharmaceuticals will continue to cause many more deaths than are caused by the safe herbs we are led to believe are dangerous. They are not! Check the Bextra, Celebrex, and Vioxx, and, let me predict, soon-to-be-heard statin, stories (three close friends of mine, too old to be worried about cholesterol, have been hospitalized from statins) and head counts of iatrogenic fatalities. The Null Numbers: The total number of annual iatrogenic deaths in America is 783,936. (Null et al, 2003).

Remember, pharmaceuticals have been with us less than 150 years. If our ancestors left Africa via the Holy Land 2000 years ago (for faith-based literalists), or maybe a million years ago (for the less literal), then our genes, tracing back to our African/Holy Land ancestors, have had at least 10 times more temporal experience with Biblical herbs (e.g., cinnamon, coriander, garlic, grape, mint, milk thistle, myrrh, olive, onion, saffron, turmeric, and the like). Pharmaceuticals and synthetic food additives are relatively new to our genes. Our bodies have had thousands, perhaps millions, of years of evolutionary experience with the thousands of phytochemicals in these species. Our bodies may even require many of them. In many cases, by my educated guess, the body has evolved homeostatic mechanisms for maintaining homeostatic balances for these phytochemicals. Our bodies can sequester them from our dietary millieux if we need them, excreting them if we do not. We can prove this for simple elemental chemicals like selenium and zinc. I believe it is the case that homeostatic balancing activities exist for hundreds of many long-familiar dietary components. We just, as Congress, signed an RDA for choline in the last decade. The farther we get from our Paleolithic diet, and

(more importantly) the more synthetic pharmaceuticals and food additives we ingest, the more liable we are to suffer imbalances. It's not only food additives that hurt us; it is the subtractives as well. The subtractive phytochemicals are those important nutrients reduced or lost in food processing:

"Of the 12 micronutrients which were plentiful in the natural grain, including vitamins B1, B2, B3, B5, B6, folic acid, E and the minerals iron, zinc, copper, manganese and selenium, less than 30%, and in some cases less than 10%, have been retained in the wheat products we eat. (Levin, 1996)"

Restoring chemical balance may require getting back to basics, those primitive Paleolithic foods rich in phytonutrients. At the same time, we should reduce over-processed nutrient-poor junk foods, avoiding additives and even pharmaceuticals where possible and plausible. I'm not saying there is no place for pharmaceuticals. But I will say that in many cases there are balanced Biblical foods that are pharmacologically competitive with unbalancing pharmaceuticals, and these food farmaceuticals should be drugs of first resort, and the pharmaceuticals last resort.

And if you believe in me and my Biblical food farmaceutical shotgun more than you believe in your allopath and her/his expensive pharmaceutical silver bullets, there's a better chance that my natural approach will help you. Believing is half the cure. Can you believe in a company whose $2-billion-a-year drug was shown in JAMA (Journal of the American Medical Association) back in 2002 to be no better than placebo for major depression? Can you believe that now, three years later, that company still has the premier lead-off ad page for the JAMA, touting the $2-billion-a-year drug as so trusted, so reliable, so efficacious? I suspect you'd be better off with Biblical walnut oil and

Biblical saffron, nourishing AND medicating your body, attenuating the depression with few or no consequential side effects. If you count all the possible side effects reported in the fine print of that ad for the $2-billion-a-year pharmaceutical, there are more than a hundred.

When that study was printed back in 2002 showing the pharmaceutical no better than placebo, almost nobody heard that the drug failed too. The news was instead blaring out "St. Johnswort no better than placebo." True, St. Johnswort (SJW) fared no better than placebo in this clinical comparison of SJW, Zoloft, and placebo. But that's the half of the story that Joan Q. Public heard a thousand times, while maybe once or twice hearing that the pharmaceutical failed too. Do I think there is a pharmaceutical/ PhDA/press conspiracy? I will say that they are all singing the same song, and the song is wrong, and is hurting Americans. Their monotonous song drives American consumers from the safer food, herb and spice farmaceuticals to the more expensive, more dangerous synthetic pharmaceuticals. All this at the expense of our health and the health of our planet. Even our rivers and lakes, and consequently our water supply, are now cocktails of pharmaceutical residues.

2. Some Biblical Herbs and Spices: Potential Alternatives to Pharmaceuticals

The following is a partial list (for more examples see Appendix IV) of long-known plants that by some definitions might be considered spices or culinary herbs. I also list here a disease or malady in which they have shown some promise, and a competitive pharmaceutical for that disease. I am campaigning for a third arm mandate, empowering a comparison of a third, herbal, arm with the pharmaceutical in any new clinical trials. Until such clinical trials, we don't really know that the pharmaceutical is

best. . The herb is almost always safer and cheaper. Pharmaceuticals and/or iatrogenesis (medically-caused adverse effects) related to conventional treatments kill 100,000 to 740,000 Americans a year, according to some published sources. Hurley in the New York Times (Feb, 2007) suggested that fewer than 30 are killed annually by herbs, nutritional supplements and vitamins.

Herb/Drug Contrast (for a continuation of the list see Appendix V)

Allium cepa - Onion - Osteoporosis - Caltrate [[Weak but possible competitor]]

Allium sativum - Garlic -Hypercholesterolemia - Lipitor [[Garlic may be as good with diet and exercise as lipitor with exercise and diet for some patients]]f

Anethum graveolens - Dill - Gas - Mylanta [[Probably equivalent]]

Armoracia rusticana - Horseradish - Sinusitis -Sudafed (Bronchosis Robitussin) [[Probably equivalent]]

Artemisia herba-alba - White Wormwood - Malaria - Chloroquin [[Probably NOT as good]]

Boswellia sacra - Frankincense - Arthrosis - Celebrex [[Possibly equivalent due to COX2Is equivalent]]

Brassica nigra - Black Mustard - Cancer - Lorenzo's Oil? [[Neither real promising]]

Capparis spinosa -Caper - Cancer -Tamoxifen

Carum carvi - Caraway - Cancer - Tamoxifen

Ceratonia siliqua - Carob - Diarrhea - Kaopectate [[Probably equivalent]]

Cichorium intybus - Chicory - Dyspepsia - Mylanta [[Probably equivalent]]

*Cinnamomum aromaticum - Cassia - Diabetes -Avandia [[I'd bet on Cinnamon/Cassia]]

*Cinnamomum verum - Ceylon cinnamon - Diabetes -Avandia [[I'd bet on Cinnamon/Cassia]]

Citrus medica - Citron - Asthma -Allegra [[Possibly equivalent]]

VI. SUMMARY AND CONCLUSIONS

Reviewing the MAM's and the IE's for the constituents of the DCO products in the manner that I have reviewed thousands of uses for hundreds of herbs for several decades, it is clear that significant evidence in support of the following uses exists:

There is a reasonable basis for the claims that the ingredients of 7 Herb Formula, "..., fights tumor formation, and fights pathogenic bacteria."

There is a reasonable basis for the claims that the ingredients of GDU, "contains natural proteolytic enzymes (from pineapple source bromelain) to help digest protein -- even that of unwanted tumors and cysts. This formula also contains ingredients known to help relieve pain and heal inflammation. GDU is also used for. . .and as an adjunct to cancer therapy. GDU possesses a wide range of actions including anti-inflammatory and antispasmodic activity. . ."

There is a reasonable basis for the claims that the ingredients of BioMixx, "boosts the immune system, ...to allow for natural healing. It is used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatments."

February 4, 2009

[Approved for signature by Dr. Duke on February 4, 2009. Signature page to follow.]

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8210 Murphy Road
Fulton, Maryland 20759
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February 4, 2009

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James A. Duke

James A. Duke

CV:

Born in Birmingham, Alabama in 1929, James A. "Jim" Duke is a Phi Beta Kappa PhD (botany, 1961) graduate of the University of North Carolina. Jim, following military service, undertook postdoctoral activities at Washington University and Missouri Botanical Garden in St. Louis, Missouri. There he began studies of neotropical ethnobotany, his overriding interest to this day. From 1963 to 1965, Duke was ecologist with the USDA (Beltsville, Maryland), joining Battelle Columbus Laboratories (1965-71) for ecological and ethnobotanical studies in Panama and Colombia. During this formative period, Duke lived with various ethnic groups, closely observing their deep dependence on forest products. The first of some twenty books, his Isthmian Ethnobotanical Dictionary catalogs hundreds of Isthmian plants and their uses. Rejoining USDA in 1971, Duke had assignments relating to crop diversification, medicinal plants, and energy plant studies in developing countries. A popular lecturer on the subjects of ethnobotany, herbs, medicinal plants, and new crops and their ecology, he has taped dozens of TV and radio shows. The National Agriculture Library has a video history of Dr. Duke's career. Duke grows hundreds of interesting plants on his six-acre farmette (Green Farmacy Garden) with his wife and illustrator, Peggy. On Sept. 30, 1995, he retired after ~ 30 years with the USDA.Before retiring, Dr. Duke brought his renowned ethnobotanical and phytochemicial database online at USDA. It is now, in Duke's retirement, one of the most frequently consulted areas of the USDA website. Since retiring Dr. Duke has served for five years as Senior Science Adviser to Nature's Herbs. and with AllHerb.Com Since 2001, he has been a distinguished herbal lecturer with the Tai Sophia Healing Institute, Laurel MD.

USDA DATABASE http://www.ars-grin.gov/duke/; Pleiotropy Database Multiple Activities Menu

Duke has already doubled the raw data content in the add-on module that he maintains for private licensure. The database is especially useful for determining biological activities and healing potentials of food ands herbs. There is a growing interest in his data from people in companies and organizations including: Proctor & Gamble Corporation, New Chapter, Herbal Science, GAIA Herbs, MD Anderson Cancer Institute and many others.

Fluent in Spanish, Duke has studied and/or lectured widely, concentrating on tropical ecology, medical botany, and crop diversification. Widely travelled, Duke "cut his tropical eye teeth" in

Panama where he was resident from 1966-68. While working on an encyclopedia of economic plants, he has collaborated with the National Cancer Institute on both their AIDS and cancer-screening programs and their Designer Food Program (to prevent cancer). His data bases on the ecology, nutritional content, folk medicinal uses and chemical constituents of economic plants are being widely utilized. Duke's major goal lately is to reverse the disdain for alternative medicines in the US, where, as in the Third World, a growing percentage of people can no longer afford nor trust pharmaceuticals. Duke has a contagious interest in natural foods and nutritional approaches to preventive medicine. Between 1990-1992, Duke was advising the Designer Food Program of the NIH, then under the aegis of Dr. Herb Pierson. Lately Duke has been very active in ecotourism in Latin America and is teaching such themes as renewable rainforest products in the rainforests of Amazonian Peru. He has become an expert in the field of non-timber forest products. In 2008, Duke has already led trips to the rain forests of Costa Rica and Peru, along with numerous honoraria speeches (see below).

With an aggregate of more then a decade in Latin America, Duke has traversed parts of Argentina, Belize, Bolivia, Brazil, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, Guadelupe, Guatemala, Honduras, Jamaica, Mexico, Panama, Peru, Puerto Rico, and Venezuela. In Asia, he has had lengthy visits in China, India, Indonesia, Pakistan, and quick looks at Burma, Japan, Laos and Vietnam. In the Middle East, he has worked in Iran, Israel, Kuwait, and Syria, with quick looks at the Mediterranean countries of Egypt, Greece, Italy, Portugal and Spain. His only tours in tropical Africa include Madagascar, Sao Tome, The Ivory Coast and Zambia. Recently he has been teaching field ethnobotany regularly in Amazonian Peru, Belize and Costa Rica (mostly in the winter) and in the Maine northwoods (in summer only).

Duke belongs to the American Botanical Council (Trustee), American Herb Association (Life), American Society of Pharmacognosy, Association for Tropical Biology (Life), Council of Agricultural Science and Technology (Cornerstone Life Member), Herb Research Foundation (Advisor), International Association of Plant Taxonomists (Life), International Society for Tropical Root Crops (Life), International Weed Science Society (Life), Organization for Tropical Studies (Life), Oriental Healing Arts Society (Honorary), Phi Beta Kappa, Sigma Xi, Smithsonian Institution (Collaborator), Society for Conservation Biology (Life), Society for Economic Botany (Life), Southern Appalachian Botanical Club (Life), and the Washington Academy of Sciences (Life).

Duke serves on the board of trustees of the American Botanical Council (ABC), and the advisory board of the Amazon Center for Environmental Education and Research ACEER, He also serves as an occasional advisor or consultant to Alternative Medicine Digest, American Health, the Center for Alternative Medicine in Women's Health (NY), Center for Mind-Body Medicine, Center for Plant Conservation, Herb Research Foundation, International Expeditions, Rodale Press, Prevention Magazine, Rosenthal Center for Alternative/Complementary Medicine, TRAMIL, and the World Health Organization (Traditional Medicine Program

Routinely queried by editors and writers for several different popular and scientific health-oriented journals, and by producers of radio and television networks, both conservative and liberal, Duke recently has given accredited continuing education lectures on herbal medicine, pros and cons, to chiropractors, nurses, nurse practitioners, pharmacists, and physicians. Early on. He was part of the Scientific Advisory Team of Shaman Pharmaceuticals (San Francisco), Medical Advisory Board of Herbalife (Los Angeles), and serves as Medicinal Plant Adviser to Reader's Digest and Time-Life.

PUBLICATIONS (1998-2008)

CORRECTED SUBSTITUTE SECTION V.1.A.

TO

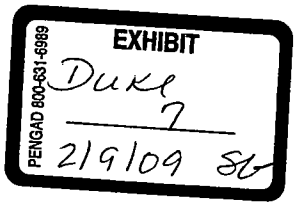
REPORT OF EXPERT WITNESS JAMES DUKE
James A. Duke, PhD, Botany
Economic Botanist, US Department of Agriculture (retired)
In the Matter of Daniel Chapter One
FTC Docket #9329

A. The MAM is a listing, recognized worldwide, which I have created and maintained for over 20 years on the United States Department of Agriculture (USDA) website. Information is put into the website about the relationship between an herb and a condition.—in this case cancer. Then the information is drawn out for a review of the current scientific status of the herb in question.

The following are Multiple Activities Menu's (MAM's) for 16 DCO herbs and their relation to cancer as recorded in the USDA website. These can be done online at my USDA website.

DANIEL CHAPTER ONE HERBS MAM's:

MAM: *Actaea (Cimicifuga) racemosa* (Black cohosh) for Cancer (15/14=1.07)
MAM: *Allium sativum* (Garlic) for Cancer (347/147=2.36)
MAM: *Ananas comosus* (Pineapple) for Cancer (73/79=0.92)
MAM: *Arctium lappa* (Burdock) for Cancer (98/61=1.61)
MAM: *Astragalus membranaceus* (Huang qi) for Cancer (110/26=4.23)
MAM: *Camellia sinensis* (Green Tea) for Cancer (483/457=1.06)
MAM: *Curcuma longa* (Turmeric) for Cancer (213/66=3.28)
MAM: *Eleutherococcus senticosus* (Eleuthero) for Cancer (163/43=3.79)
MAM: *Glycine max* (Soybean) for Cancer (483/457=1.06
MAM: *Nasturtium officinale* (Watercress) for Cancer (3/5=0.6)
MAM: *Rheum palmatum* (Chinese Rhubarb) for Cancer (85/21=4.05)
MAM: *Rumex acetosella* (Sheep sorrel) for Cancer (11/27=0.41)
MAM: *Smilax sarsaparilla* (Sarsparilla) for Cancer (0/13=0)
MAM: *Tanacetum parthenium* (Feverfew) for Cancer (88/19=4.63)
MAM: *Ulmus rubra* (Slippery Elm) for Cancer (4/17=0.24)
MAM: *Uncaria tomentosa* (Cat's Claw) for Cancer (79/31=2.55)



The number on the right hand side of the "/" is the number of cancer affecting aspects of the herb being evaluated.

See Appendix II for detailed presentation of the MAM's for DCO herbs, such as the following one for Turmeric, presented as an example. (Turmeric, one of the 16 DCO herbs, would certainly be in my meals were I subject to cancer, and I am genetically targeted for colon cancer. Turmeric's curcumin is probably better than Celebrex, which like other synthetic COX-2-I's was once touted off-label for the prevention of colon cancer. There are 66 indications of Turmeric affecting cancer in this MAM. Some are bolded.)

MAM: *Curcuma longa* (Turmeric) for Cancer (213/66=3.28)

5-Alpha-Reductase-Inhibitor: curcumin
AntiEBV: curcumin
AntiHIV: caffeic-acid, curcumin, quercetin
AntiX-Radiation: curdione
Antiadenomacarcinogenic: curcumin
Antiadenomic: limonene
Antiaflatoxin: bis-demethoxycurcumin, curcumin, demethoxycurcumin, quercetin, tetrahydrocurcumin
Antiaggregant: caffeic-acid, curcumin, eugenol, quercetin, salicylates
Antiaging: caffeic-acid, quercetin
Antiangiogenic: bis-desmethoxycurcumin, curcumin, demethoxycurcumin, quercetin
Antiarachidonate: curcumin, eugenol
Anticancer: alpha-terpineol, ar-turmerone, beta-turmerone, caffeic-acid, curcumenol, curcumin, curcuminoids, limonene, terpineol, vanillic-acid
Anticancer (Breast): curcumin
Anticancer (Cervix): curcumol, curdione
Anticancer (Colon): curcumin
Anticancer (Duodenum): curcumin
Anticancer (Mammary): curcumin
Anticancer (Skin): curcumin
Anticancer (Stomach): curcumin
Anticarcinogenic: caffeic-acid, curcumin
Antiestrogenic: eugenol, quercetin
Antifibrosarcomic: quercetin
Antihepatotoxic: caffeic-acid, p-coumaric-acid, protocatechuic-acid, quercetin

Antiinflammatory: 1,8-cineole, alpha-curcumene, alpha-pinene, alpha-terpineol, ar-turmerone, azulene, beta-pinene, beta-turmerone, bis-(4-hydroxy-cinnamoyl)-methane, bis-desmethoxycurcumin, borneol, caffeic-acid, caryophyllene, cinnamic-acid, curcumin, curcuminoids, dehydrocurdione, demethoxycurcumin, epi-procurcumenol, eugenol, feruloyl-4-hydroxycinnamoyl-methane, germacrone, limonene, linalool, procurcumenol, protocatechuic-acid, quercetin, salicylates, sodium-curcumate, tetrahydrocurcumin, triethylcurcumin, vanillic-acid
Antileukemic: 2-hydroxy-methyl-anthraquinone, caffeic-acid, curcumin, linalool, p-coumaric-acid, protocatechuic-acid, quercetin, vanillic-acid
Antileukotriene: caffeic-acid, curcumin, curcuminoids, quercetin
Antilipoperoxidant: bis-demethoxycurcumin, curcumin, demethoxycurcumin, quercetin
Antilymphomic: curcumin, limonene, linalool
Antimelanomic: curcumin, quercetin
Antimetastatic: curcumin, quercetin
Antimutagenic: bis-demethoxycurcumin, caffeic-acid, cinnamic-acid, curcumin, demethoxycurcumin, eugenol, limonene, linalool, protocatechuic-acid, quercetin, turmerin
Antinitrosaminic: alpha-terpinene, caffeic-acid, curcumin, p-coumaric-acid, quercetin, terpinolene
Antioxidant: bis-demethoxycurcumin, caffeic-acid, campesterol, camphene, curcumin, dehydrocurdione, eugenol, gamma-terpinene, p-coumaric-acid, protocatechuic-acid, quercetin, terpinolene, tetrahydrocurcumin, turmerin, turmeronol-a, turmeronol-b, vanillic-acid
Antiperoxidant: caffeic-acid, curcumin, p-coumaric-acid, protocatechuic-acid, quercetin, vanillic-acid
Antiproliferant: alpha-terpineol, ar-turmerone, caffeic-acid, caryophyllene, curcumin, quercetin, terpineol
Antiprostaglandin: caffeic-acid, curcumin, curcuminoids, eugenol
Antisarcomic: curcumol, curdione
Antistress: germacrone
Antithromboxane: curcumin, eugenol
Antitumor: alpha-curcumene, ar-turmerone, caffeic-acid, caryophyllene, curcumenol, curcumin, curcuminoids, curdione, eugenol, limonene, p-coumaric-acid, quercetin, vanillic-acid
Antitumor-Promoter: bis-demethoxycurcumin, caffeic-acid, curcumin, demethoxycurcumin, quercetin, tetrahydrocurcumin, vanillic-acid
Antiviral: alpha-pinene, beta-bisabolene, caffeic-acid, curcumin, eugenol, isoborneol, limonene, linalool, p-cymene, protocatechuic-acid, quercetin
Anxiolytic: caffeic-acid
Apoptotic: curcumin, limonene, protocatechuic-acid, quercetin
COX-2-Inhibitor: ar-turmerone, beta-turmerone, caffeic-acid, curcumin, eugenol, quercetin
Cancer-Preventive: alpha-pinene, caffeic-acid, camphor, cinnamic-acid, curcumin, eugenol, limonene, linalool, p-coumaric-acid, quercetin, vanillic-acid
Chemopreventive: caffeic-acid, curcumin, limonene, p-coumaric-acid, protocatechuic-acid

Cyclooxygenase-Inhibitor: curcumin, quercetin
Cytochrome-P450-Inducer: 1,8-cineole
Cytoprotective: caffeic-acid
Cytotoxic: 2-hydroxy-methyl-anthraquinone, caffeic-acid, curcumin, curcuminoids, di-p-coumaroyl-methane, diferuloyl-methane, eugenol, feruloyl-p-coumaroyl-methane, linalool, p-coumaric-acid, quercetin
Fibrinolytic: curcumin
GST-Inducer: limonene
Glutathionigenic: curcumin
Hepatoprotective: borneol, caffeic-acid, curcumin, di-p-coumaroyl-methane, eugenol, p-coumaroyl-feruloyl-methane, quercetin
Hepatotonic: 1,8-cineole, turmerone
Hypocholesterolemic: campesterol, curcumin, phytosterols
Immunostimulant: caffeic-acid, curcumin, protocatechuic-acid, ukonan-a
Lipoxygenase-Inhibitor: caffeic-acid, cinnamic-acid, p-coumaric-acid, quercetin
MDR-Inhibitor: curcumin
Mast-Cell-Stabilizer: quercetin
Ornithine-Decarboxylase-Inhibitor: caffeic-acid, curcumin, limonene, quercetin
P450-Inducer: 1,8-cineole, limonene, quercetin
PTK-Inhibitor: curcumin, quercetin
Prostaglandigenic: caffeic-acid, p-coumaric-acid, protocatechuic-acid
Protease-Inhibitor: curcumin
Protein-Kinase-C-Inhibitor: curcumin, quercetin
Protein-Kinase-Inhibitor: curcumin
Pulmonoprotective: curcumin
Sunscreen: caffeic-acid
Topoisomerase-II-Inhibitor: bis-demethoxycurcumin, curcumin, demethoxycurcumin, quercetin
Tyrosine-Kinase-Inhibitor: quercetin

APPENDICES TO REPORT OF EXPERT WITNESS JAMES DUKE
James A. Duke, PhD, Botany
Economic Botanist, US Department of Agriculture (retired)
In the Matter of Daniel Chapter One
FTC Docket #9329

APPENDIX I: ADDITIONAL MATERIALS RELIED ON

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CORRECTED

EXHIBIT II

CANCER MAMs

Tanacetum parthenium (Feverfew) for Cancer (88/19=4.63)
Astragalus membranaceus (Huang qi; Yellow Root) for Cancer (110/26=4.23)
Rheum palmatum (Chinese Rhubarb) for Cancer (85/21=4.05)
Eleutherococcus senticosus (Eleuthero) for Cancer (163/43=3.79)
Curcuma longa (Turmeric) for Cancer (213/66=3.28)
Uncaria tomentosa (Cat's Claw) for Cancer (79/31=2.55)
Allium sativum (Garlic) for Cancer (347/147=2.36)
Arctium lappa (Burdock) for Cancer (98/61=1.61)
Cimicifuga racemosa (Black cohosh) for Cancer (15/14=1.07)
Camellia sinensis (Green Tea) for Cancer (483/453=1.07)
Glycine max (Soybean) for Cancer (483/457=1.06)
Ananas comosus (Pineapple) for Cancer (73/79=0.92)
Rumex acetosella (Sheep sorrel) for Cancer (11/27=0.41)
Ulmus rubra (Slippery Elm) for Cancer (4/17=0.24)
Nasturtium officinale (Watercress) for Cancer (3/5=0.6)
Smilax sarsaparilla (Sarsparilla) for Cancer (0/13=0)

MAM: *Actaea (Cimicifuga) racemosa* (Black cohosh) for Cancer (15/14=1.07)

AntiHIV: gallic-acid, tannic-acid
Antiangiogenic: gallic-acid
Anticancer: gallic-acid
Anticarcinomic: gallic-acid
Antihepatotoxic: gallic-acid
Antiinflammatory: gallic-acid, isoferulic-acid, salicylic-acid
Antimutagenic: gallic-acid, tannic-acid
Antinitrosaminic: gallic-acid, tannic-acid
Antioxidant: gallic-acid, isoferulic-acid, salicylic-acid, tannic-acid
Antiperoxidant: gallic-acid
Antitumor: gallic-acid, salicylic-acid
Antitumor-Promoter: gallic-acid
Antiviral: gallic-acid, tannic-acid
Apoptotic: gallic-acid
COX-2-Inhibitor: salicylic-acid
Cancer-Preventive: formononetin, gallic-acid, salicylic-acid
Cyclooxygenase-Inhibitor: gallic-acid, salicylic-acid
Cytotoxic: gallic-acid, tannic-acid
Hepatoprotective: gallic-acid
Hypocholesterolemic: formononetin
Immunostimulant: gallic-acid, tannic-acid

MAM: *Allium sativum* (Garlic) for Cancer (347/147=2.36)

5-Alpha-Reductase-Inhibitor: alpha-linolenic-acid
AntiEBV: chlorogenic-acid
AntiHIV: ajoene, allyl-alcohol, apigenin, caffeic-acid, chlorogenic-acid, diallyl-disulfide, lignin, myricetin, oleanolic-acid, quercetin
Antiaflatoxin: apigenin, kaempferol, quercetin
Antiaggregant: (-)-n-(1'-deoxy-1'-d-fructopyranosyl)-s-allyl-l-cysteine-sulfoxide, 2-vinyl-4h-1,3-dithiin, adenosine, ajoene, allicin, alliin, allyl-methyl-trisulfide, allyl-trisulfide, alpha-linolenic-acid, apigenin, caffeic-acid, cycloalliin, ferulic-acid, kaempferol, methyl-allyl-trisulfide, phytic-acid, quercetin, rutin, salicylates
Antiaging: apigenin, caffeic-acid, quercetin, s-allyl-l-cysteine
Antiangiogenic: apigenin, quercetin
Anticancer: allixin, caffeic-acid, kaempferol, lignin, phytic-acid, rutin, s-allyl-l-cysteine, s-allylmercaptocysteine, vanillic-acid
Anticancer (Cervix): trigonelline
Anticancer (Colon): chlorogenic-acid, diallyl-sulfide, ferulic-acid, s-allyl-l-cysteine
Anticancer (Forestomach): chlorogenic-acid, ferulic-acid
Anticancer (Liver): chlorogenic-acid, diallyl-sulfide, ferulic-acid, s-allyl-l-cysteine, trigonelline
Anticancer (Lung): apigenin
Anticancer (Pancreas): geraniol
Anticancer (Skin): chlorogenic-acid, ferulic-acid
Anticancer (Stomach): allyl-methyl-disulfide, allyl-methyl-trisulfide, diallyl-sulfide, diallyl-trisulfide
Anticarcinogenic: caffeic-acid, chlorogenic-acid, ferulic-acid
Anticarcinomic: oleanolic-acid
Anticytotoxic: glutathione
Antiestrogenic: apigenin, ferulic-acid, quercetin
Antifibrosarcomic: quercetin
Antihepatotoxic: alliin, caffeic-acid, chlorogenic-acid, ferulic-acid, oleanolic-acid, p-coumaric-acid, quercetin, rutin, s-allyl-l-cysteine, s-allylmercaptocysteine, sinapic-acid
Antiinflammatory: ajoene, allicin, alpha-linolenic-acid, apigenin, caffeic-acid, chlorogenic-acid, ferulic-acid, kaempferol, linalool, myricetin, oleanolic-acid, quercetin, quercetin-3-o-beta-d-glucoside, rutin, salicylates, salicylic-acid, vanillic-acid
Antileukemic: ajoene, allicin, apigenin, caffeic-acid, ferulic-acid, kaempferol, linalool, oleanolic-acid, p-coumaric-acid, quercetin, s-allylmercaptocysteine, vanillic-acid
Antileukotriene: ajoene, allicin, caffeic-acid, chlorogenic-acid, oleanolic-acid, quercetin
Antilipoperoxidant: quercetin
Antilymphomic: ajoene, allicin, linalool
Antimelanomic: apigenin, geraniol, quercetin, rutin, s-allyl-l-cysteine
Antimetastatic: ajoene, alpha-linolenic-acid, apigenin, quercetin, rutin
Antimutagenic: ajoene, allicin, allixin, apigenin, caffeic-acid, chlorogenic-acid, diallyl-sulfide, ferulic-acid, kaempferol, linalool, myricetin, p-hydroxy-benzoic-acid, quercetin, rutin, saponins
Antineoplastic: ferulic-acid
Antineuroblastomic: s-allyl-l-cysteine

Antinitrosaminic: caffeic-acid, chlorogenic-acid, ferulic-acid, lignin, p-coumaric-acid, quercetin
Antioxidant: allicin, alliin, allixin, allyl-mercaptan, apigenin, caffeic-acid, campesterol, chlorogenic-acid, diallyl-disulfide, diallyl-heptasulfide, diallyl-hexasulfide, diallyl-pentasulfide, diallyl-sulfide, diallyl-tetrasulfide, diallyl-trisulfide, ferulic-acid, glutathione, ionol, kaempferol, lignin, myricetin, oleanolic-acid, p-coumaric-acid, p-hydroxy-benzoic-acid, pentadecanoic-acid, phytic-acid, quercetin, rutin, s-allyl-cysteine-sulfoxide, s-allyl-l-cysteine, s-allylmercaptocysteine, salicylic-acid, sinapic-acid, taurine, vanillic-acid
Antiperoxidant: caffeic-acid, chlorogenic-acid, diallyl-pentasulfide, oleanolic-acid, p-coumaric-acid, quercetin, rutin, s-allyl-cysteine-sulfoxide, vanillic-acid
Antiproliferant: ajoene, allicin, apigenin, caffeic-acid, quercetin, rutin, s-allyl-l-cysteine, s-allylmercaptocysteine
Antiproliferative: diallyl-disulfide
Antipromoter: allixin
Antiprostaglandin: ajoene, allicin, caffeic-acid
Antisarcomic: allicin, alliin, oleanolic-acid
Antistress: apigenin
Antitumor: ajoene, allicin, alliin, allixin, apigenin, caffeic-acid, chlorogenic-acid, desgalactotigonin, diallyl-disulfide, diallyl-sulfide, ferulic-acid, geraniol, guanylate-cyclase-inhibitor, kaempferol, lignin, oleanolic-acid, p-coumaric-acid, phytic-acid, quercetin, rutin, salicylic-acid, vanillic-acid
Antitumor-Promoter: caffeic-acid, chlorogenic-acid, ferulic-acid, kaempferol, phloroglucinol, quercetin, rutin, vanillic-acid
Antiviral: ajoene, allicin, allyl-alcohol, apigenin, caffeic-acid, chlorogenic-acid, diallyl-disulfide, diallyl-trisulfide, ferulic-acid, kaempferol, lignin, linalool, myricetin, oleanolic-acid, quercetin, rutin
Anxiolytic: adenosine, apigenin, caffeic-acid
Apoptotic: ajoene, allicin, apigenin, diallyl-trisulfide, kaempferol, myricetin, quercetin, rutin, s-allylmercaptocysteine
Beta-Glucuronidase-Inhibitor: apigenin, oleanolic-acid
COX-2-Inhibitor: ajoene, apigenin, caffeic-acid, kaempferol, oleanolic-acid, quercetin, salicylic-acid
Cancer-Preventive: alpha-linolenic-acid, apigenin, caffeic-acid, chlorogenic-acid, citral, diallyl-disulfide, ferulic-acid, geraniol, glutathione, kaempferol, linalool, myricetin, oleanolic-acid, p-coumaric-acid, p-hydroxy-benzoic-acid, phloroglucinol, phytic-acid, prostaglandin-a-1, prostaglandin-e-1, quercetin, quercetin-3-o-beta-d-glucoside, rutin, salicylic-acid, sinapic-acid, taurine, vanillic-acid
Chemopreventive: allixin, caffeic-acid, chlorogenic-acid, p-coumaric-acid, rutin, s-allyl-l-cysteine
Cyclooxygenase-Inhibitor: ajoene, allicin, apigenin, kaempferol, oleanolic-acid, quercetin, salicylic-acid
Cytoprotective: caffeic-acid, rutin
Cytotoxic: ajoene, apigenin, caffeic-acid, kaempferol, linalool, p-coumaric-acid, quercetin
Fibrinolytic: cycloalliin
Hepatoprotective: alliin, caffeic-acid, chlorogenic-acid, ferulic-acid, kaempferol, oleanolic-acid, quercetin, rutin, s-allyl-l-cysteine, s-allylmercaptocysteine
Hyaluronidase-Inhibitor: apigenin

Hypocholesterolemic: 2-vinyl-4h-1,3-dithiin, adenosine, ajoene, allicin, alliin, campesterol, diallyl-disulfide, diallyl-sulfide, diallyl-trisulfide, inulin, lignin, methyl-ajoene, nicotinic-acid, phytic-acid, phytosterols, rutin, s-allyl-cysteine-sulfoxide, s-allyl-l-cysteine, s-methyl-l-cysteine-sulfoxide, taurine, trigonelline
Immunostimulant: allicin, alliin, alpha-linolenic-acid, caffeic-acid, chlorogenic-acid, diallyl-disulfide, ferulic-acid, inulin, s-allyl-l-cysteine
Interferonogenic: chlorogenic-acid
Leucocytogenic: oleanolic-acid
Lipoxygenase-Inhibitor: ajoene, allicin, caffeic-acid, chlorogenic-acid, kaempferol, myricetin, p-coumaric-acid, quercetin, rutin
Lymphocytogenic: alpha-linolenic-acid
Mast-Cell-Stabilizer: quercetin
Ornithine-Decarboxylase-Inhibitor: apigenin, caffeic-acid, chlorogenic-acid, ferulic-acid, quercetin
P450-Inducer: quercetin
PKC-Inhibitor: apigenin
PTK-Inhibitor: apigenin, quercetin
Prostaglandigenic: caffeic-acid, ferulic-acid, p-coumaric-acid, p-hydroxy-benzoic-acid
Protein-Kinase-C-Inhibitor: apigenin, quercetin
Sunscreen: apigenin, caffeic-acid, chlorogenic-acid, ferulic-acid, rutin
Topoisomerase-II-Inhibitor: apigenin, kaempferol, myricetin, quercetin, rutin
Tyrosine-Kinase-Inhibitor: myricetin, quercetin

MAM: *Ananas comosus* (Pineapple) for Cancer (73/79=0.92)

5-Alpha-Reductase-Inhibitor: alpha-linolenic-acid
AntiHIV: caffeic-acid, methanol
Antiaggregant: alpha-linolenic-acid, bromelain, caffeic-acid, ferulic-acid, salicylates, serotonin
Antiaging: caffeic-acid
Anticancer: alpha-terpineol, caffeic-acid, vanillin
Anticancer (Colon): ferulic-acid
Anticancer (Forestomach): ferulic-acid
Anticancer (Liver): ferulic-acid
Anticancer (Skin): ferulic-acid
Anticarcinogenic: caffeic-acid, ferulic-acid
Antiestrogenic: ferulic-acid
Antihepatotoxic: caffeic-acid, ferulic-acid, p-coumaric-acid, sinapic-acid
Antiinflammatory: alpha-linolenic-acid, alpha-terpineol, bromelain, caffeic-acid, ferulic-acid, linalool, salicylates
Antileukemic: bromelain, caffeic-acid, ferulic-acid, linalool, p-coumaric-acid
Antileukotriene: caffeic-acid
Antilymphomic: linalool
Antimetastatic: alpha-linolenic-acid, bromelain
Antimutagenic: caffeic-acid, ferulic-acid, linalool, vanillin
Antineoplastic: ferulic-acid
Antinitrosaminic: caffeic-acid, ferulic-acid, p-coumaric-acid

Antioxidant: caffeic-acid, campesterol, ferulic-acid, p-coumaric-acid, sinapic-acid, vanillin
Antioxidant Synergist: malic-acid
Antiperoxidant: caffeic-acid, p-coumaric-acid
Antiproliferant: alpha-terpineol, bromelain, caffeic-acid
Antiprostaglandin: bromelain, caffeic-acid
Antiradiation: bromelain
Antistress: gaba, gamma-aminobutyric-acid
Antitumor: bromelain, caffeic-acid, ferulic-acid, malic-acid, p-coumaric-acid, vanillin
Antitumor-Promoter: caffeic-acid, ferulic-acid, vanillin
Antiviral: caffeic-acid, cyanin, ferulic-acid, linalool, subaphyllin, vanillin
Anxiolytic: caffeic-acid, gaba, gamma-aminobutyric-acid
COX-2-Inhibitor: caffeic-acid
Cancer-Preventive: 5-hydroxytryptamine, alpha-linolenic-acid, caffeic-acid, ferulic-acid, linalool, p-coumaric-acid, sinapic-acid, vanillin
Chemopreventive: bromelain, caffeic-acid, p-coumaric-acid
Cytoprotective: caffeic-acid
Cytotoxic: caffeic-acid, linalool, p-coumaric-acid
Fibrinolytic: bromelain
Hepatoprotective: caffeic-acid, ferulic-acid
Hypocholesterolemic: campesterol, phytosterols
Immunostimulant: alpha-linolenic-acid, caffeic-acid, ferulic-acid
Lipoxygenase-Inhibitor: caffeic-acid, p-coumaric-acid
Lymphocytogenic: alpha-linolenic-acid
Ornithine-Decarboxylase-Inhibitor: caffeic-acid, ferulic-acid
Prostaglandigenic: caffeic-acid, ferulic-acid, p-coumaric-acid
Sunscreen: caffeic-acid, ferulic-acid, p-aminobenzoic-acid

MAM: *Arctium lappa* (Burdock) for Cancer (98/61=1.61)

AntiEBV: beta-eudesmol, chlorogenic-acid, lupeol
AntiHIV: (-)-arctigenin, arctigenin, caffeic-acid, chlorogenic-acid, lignin, polyphenols, trachelogenin
Antiaggregant: caffeic-acid
Antiaging: caffeic-acid
Antiangiogenic: lupeol, polyphenols
Anticancer: arctiin, benzaldehyde, caffeic-acid, lignin
Anticancer (Cervix): beta-elemene
Anticancer (Colon): chlorogenic-acid
Anticancer (Forestomach): chlorogenic-acid
Anticancer (Liver): chlorogenic-acid
Anticancer (Skin): chlorogenic-acid
Anticarcinogenic: caffeic-acid, chlorogenic-acid
Antigliomic: beta-elemene
Antihepatotoxic: caffeic-acid, chlorogenic-acid, polyphenols
Antiinflammatory: alpha-amyrin, alpha-amyrin-acetate, beta-amyrin, beta-amyrin-acetate, caffeic-acid, caryophyllene, chlorogenic-acid, lupeol, taraxasterol, taraxasterol-acetate

Antileukemic: arctigenin, caffeic-acid, daucosterol, matairesinol, trachelogenin
Antileukotriene: caffeic-acid, chlorogenic-acid
Antilymphomic: (-)-arctigenin, arctigenin, trachelogenin
Antimutagenic: benzaldehyde, beta-eudesmol, caffeic-acid, chlorogenic-acid, dehydrocostus-lactone, desmutagenic factor, polyphenols
Antinitrosaminic: caffeic-acid, chlorogenic-acid, lignin
Antioxidant: beta-amyrin-acetate, caffeic-acid, chlorogenic-acid, isochlorogenic-acid, lignin, lupeol, polyphenols
Antiperoxidant: caffeic-acid, chlorogenic-acid, lupeol
Antiproliferant: arctigenin, beta-elemene, caffeic-acid, caryophyllene
Antiprostaglandin: caffeic-acid, lupeol
Antistress: gaba
Antitopoisomerase-II: arctigenin, trachelogenin
Antitumor: alpha-amyrin, arctigenin, benzaldehyde, caffeic-acid, caryophyllene, chlorogenic-acid, daucosterol, lignin, lupeol, polyphenols
Antitumor-Promoter: caffeic-acid, chlorogenic-acid
Antiviral: arctigenin, atropine, caffeic-acid, chlorogenic-acid, lignin, lupeol, polyphenols
Anxiolytic: caffeic-acid, gaba
Apoptotic: beta-elemene
COX-2-Inhibitor: caffeic-acid
Cancer-Preventive: caffeic-acid, chlorogenic-acid, decan-1-al, isochlorogenic-acid, mucilage, phytol, polyphenols
Chemopreventive: caffeic-acid, chlorogenic-acid
Cyclooxygenase-Inhibitor: polyphenols
Cytoprotective: caffeic-acid
Cytotoxic: (-)-arctigenin, alpha-amyrin, arctigenin, caffeic-acid, lupeol
Hepatoprotective: alpha-amyrin, beta-amyrin, beta-eudesmol, caffeic-acid, chlorogenic-acid, polyphenols
Hypocholesterolemic: inulin, lignin, mucilage, phytosterols
Immunostimulant: arctigenin, benzaldehyde, caffeic-acid, chlorogenic-acid, inulin
Interferonogenic: chlorogenic-acid
Lipoxygenase-Inhibitor: caffeic-acid, chlorogenic-acid, polyphenols
Ornithine-Decarboxylase-Inhibitor: caffeic-acid, chlorogenic-acid, polyphenols
Phytohormonal: dehydrocostus-lactone
Prostaglandigenic: caffeic-acid
Sunscreen: caffeic-acid, chlorogenic-acid
Topoisomerase-Inhibitor: (-)-arctigenin, trachelogenin

MAM: *Astragalus membranaceus* (Huang qi) for Cancer (110/26=4.23)

AntiEBV: chlorogenic-acid
AntiHIV: caffeic-acid, chlorogenic-acid, quercetin
Antiaflatoxin: kaempferol, quercetin
Antiaggregant: caffeic-acid, coumarin, ferulic-acid, isoliquiritigenin, kaempferol, quercetin
Antiaging: caffeic-acid, quercetin
Antiandrogenic: coumarin

Antiangiogenic: quercetin
Anticancer: caffeic-acid, kaempferol
Anticancer (Colon): chlorogenic-acid, ferulic-acid
Anticancer (Forestomach): chlorogenic-acid, ferulic-acid
Anticancer (Kidney): coumarin
Anticancer (Liver): chlorogenic-acid, ferulic-acid
Anticancer (Prostate): coumarin
Anticancer (Skin): chlorogenic-acid, ferulic-acid
Anticarcinogenic: caffeic-acid, chlorogenic-acid, ferulic-acid
Anticervicaldysplasic: folic-acid
Antiestrogenic: ferulic-acid, quercetin
Antifibrosarcomic: quercetin
Antihepatotoxic: caffeic-acid, chlorogenic-acid, ferulic-acid, quercetin
Antiinflammatory: astramembranin-i, caffeic-acid, chlorogenic-acid, coumarin, ferulic-acid, isoferulic-acid, isorhamnetin, kaempferol, quercetin
Antileukemic: caffeic-acid, ferulic-acid, kaempferol, quercetin
Antileukotriene: caffeic-acid, chlorogenic-acid, quercetin
Antilipoperoxidant: quercetin
Antimelanomic: coumarin, quercetin
Antimetaplastic: folic-acid
Antimetastatic: coumarin, quercetin
Antimutagenic: caffeic-acid, chlorogenic-acid, coumarin, ferulic-acid, kaempferol, quercetin
Antineoplastic: ferulic-acid
Antinitrosaminic: caffeic-acid, chlorogenic-acid, ferulic-acid, quercetin
Antioxidant: caffeic-acid, chlorogenic-acid, ferulic-acid, isoferulic-acid, isorhamnetin, kaempferol, quercetin
Antiperoxidant: caffeic-acid, chlorogenic-acid, quercetin
Antipolyp: folic-acid
Antiproliferant: caffeic-acid, quercetin
Antiprostaglandin: caffeic-acid
Antistress: gaba
Antitumor: caffeic-acid, canavanine, chlorogenic-acid, coumarin, ferulic-acid, kaempferol, quercetin
Antitumor-Promoter: caffeic-acid, chlorogenic-acid, ferulic-acid, kaempferol, quercetin
Antiviral: caffeic-acid, canavanine, chlorogenic-acid, ferulic-acid, kaempferol, quercetin
Anxiolytic: caffeic-acid, gaba
Apoptotic: isoliquiritigenin, kaempferol, quercetin
COX-2-Inhibitor: caffeic-acid, kaempferol, quercetin
Cancer-Preventive: caffeic-acid, chlorogenic-acid, coumarin, ferulic-acid, folic-acid, formononetin, isoliquiritigenin, isorhamnetin, kaempferol, quercetin
Chemopreventive: caffeic-acid, chlorogenic-acid, coumarin
Cyclooxygenase-Inhibitor: isoliquiritigenin, kaempferol, quercetin
Cytoprotective: caffeic-acid
Cytotoxic: caffeic-acid, canavanine, kaempferol, quercetin
Hepatoprotective: betaine, caffeic-acid, chlorogenic-acid, ferulic-acid, isorhamnetin, kaempferol, quercetin

Hypocholesterolemic: formononetin
Immunostimulant: caffeic-acid, chlorogenic-acid, coumarin, ferulic-acid, folic-acid
Interferonogenic: chlorogenic-acid
Lipoxygenase-Inhibitor: caffeic-acid, chlorogenic-acid, isoliquiritigenin, kaempferol, quercetin
Lymphocytogenic: coumarin
Lymphokinetic: coumarin
Mast-Cell-Stabilizer: quercetin
Mitogenic: canavanine
Ornithine-Decarboxylase-Inhibitor: caffeic-acid, chlorogenic-acid, ferulic-acid, quercetin
P450-Inducer: quercetin
PTK-Inhibitor: quercetin
Prostaglandigenic: caffeic-acid, ferulic-acid
Protein-Kinase-C-Inhibitor: quercetin
Sunscreen: caffeic-acid, chlorogenic-acid, ferulic-acid
Topoisomerase-II-Inhibitor: kaempferol, quercetin
Tyrosine-Kinase-Inhibitor: isoliquiritigenin, quercetin
cAMP-genic: astramembranin-i

MAM: *Camellia sinensis* (Green Tea) for Cancer (483/453=1.07)

AntiEBV: (-)-epicatechin, chlorogenic-acid, epicatechin, geranial, lupeol
AntiHIV: (+)-catechin, (-)-epicatechin, (-)-epicatechin-3-o-gallate, apigenin, caffeic-acid, chlorogenic-acid, epicatechin, gallic-acid, lignin, myricetin, naringenin, opcs, polyphenols, quercetin, tannic-acid
Antiadenomic: farnesol, limonene
Antiaflatoxin: apigenin, kaempferol, naringenin, quercetin
Antiaggregant: (+)-catechin, (-)-epicatechin, (-)-epigallocatechin-gallate, apigenin, caffeic-acid, epicatechin, eugenol, kaempferol, ligustrazine, menthol, naringenin, quercetin, rutin, safrole, salicylates, tetramethyl-pyrazine, thymol
Antiaging: apigenin, caffeic-acid, hyperoside, quercetin
Antiangiogenic: (-)-epigallocatechin-3-gallate, (-)-epigallocatechin-gallate, apigenin, epigallocatechin-gallate, gallic-acid, lupeol, polyphenols, quercetin
Antiarachidonate: eugenol
Anticancer: (-)-epigallocatechin-gallate, alpha-terpineol, benzaldehyde, caffeic-acid, gallic-acid, hyperoside, isoquercitrin, kaempferol, lignin, limonene, naringenin, rutin
Anticancer (Bladder): lycopene
Anticancer (Breast): lutein, lycopene, zeaxanthin
Anticancer (Cervix): lycopene
Anticancer (Colon): chlorogenic-acid
Anticancer (Forestomach): chlorogenic-acid
Anticancer (Liver): chlorogenic-acid
Anticancer (Lung): apigenin
Anticancer (Pancreas): farnesol, geraniol
Anticancer (Prostate): lycopene
Anticancer (Skin): chlorogenic-acid
Anticarcinogenic: (-)-epigallocatechin, caffeic-acid, caffeine, chlorogenic-acid, theaflavin

Anticarcinomic: gallic-acid
Antiestrogenic: apigenin, eugenol, naringenin, quercetin
Antifibrosarcomic: quercetin
Antihepatotoxic: (-)-epigallocatechin-gallate, caffeic-acid, chlorogenic-acid, epicatechin-gallate, gallic-acid, hyperoside, naringenin, pedunculagin, polyphenols, procyanidin-b-2-3'-o-gallate, procyanidin-b-2-3,3'-di-o-gallate, quercetin, quercitrin, rutin
Antiinflammatory: (+)-catechin, (-)-epicatechin, allantoin, alpha-amyrin, alpha-pinene, alpha-spinasterol, alpha-terpineol, apigenin, beta-amyrin, beta-damascenone, caffeic-acid, carvacrol, chlorogenic-acid, cinnamic-acid, epicatechin, eugenol, gallic-acid, hyperoside, isoquercitrin, kaempferitrin, kaempferol, limonene, linalool, lupeol, menthol, methyl-salicylate, myricetin, naringenin, neo-chlorogenic-acid, opcs, quercetin, quercetin-3-o-beta-d-glucoside, quercitrin, rutin, salicylates, salicylic-acid, thymol, umbelliferone, vitexin
Antileukemic: (-)-epicatechin, (-)-epigallocatechin-gallate, apigenin, astragalin, caffeic-acid, epicatechin, farnesol, kaempferol, linalool, naringenin, quercetin
Antileukotriene: (-)-epicatechin, caffeic-acid, chlorogenic-acid, quercetin
Antilipoperoxidant: (-)-epicatechin, epicatechin, quercetin
Antilymphomic: limonene, linalool
Antimelanomic: apigenin, beta-ionone, carvacrol, farnesol, geraniol, quercetin, rutin, thymol
Antimetastatic: apigenin, quercetin, rutin, tetramethyl-pyrazine
Antimutagenic: (+)-catechin, (+)-gallocatechin, (-)-epicatechin, (-)-epicatechin-gallate, (-)-epigallocatechin, (-)-epigallocatechin-gallate, apigenin, benzaldehyde, caffeic-acid, chlorogenic-acid, cinnamic-acid, cryptoxanthin, epicatechin, epicatechin-gallate, epigallocatechin, eugenol, gallic-acid, kaempferol, limonene, linalool, myrcene, myricetin, naringenin, o-cresol, p-cresol, pedunculagin, polyphenols, quercetin, quercitrin, rutin, tannic-acid, umbelliferone
Antinitrosaminic: caffeic-acid, chlorogenic-acid, gallic-acid, lignin, myrcene, quercetin, tannic-acid
Antioxidant: (+)-catechin, (+)-gallocatechin, (-)-epicatechin, (-)-epicatechin-3-o-gallate, (-)-epigallocatechin, (-)-epigallocatechin-3-o-gallate, (-)-epigallocatechin-gallate, 4-terpineol, allantoin, apigenin, caffeic-acid, caffeine, campesterol, carvacrol, chlorogenic-acid, epicatechin, epicatechin-3-o-gallate, epicatechin-gallate, epigallocatechin, epigallocatechin-3-o-gallate, eugenol, gallic-acid, hyperoside, isoquercitrin, isovitexin, kaempferol, lignin, lupeol, lutein, lycopene, methyl-salicylate, myrcene, myricetin, naringenin, opcs, pedunculagin, polyphenols, procyanidin-b-2-3'-o-gallate, procyanidin-b-2-3,3'-di-o-gallate, procyanidin-b-5-3,3'-di-o-gallate, quercetin, quercitrin, rutin, salicylic-acid, tannic-acid, theaflavin, thymol, vitexin
Antioxidant Synergist: malic-acid
Antiperoxidant: (+)-catechin, (-)-epicatechin, (-)-epigallocatechin-gallate, caffeic-acid, chlorogenic-acid, epicatechin, epicatechin-gallate, gallic-acid, lupeol, pedunculagin, procyanidin-b-2-3'-o-gallate, quercetin, rutin
Antiperoxidative: naringenin
Antiproliferant: alpha-terpineol, apigenin, caffeic-acid, lutein, quercetin, rutin
Antiprostaglandin: (+)-catechin, caffeic-acid, carvacrol, eugenol, lupeol, umbelliferone
Antistress: apigenin
Antithromboxane: eugenol, theanine
Antitumor: (-)-epigallocatechin-gallate, alpha-amyrin, apigenin, benzaldehyde, beta-ionone, caffeic-acid, caffeine, chlorogenic-acid, epigallocatechin-gallate, eugenol, gallic-acid, geraniol,

isoquercitrin, kaempferol, lignin, limonene, lupeol, lycopene, malic-acid, naringenin, polyphenols, quercetin, quercitrin, rutin, salicylic-acid
Antitumor-Promoter: caffeic-acid, chlorogenic-acid, gallic-acid, isoquercitrin, kaempferol, naringenin, quercetin, rutin
Antiviral: (-)-epicatechin, (-)-epicatechin-3-o-gallate, (-)-epigallocatechin-gallate, adenine, alpha-pinene, apigenin, caffeic-acid, caffeine, chlorogenic-acid, dammaradienol, epicatechin, eugenol, gallic-acid, geranial, hyperoside, kaempferol, lignin, limonene, linalool, lupeol, myricetin, naringenin, opcs, polyphenols, quercetin, quercimeritrin, quercitrin, rutin, tannic-acid, theaflavin, theophylline
Anxiolytic: apigenin, caffeic-acid
Apoptotic: (-)-epigallocatechin-3-o-gallate, (-)-epigallocatechin-gallate, apigenin, caffeine, farnesol, gallic-acid, kaempferol, limonene, myricetin, quercetin, rutin
Beta-Glucuronidase-Inhibitor: apigenin
COX-2-Inhibitor: (+)-catechin, apigenin, caffeic-acid, eugenol, kaempferol, quercetin, salicylic-acid
Cancer-Preventive: (+)-catechin, (-)-epicatechin, alpha-pinene, apigenin, aromadendrin, beta-ionone, caffeic-acid, caffeine, chlorogenic-acid, cinnamic-acid, epicatechin, epicatechin-gallate, eugenol, gallic-acid, geraniol, hyperoside, indole, isoquercitrin, isovitexin, jasmone, kaempferol, limonene, linalool, lycopene, methyl-salicylate, myricetin, naringenin, o-cresol, opcs, p-cresol, polyphenols, quercetin, quercetin-3-o-beta-d-glucoside, quercitrin, rutin, safrole, salicylic-acid, umbelliferone, vitexin
Chemopreventive: caffeic-acid, chlorogenic-acid, limonene, myrcene, rutin
Cyclooxygenase-Inhibitor: (+)-catechin, (-)-epiafzelechin, (-)-epigallocatechin-gallate, apigenin, carvacrol, gallic-acid, kaempferol, polyphenols, quercetin, salicylic-acid, thymol
Cytochrome-P450-Inducer: beta-ionone, delta-cadinene, safrole
Cytoprotective: caffeic-acid, rutin
Cytotoxic: (+)-catechin, (-)-epicatechin, (-)-epicatechin-3-o-gallate, (-)-epigallocatechin-gallate, alpha-amyrin, apigenin, caffeic-acid, eugenol, gallic-acid, kaempferol, linalool, lupeol, quercetin, tannic-acid
DNA-Binder: safrole
GST-Inducer: limonene
Hepatoprotective: (+)-catechin, (-)-epigallocatechin-gallate, alpha-amyrin, beta-amyrin, caffeic-acid, chlorogenic-acid, eugenol, gallic-acid, hyperoside, kaempferol, naringenin, polyphenols, quercetin, rutin, zeaxanthin
Hepatotonic: quercitrin
Hyaluronidase-Inhibitor: apigenin, opcs
Hypocholesterolemic: (-)-epicatechin, (-)-epigallocatechin-gallate, beta-ionone, campesterol, epicatechin, lignin, lycopene, nicotinic-acid, phytosterols, rutin, theanine
Immunostimulant: (+)-catechin, (-)-epicatechin, (-)-epigallocatechin-gallate, allantoin, astragalin, benzaldehyde, caffeic-acid, chlorogenic-acid, epicatechin-gallate, gallic-acid, tannic-acid, theaflavin-digallate
Interferonogenic: chlorogenic-acid
Lipoxygenase-Inhibitor: (-)-epicatechin, (-)-epigallocatechin, (-)-epigallocatechin-gallate, caffeic-acid, chlorogenic-acid, cinnamic-acid, epicatechin, epicatechin-gallate, epigallocatechin, kaempferol, myricetin, polyphenols, quercetin, rutin, theaflavin, theaflavin-digallate, theaflavin-monogallate-b, umbelliferone

Mast-Cell-Stabilizer: quercetin
Mitogen: (-)-epigallocatechin-gallate, epicatechin-gallate, theaflavin
Nephroprotective: (-)-epicatechin-3-o-gallate, (-)-epigallocatechin-3-o-gallate
Ornithine-Decarboxylase-Inhibitor: apigenin, caffeic-acid, chlorogenic-acid, limonene, polyphenols, quercetin
P450-Inducer: beta-ionone, delta-cadinene, limonene, quercetin
PKC-Inhibitor: apigenin
PTK-Inhibitor: (-)-epigallocatechin-gallate, apigenin, quercetin
Phytohormonal: brassinolide
Prostaglandigenic: caffeic-acid
Protein-Kinase-C-Inhibitor: (-)-epigallocatechin-gallate, apigenin, quercetin
Reverse-Transcriptase-Inhibitor: (-)-epicatechin, (-)-epigallocatechin-gallate
Sunscreen: allantoin, apigenin, caffeic-acid, chlorogenic-acid, opcs, rutin, umbelliferone
Topoisomerase-II-Inhibitor: apigenin, caffeine, isoquercitrin, kaempferol, myricetin, pedunculagin, quercetin, rutin, strictinin
Tyrosine-Kinase-Inhibitor: myricetin, quercetin
Vitamin-A-Activity: cryptoxanthin

MAM: *Curcuma longa* (Turmeric) for Cancer (213/66=3.28)

5-Alpha-Reductase-Inhibitor: curcumin
AntiEBV: curcumin
AntiHIV: caffeic-acid, curcumin, quercetin
AntiX-Radiation: curdione
Antiadenomacarcinogenic: curcumin
Antiadenomic: limonene
Antiaflatoxin: bis-demethoxycurcumin, curcumin, demethoxycurcumin, quercetin, tetrahydrocurcumin
Antiaggregant: caffeic-acid, curcumin, eugenol, quercetin, salicylates
Antiaging: caffeic-acid, quercetin
Antiangiogenic: bis-desmethoxycurcumin, curcumin, demethoxycurcumin, quercetin
Antiarachidonate: curcumin, eugenol
Anticancer: alpha-terpineol, ar-turmerone, beta-turmerone, caffeic-acid, curcumenol, curcumin, curcuminoids, limonene, terpineol, vanillic-acid
Anticancer (Breast): curcumin
Anticancer (Cervix): curcumol, curdione
Anticancer (Colon): curcumin
Anticancer (Duodenum): curcumin
Anticancer (Mammary): curcumin
Anticancer (Skin): curcumin
Anticancer (Stomach): curcumin
Anticarcinogenic: caffeic-acid, curcumin
Antiestrogenic: eugenol, quercetin
Antifibrosarcomic: quercetin
Antihepatotoxic: caffeic-acid, p-coumaric-acid, protocatechuic-acid, quercetin
Antiinflammatory: 1,8-cineole, alpha-curcumene, alpha-pinene, alpha-terpineol, ar-turmerone,

azulene, beta-pinene, beta-turmerone, bis-(4-hydroxy-cinnamoyl)-methane, bis-desmethoxycurcumin, borneol, caffeic-acid, caryophyllene, cinnamic-acid, curcumin, curcuminoids, dehydrocurdione, demethoxycurcumin, epi-procurcumenol, eugenol, feruloyl-4-hydroxycinnamoyl-methane, germacrone, limonene, linalool, procurcumenol, protocatechuic-acid, quercetin, salicylates, sodium-curcumate, tetrahydrocurcumin, triethylcurcumin, vanillic-acid

Antileukemic: 2-hydroxy-methyl-anthraquinone, caffeic-acid, curcumin, linalool, p-coumaric-acid, protocatechuic-acid, quercetin, vanillic-acid

Antileukotriene: caffeic-acid, curcumin, curcuminoids, quercetin

Antilipoperoxidant: bis-demethoxycurcumin, curcumin, demethoxycurcumin, quercetin

Antilymphomic: curcumin, limonene, linalool

Antimelanomic: curcumin, quercetin

Antimetastatic: curcumin, quercetin

Antimutagenic: bis-demethoxycurcumin, caffeic-acid, cinnamic-acid, curcumin, demethoxycurcumin, eugenol, limonene, linalool, protocatechuic-acid, quercetin, turmerin

Antinitrosaminic: alpha-terpinene, caffeic-acid, curcumin, p-coumaric-acid, quercetin, terpinolene

Antioxidant: bis-demethoxycurcumin, caffeic-acid, campesterol, camphene, curcumin, dehydrocurdione, eugenol, gamma-terpinene, p-coumaric-acid, protocatechuic-acid, quercetin, terpinolene, tetrahydrocurcumin, turmerin, turmeronol-a, turmeronol-b, vanillic-acid

Antiperoxidant: caffeic-acid, curcumin, p-coumaric-acid, protocatechuic-acid, quercetin, vanillic-acid

Antiproliferant: alpha-terpineol, ar-turmerone, caffeic-acid, caryophyllene, curcumin, quercetin, terpineol

Antiprostaglandin: caffeic-acid, curcumin, curcuminoids, eugenol

Antisarcomic: curcumol, curdione

Antistress: germacrone

Antithromboxane: curcumin, eugenol

Antitumor: alpha-curcumene, ar-turmerone, caffeic-acid, caryophyllene, curcumenol, curcumin, curcuminoids, curdione, eugenol, limonene, p-coumaric-acid, quercetin, vanillic-acid

Antitumor-Promoter: bis-demethoxycurcumin, caffeic-acid, curcumin, demethoxycurcumin, quercetin, tetrahydrocurcumin, vanillic-acid

Antiviral: alpha-pinene, beta-bisabolene, caffeic-acid, curcumin, eugenol, isoborneol, limonene, linalool, p-cymene, protocatechuic-acid, quercetin

Anxiolytic: caffeic-acid

Apoptotic: curcumin, limonene, protocatechuic-acid, quercetin

COX-2-Inhibitor: ar-turmerone, beta-turmerone, caffeic-acid, curcumin, eugenol, quercetin

Cancer-Preventive: alpha-pinene, caffeic-acid, camphor, cinnamic-acid, curcumin, eugenol, limonene, linalool, p-coumaric-acid, quercetin, vanillic-acid

Chemopreventive: caffeic-acid, curcumin, limonene, p-coumaric-acid, protocatechuic-acid

Cyclooxygenase-Inhibitor: curcumin, quercetin

Cytochrome-P450-Inducer: 1,8-cineole

Cytoprotective: caffeic-acid

Cytotoxic: 2-hydroxy-methyl-anthraquinone, caffeic-acid, curcumin, curcuminoids, di-p-coumaroyl-methane, diferuloyl-methane, eugenol, feruloyl-p-coumaroyl-methane, linalool, p-coumaric-acid, quercetin

Fibrinolytic: curcumin
GST-Inducer: limonene
Glutathionigenic: curcumin
Hepatoprotective: borneol, caffeic-acid, curcumin, di-p-coumaroyl-methane, eugenol, p-coumaroyl-feruloyl-methane, quercetin
Hepatotonic: 1,8-cineole, turmerone
Hypocholesterolemic: campesterol, curcumin, phytosterols
Immunostimulant: caffeic-acid, curcumin, protocatechuic-acid, ukonan-a
Lipoxygenase-Inhibitor: caffeic-acid, cinnamic-acid, p-coumaric-acid, quercetin
MDR-Inhibitor: curcumin
Mast-Cell-Stabilizer: quercetin
Ornithine-Decarboxylase-Inhibitor: caffeic-acid, curcumin, limonene, quercetin
P450-Inducer: 1,8-cineole, limonene, quercetin
PTK-Inhibitor: curcumin, quercetin
Prostaglandigenic: caffeic-acid, p-coumaric-acid, protocatechuic-acid
Protease-Inhibitor: curcumin
Protein-Kinase-C-Inhibitor: curcumin, quercetin
Protein-Kinase-Inhibitor: curcumin
Pulmonoprotective: curcumin
Sunscreen: caffeic-acid
Topoisomerase-II-Inhibitor: bis-demethoxycurcumin, curcumin, demethoxycurcumin, quercetin
Tyrosine-Kinase-Inhibitor: quercetin

MAM: *Eleutherococcus senticosus* (Eleuthero) for Cancer (163/43=3.79)

Adaptogenic: syringin
AntiEBV: chlorogenic-acid
AntiHIV: betulinic-acid, caffeic-acid, chlorogenic-acid, oleanolic-acid
Antiaflatoxin: scopoletin
Antiaggregant: 3,4-dihydroxybenzoic-acid, caffeic-acid, coniferyl-alcohol, falcarindiol, ferulic-acid, vitamin-e
Antiaging: caffeic-acid, vitamin-e
Anticancer: betulinic-acid, caffeic-acid, vanillic-acid, vanillin
Anticancer (Colon): chlorogenic-acid, ferulic-acid
Anticancer (Forestomach): chlorogenic-acid, ferulic-acid
Anticancer (Liver): chlorogenic-acid, ferulic-acid
Anticancer (Skin): chlorogenic-acid, ferulic-acid
Anticarcinogenic: caffeic-acid, chlorogenic-acid, ferulic-acid
Anticarcinomic: betulinic-acid, oleanolic-acid
Antiestrogenic: ferulic-acid, lignans
Antihepatotoxic: caffeic-acid, chlorogenic-acid, ferulic-acid, oleanolic-acid, p-coumaric-acid, protocatechuic-acid, scopoletin
Antiinflammatory: amygdalin, betulinic-acid, caffeic-acid, chlorogenic-acid, coniferyl-aldehyde, ferulic-acid, friedelin, oleanolic-acid, protocatechuic-acid, scopoletin, vanillic-acid, vitamin-e
Antileukemic: betulinic-acid, caffeic-acid, daucosterol, ferulic-acid, isofraxidin, oleanolic-acid, p-coumaric-acid, protocatechuic-acid, sesamin, vanillic-acid, vitamin-e

Antileukotriene: caffeic-acid, chlorogenic-acid, oleanolic-acid, vitamin-e
Antimelanomic: betulinic-acid
Antimutagenic: caffeic-acid, chlorogenic-acid, falcarindiol, ferulic-acid, lignans, p-hydroxy-benzoic-acid, protocatechuic-acid, saponins, scopoletin, vanillin
Antineoplastic: ferulic-acid
Antinitrosaminic: caffeic-acid, chlorogenic-acid, ferulic-acid, p-coumaric-acid, vitamin-e
Antioxidant: caffeic-acid, chlorogenic-acid, coniferyl-alcohol, ferulic-acid, lignans, oleanolic-acid, p-coumaric-acid, p-hydroxy-benzoic-acid, protocatechuic-acid, scopoletin, sesamin, vanillic-acid, vanillin, vitamin-e
Antiperoxidant: caffeic-acid, chlorogenic-acid, oleanolic-acid, p-coumaric-acid, protocatechuic-acid, vanillic-acid
Antiproliferant: caffeic-acid, scopoletin, vitamin-e
Antiprostaglandin: caffeic-acid, coniferyl-alcohol, coniferyl-aldehyde, scopoletin
Antisarcomic: oleanolic-acid
Antistress: acanthoside-d, eleutheroside-c, eleutheroside-e, eleutherosides, syringaresinol-di-o-glucoside, syringin
Antitumor: betulinic-acid, caffeic-acid, chlorogenic-acid, daucosterol, ferulic-acid, lignans, oleanolic-acid, p-coumaric-acid, scopoletin, vanillic-acid, vanillin, vitamin-e
Antitumor-Promoter: caffeic-acid, chlorogenic-acid, ferulic-acid, vanillic-acid, vanillin
Antiviral: betulinic-acid, caffeic-acid, chlorogenic-acid, ferulic-acid, lignans, oleanolic-acid, protocatechuic-acid, vanillin
Anxiolytic: caffeic-acid
Apoptotic: betulinic-acid, protocatechuic-acid, scopoletin, vitamin-e
Beta-Glucuronidase-Inhibitor: oleanolic-acid
COX-2-Inhibitor: caffeic-acid, oleanolic-acid
Cancer-Preventive: amygdalin, caffeic-acid, chlorogenic-acid, ferulic-acid, isofraxidin, lignans, oleanolic-acid, p-coumaric-acid, p-hydroxy-benzoic-acid, scopoletin, vanillic-acid, vanillin, vitamin-e
Chemopreventive: caffeic-acid, chlorogenic-acid, p-coumaric-acid, protocatechuic-acid
Cyclooxygenase-Inhibitor: oleanolic-acid
Cytoprotective: caffeic-acid
Cytotoxic: betulinic-acid, caffeic-acid, falcarindiol, liriodendrin, p-coumaric-acid, scopoletin
Hepatoprotective: caffeic-acid, chlorogenic-acid, ferulic-acid, oleanolic-acid, scopoletin, sesamin, vitamin-e
Hypocholesterolemic: phytosterols, sesamin, vitamin-e
Immunostimulant: caffeic-acid, chlorogenic-acid, eleutherosides, ferulic-acid, protocatechuic-acid, syringin, vitamin-e
Interferonogenic: chlorogenic-acid
Leucocytogenic: oleanolic-acid
Lipoxygenase-Inhibitor: caffeic-acid, chlorogenic-acid, p-coumaric-acid, vitamin-e
Ornithine-Decarboxylase-Inhibitor: caffeic-acid, chlorogenic-acid, ferulic-acid, vitamin-e
Phytohormonal: scopoletin
Prostaglandigenic: caffeic-acid, ferulic-acid, p-coumaric-acid, p-hydroxy-benzoic-acid, protocatechuic-acid
Protein-Kinase-C-Inhibitor: vitamin-e
Sunscreen: caffeic-acid, chlorogenic-acid, ferulic-acid

Tocopherol-Synergist: sesamin

MAM: *Glycine max* (Soybean) for Cancer (483/457=1.06)

5-Alpha-Reductase-Inhibitor: alpha-linolenic-acid, biochanin-a
Alpha-Reductase-Inhibitor: biochanin-a, genistein
AntiEBV: chlorogenic-acid, lupeol
AntiHIV: (+)-catechin, caffeic-acid, chlorogenic-acid, gallic-acid, gossypol, lignin, methanol, naringenin, quercetin, tannic-acid
Antiaflatoxin: kaempferol, naringenin, quercetin
Antiaggregant: (+)-catechin, adenosine, alpha-linolenic-acid, caffeic-acid, ferulic-acid, genistein, isoliquiritigenin, kaempferol, naringenin, phytic-acid, pyridoxine, quercetin, rutin, salicylates, tetramethyl-pyrazine, vitamin-e
Antiaging: caffeic-acid, quercetin, vitamin-e
Antiangiogenic: ergosterol, gallic-acid, genistein, lupeol, quercetin
Anticancer: caffeic-acid, daidzein, gallic-acid, gamma-tocopherol, gossypol, inositol-hexaphosphate, isoquercitrin, kaempferol, lignin, naringenin, phytic-acid, rutin, vanillic-acid
Anticancer (Breast): genistein, lutein
Anticancer (Cervix): trigonelline
Anticancer (Colon): chlorogenic-acid, ferulic-acid
Anticancer (Forestomach): chlorogenic-acid, ferulic-acid
Anticancer (Liver): chlorogenic-acid, ferulic-acid, trigonelline
Anticancer (Skin): chlorogenic-acid, crocetin, ferulic-acid
Anticarcinogenic: biochanin-a, caffeic-acid, chlorogenic-acid, cis-aconitic-acid, ferulic-acid
Anticarcinomic: gallic-acid
Antiestrogenic: daidzein, ferulic-acid, genistein, gossypol, naringenin, quercetin
Antifibrosarcomic: quercetin
Antihepatocarcinogenic: fumaric-acid
Antihepatotoxic: caffeic-acid, chlorogenic-acid, ferulic-acid, gallic-acid, glucuronic-acid, naringenin, p-coumaric-acid, protocatechuic-acid, quercetin, quercitrin, rutin, sinapic-acid
Antiinflammatory: (+)-catechin, 24-methylene-cycloartanol, allantoin, alpha-amyrin, alpha-linolenic-acid, beta-amyrin, caffeic-acid, chlorogenic-acid, cycloartenol, daidzein, ferulic-acid, gallic-acid, gamma-tocopherol, genistein, gentisic-acid, isoferulic-acid, isoquercitrin, kaempferol, lupeol, naringenin, neo-chlorogenic-acid, protocatechuic-acid, quercetin, quercitrin, rutin, salicylates, salicylic-acid, taraxasterol, vanillic-acid, vitamin-e, vitexin
Antileukemic: astragalin, caffeic-acid, daidzein, ferulic-acid, genistein, kaempferol, naringenin, p-coumaric-acid, protocatechuic-acid, quercetin, vanillic-acid, vitamin-e
Antileukotriene: caffeic-acid, chlorogenic-acid, genistein, quercetin, vitamin-e
Antilipoperoxidant: quercetin
Antilymphomic: genistein
Antimelanomic: daidzein, genistein, inositol-hexaphosphate, quercetin, rutin
Antimetastatic: alpha-linolenic-acid, quercetin, rutin, tetramethyl-pyrazine
Antimicrobial: coumestrol, daidzein, genistein
Antimutagenic: (+)-catechin, biochanin-a, caffeic-acid, chlorogenic-acid, crocetin, daidzein,

ferulic-acid, fisetin, gallic-acid, genistein, kaempferol, naringenin, p-hydroxy-benzoic-acid, protocatechuic-acid, quercetin, quercitrin, rutin, saponins, tannic-acid
Antineoplastic: ferulic-acid
Antineuroblastomic: genistein
Antinitrosaminic: caffeic-acid, chlorogenic-acid, ferulic-acid, gallic-acid, lignin, p-coumaric-acid, quercetin, tannic-acid, vitamin-e
Antioxidant: (+)-catechin, 6"-o-acetyl-daidzin, 6"-o-acetyl-genistin, allantoin, caffeic-acid, campesterol, catalase, chlorogenic-acid, crocetin, daidzein, daidzin, delta-tocopherol, demethyltexasin, ferulic-acid, fisetin, fumaric-acid, gallic-acid, gamma-tocopherol, genistein, genistin, gentisic-acid, glycitein, gossypol, isoferulic-acid, isoquercitrin, kaempferol, lignin, lupeol, lutein, malonyldaidzin, malonylgenistin, naringenin, p-coumaric-acid, p-hydroxy-benzoic-acid, phytic-acid, protocatechuic-acid, quercetin, quercitrin, rutin, salicylic-acid, sinapic-acid, spermidine, spermine, squalene, tannic-acid, vanillic-acid, vitamin-e, vitexin
Antioxidant Synergist: malic-acid
Antiperoxidant: (+)-catechin, caffeic-acid, chlorogenic-acid, gallic-acid, lupeol, p-coumaric-acid, protocatechuic-acid, quercetin, rutin, vanillic-acid
Antiperoxidative: naringenin
Antiprolactin: pyridoxine
Antiproliferant: biochanin-a, caffeic-acid, gossypol, inositol-hexaphosphate, lutein, quercetin, rutin, vitamin-e
Antiproliferative: daidzein, genistein
Antiprostaglandin: (+)-catechin, caffeic-acid, gamma-tocopherol, lupeol
Antiradiation: pyridoxine
Antitumor: alpha-amyrin, caffeic-acid, canavanine, chlorogenic-acid, delta-tocopherol, ergosterol, ferulic-acid, fumaric-acid, gallic-acid, gamma-tocopherol, gossypol, isoquercitrin, kaempferol, lignin, lupeol, malic-acid, naringenin, p-coumaric-acid, phytic-acid, quercetin, quercitrin, rutin, salicylic-acid, squalene, vanillic-acid, vitamin-e
Antitumor-Promoter: caffeic-acid, chlorogenic-acid, crocetin, daidzein, ferulic-acid, gallic-acid, isoquercitrin, kaempferol, naringenin, quercetin, rutin, vanillic-acid
Antiviral: adenine, anthocyanin, caffeic-acid, canavanine, chlorogenic-acid, daidzein, dammaradienol, ergosterol, ferulic-acid, fisetin, gallic-acid, genistein, gentisic-acid, gossypol, kaempferol, lignin, lupeol, naringenin, protocatechuic-acid, quercetin, quercitrin, rutin, tannic-acid
Anxiolytic: adenosine, caffeic-acid
Apoptotic: biochanin-a, delta-tocopherol, gallic-acid, genistein, isoliquiritigenin, kaempferol, protocatechuic-acid, quercetin, rutin, vitamin-e
COX-2-Inhibitor: (+)-catechin, caffeic-acid, kaempferol, quercetin, salicylic-acid
Cancer-Preventive: (+)-catechin, 24-methylene-cycloartanol, 4-hydroxycinnamic-acid, alpha-linolenic-acid, biochanin-a, caffeic-acid, chlorogenic-acid, daidzein, daidzin, ferulic-acid, formononetin, gallic-acid, genistein, glycitein, indole-3-acetic-acid, isoliquiritigenin, isoquercitrin, kaempferol, lanosterol, naringenin, p-coumaric-acid, p-hydroxy-benzoic-acid, phytic-acid, quercetin, quercitrin, rutin, salicylic-acid, sinapic-acid, squalene, vanillic-acid, vitamin-e, vitexin, vitexin-2"-o-rhamnoside
Chemopreventive: biochanin-a, caffeic-acid, chlorogenic-acid, p-coumaric-acid, protocatechuic-acid, rutin, squalene

Cyclooxygenase-Inhibitor: (+)-catechin, fisetin, gallic-acid, gamma-tocopherol, isoliquiritigenin, kaempferol, quercetin, salicylic-acid
Cytoprotective: caffeic-acid, rutin
Cytotoxic: (+)-catechin, alpha-amyrin, caffeic-acid, canavanine, gallic-acid, genistein, gossypol, kaempferol, lupeol, p-coumaric-acid, quercetin, tannic-acid
Estrogen-Agonist: biochanin-a, daidzein, genistein
Hepatoprotective: (+)-catechin, alpha-amyrin, beta-amyrin, betaine, caffeic-acid, chlorogenic-acid, ferulic-acid, gallic-acid, kaempferol, naringenin, quercetin, rutin, vitamin-e
Hepatotonic: glycolic-acid, quercitrin
Hypocholesterolemic: 24-methylene-cycloartanol, adenosine, biochanin-a, campesterol, coumestrol, crocetin, cycloartenol, delta-tocopherol, formononetin, gamma-tocopherol, genistein, lignin, phytic-acid, phytosterols, rutin, trigonelline, vitamin-e
Immunostimulant: (+)-catechin, allantoin, alpha-linolenic-acid, arabinogalactan, astragalin, caffeic-acid, chlorogenic-acid, ferulic-acid, gallic-acid, genistein, gossypol, protocatechuic-acid, squalene, tannic-acid, vitamin-e
Interferonogenic: arabinogalactan, chlorogenic-acid, gossypol
Lipoxygenase-Inhibitor: caffeic-acid, chlorogenic-acid, fisetin, isoliquiritigenin, kaempferol, p-coumaric-acid, quercetin, rutin, squalene, vitamin-e
Lymphocytogenic: alpha-linolenic-acid
MDR-Inhibitor: genistein
Mast-Cell-Stabilizer: quercetin
Mitogenic: arabinogalactan, canavanine
Ornithine-Decarboxylase-Inhibitor: caffeic-acid, chlorogenic-acid, ferulic-acid, genistein, quercetin, vitamin-e
P450-Inducer: quercetin
PKC-Inhibitor: gamma-tocopherol
PTK-Inhibitor: genistein, quercetin
Phytohormonal: cadaverine
Prostaglandigenic: caffeic-acid, ferulic-acid, gossypol, p-coumaric-acid, p-hydroxy-benzoic-acid, protocatechuic-acid
Protein-Kinase-C-Inhibitor: quercetin, vitamin-e
Sunscreen: allantoin, caffeic-acid, chlorogenic-acid, ferulic-acid, rutin, squalene
Topoisomerase-II-Inhibitor: biochanin-a, daidzein, fisetin, genistein, gossypol, isoquercitrin, kaempferol, quercetin, rutin
Topoisomerase-II-Poison: genistein
Tyrosine-Kinase-Inhibitor: genistein, isoliquiritigenin, quercetin

MAM: *Nasturtium officinale* (Watercress) for Cancer (3/5=0.6)

Antiaggregant: rutin, salicylates
Anticancer: rutin
Antihepatotoxic: rutin
Antiinflammatory: rutin, salicylates
Antimelanomic: rutin
Antimetastatic: rutin
Antimutagenic: rutin
Antioxidant: rutin

Antiperoxidant: rutin
Antiproliferant: rutin
Antitumor: rutin
Antitumor-Promoter: rutin
Antiviral: rutin
Apoptotic: rutin
Cancer-Preventive: 2-phenylethyl-isothiocyanate, rutin
Chemopreventive: rutin
Cytoprotective: rutin
Hepatoprotective: rutin
Hypocholesterolemic: rutin
Lipoxygenase-Inhibitor: rutin
Sunscreen: rutin
Topoisomerase-II-Inhibitor: rutin

MAM: *Rheum palmatum* (Chinese Rhubarb) for Cancer (85/21=4.05)

5-Alpha-Reductase-Inhibitor: alizarin
Adaptogenic: paeonol
AntiEBV: beta-eudesmol
AntiHIV: (+)-catechin, gallic-acid
Antiaggregant: (+)-catechin, emodin, menthol, paeonol, safrole, tetramethyl-pyrazine
Antiangiogenic: emodin, gallic-acid
Anticancer: alpha-terpineol, benzaldehyde, gallic-acid
Anticancer (Cervix): beta-elemene
Anticarcinomic: gallic-acid, rhein
Antigliomic: beta-elemene
Antihepatotoxic: gallic-acid, quercitrin
Antiinflammatory: (+)-catechin, alpha-terpineol, anethole, cinnamic-acid, emodin, gallic-acid, hyperin, menthol, paeonol, quercitrin
Antileukemic: alizarin, aloe-emodin, emodin
Antilymphomic: emodin
Antimetastatic: tetramethyl-pyrazine
Antimutagenic: (+)-catechin, alizarin, benzaldehyde, beta-eudesmol, cinnamic-acid, emodin, gallic-acid, p-cresol, paeonol, quercitrin
Antineoplastic: emodin, rhein
Antinitrosaminic: gallic-acid
Antioxidant: (+)-catechin, 1,2,6-tri-o-galloyl-beta-d-glucose, alizarin, anethole, gallic-acid, hyperin, methyl-eugenol, pentadecanoic-acid, phenol, quercitrin, tridecanoic-acid
Antiperoxidant: (+)-catechin, gallic-acid
Antiproliferant: alpha-terpineol, beta-elemene
Antiprostaglandin: (+)-catechin
Antisarcomic: emodin
Antistress: paeonol
Antitumor: aloe-emodin, alpha-humulene, anethole, benzaldehyde, gallic-acid, quercitrin, rhein
Antitumor-Promoter: gallic-acid

Antiviral: aloe-emodin, ar-curcumene, emodin, gallic-acid, hyperin, p-cymene, phenol, quercitrin, rhein
Apoptotic: beta-elemene, gallic-acid
COX-2-Inhibitor: (+)-catechin
Cancer-Preventive: (+)-catechin, anethole, cinnamic-acid, gallic-acid, methyl-eugenol, p-cresol, phenol, quercitrin, safrole
Cyclooxygenase-Inhibitor: (+)-catechin, gallic-acid
Cytochrome-P450-Inducer: delta-cadinene, safrole
Cytotoxic: (+)-catechin, aloe-emodin, emodin, gallic-acid, rhein
DNA-Binder: safrole
Hepatoprotective: (+)-catechin, alizarin, beta-eudesmol, gallic-acid, hyperin
Hepatotonic: quercitrin
Immunostimulant: (+)-catechin, anethole, benzaldehyde, emodin, gallic-acid
Leucocytogenic: anethole, emodin
Lipoxygenase-Inhibitor: cinnamic-acid
Nephroprotective: anethole
P450-Inducer: delta-cadinene
PTK-Inhibitor: emodin
Topoisomerase-II-Inhibitor: 1,2,6-tri-o-galloyl-beta-d-glucose, aloe-emodin, chrysazin, emodin

MAM: *Rumex acetosella* (Sheep sorrel) for Cancer (11/27=0.41)

Antiaggregant: adenosine, emodin, rutin
Antiangiogenic: emodin
Anticancer: rutin
Antihepatotoxic: rutin
Antiinflammatory: emodin, hyperin, rutin
Antileukemic: emodin
Antilymphomic: emodin
Antimelanomic: rutin
Antimetastatic: rutin
Antimutagenic: emodin, rutin
Antineoplastic: emodin
Antioxidant: hyperin, rutin
Antiperoxidant: rutin
Antiproliferant: rutin
Antisarcomic: emodin
Antitumor: rutin
Antitumor-Promoter: rutin
Antiviral: emodin, hyperin, rutin
Anxiolytic: adenosine
Apoptotic: rutin
Cancer-Preventive: rutin
Chemopreventive: rutin
Cytoprotective: rutin
Cytotoxic: emodin

Hepatoprotective: hyperin, rutin
Hypocholesterolemic: adenosine, rutin
Immunostimulant: emodin
Leucocytogenic: emodin
Lipoxygenase-Inhibitor: rutin
PTK-Inhibitor: emodin
Phytohormonal: zeatin
Sunscreen: rutin
Topoisomerase-II-Inhibitor: emodin, rutin

MAM: *Smilax sarsaparilla* (Sarsparilla) for Cancer (0/13=0)

Anticarcinomic: parillin

MAM: *Tanacetum parthenium* (Feverfew) for Cancer (88/19=4.63)

Antiadenomic: limonene
Antiaggregant: 3-beta-hydroxyparthenolide, artecanin, canin, eugenol, melatonin, parthenolide, thymol
Antiangiogenic: costunolide
Antiarachidonate: eugenol
Anticancer: alpha-terpineol, benzaldehyde, limonene, parthenolide
Antiestrogenic: eugenol
Antiinflammatory: 1,8-cineole, alantolactone, alpha-pinene, alpha-terpineol, artecanin, beta-pinene, borneol, carvacrol, caryophyllene, caryophyllene-oxide, eugenol, limonene, linalool, parthenolide, santamarin, santamarine, thymol
Antileukemic: isofraxidin, linalool
Antilymphomic: limonene, linalool
Antimelanomic: carvacrol, thymol
Antimutagenic: benzaldehyde, costunolide, eugenol, limonene, linalool, myrcene
Antinitrosaminic: alpha-terpinene, myrcene, terpinolene
Antioxidant: alantolactone, camphene, carvacrol, eugenol, gamma-terpinene, luteolin-7-glucuronide, melatonin, myrcene, terpinen-4-ol, terpinolene, thymol
Antiproliferant: alpha-terpineol, caryophyllene
Antiprostaglandin: carvacrol, chrysanthenyl-acetate, eugenol, parthenolide
Antithromboxane: eugenol
Antitumor: alantolactone, alpha-humulene, benzaldehyde, canin, caryophyllene, caryophyllene-oxide, costunolide, eugenol, limonene, parthenolide, santamarin, santamarine
Antiviral: alpha-pinene, bornyl-acetate, eugenol, limonene, linalool, p-cymene
Anxiolytic: alantolactone
Apoptotic: limonene
COX-2-Inhibitor: eugenol, melatonin, parthenolide
Cancer-Preventive: alpha-pinene, camphor, eugenol, isofraxidin, limonene, linalool
Chemopreventive: limonene, myrcene
Cyclooxygenase-Inhibitor: carvacrol, melatonin, parthenolide, thymol
Cytochrome-P450-Inducer: 1,8-cineole, delta-cadinene

Cytotoxic: alantolactone, canin, eugenol, linalool, parthenolide, santamarin
GST-Inducer: limonene
Hepatoprotective: borneol, eugenol
Hepatotonic: 1,8-cineole
Hypocholesterolemic: cynaroside, melatonin
Immunostimulant: alantolactone, benzaldehyde, melatonin
Ornithine-Decarboxylase-Inhibitor: limonene
P450-Inducer: 1,8-cineole, delta-cadinene, limonene

MAM: *Ulmus rubra* (Slippery Elm) for Cancer (4/17=0.24)

Antiinflammatory: salicylic-acid
Antioxidant: campesterol, salicylic-acid
Antitumor: salicylic-acid
COX-2-Inhibitor: salicylic-acid
Cancer-Preventive: mucilage, salicylic-acid
Cyclooxygenase-Inhibitor: salicylic-acid
Hypocholesterolemic: campesterol, mucilage, phytosterols

MAM: *Uncaria tomentosa* (Cat's Claw) for Cancer (79/31=2.55)

AntiEBV: (-)-epicatechin, chlorogenic-acid, ursolic-acid
AntiHIV: (-)-epicatechin, chlorogenic-acid, oleanolic-acid, ursolic-acid
Antiaggregant: (-)-epicatechin, rhynchophylline, rutin
Anticancer: rutin, ursolic-acid
Anticancer (Colon): chlorogenic-acid, ursolic-acid
Anticancer (Forestomach): chlorogenic-acid
Anticancer (Liver): chlorogenic-acid
Anticancer (Skin): chlorogenic-acid
Anticarcinogenic: chlorogenic-acid
Anticarcinomic: oleanolic-acid, ursolic-acid
Antifibrosarcomic: ursolic-acid
Antihepatotoxic: chlorogenic-acid, oleanolic-acid, rutin, ursolic-acid
Antiinflammatory: (-)-epicatechin, chlorogenic-acid, oleanolic-acid, rutin, ursolic-acid
Antileukemic: (-)-epicatechin, isomitraphylline, isopteropodine, mitraphylline, oleanolic-acid, speciophylline, uncarine-f, ursolic-acid
Antileukotriene: (-)-epicatechin, chlorogenic-acid, oleanolic-acid
Antilipoperoxidant: (-)-epicatechin
Antilymphomic: ursolic-acid
Antimelanomic: rutin
Antimetastatic: rutin, ursolic-acid
Antimutagenic: (-)-epicatechin, chlorogenic-acid, rutin, ursolic-acid
Antinitrosaminic: chlorogenic-acid
Antioxidant: (-)-epicatechin, campesterol, chlorogenic-acid, isorhynchophylline, oleanolic-acid, rhynchophylline, rutin, ursolic-acid
Antiperoxidant: (-)-epicatechin, chlorogenic-acid, oleanolic-acid, rutin, ursolic-acid

Antiproliferant: rutin
Antiproliferative: ursolic-acid
Antisarcomic: oleanolic-acid
Antithromboxane: ursolic-acid
Antitumor: chlorogenic-acid, oleanolic-acid, pteropodine, rutin, ursolic-acid
Antitumor-Promoter: chlorogenic-acid, rutin, ursolic-acid
Antiviral: (-)-epicatechin, chlorogenic-acid, oleanolic-acid, rutin, ursolic-acid
Apoptotic: rutin
Beta-Glucuronidase-Inhibitor: oleanolic-acid, ursolic-acid
COX-2-Inhibitor: oleanolic-acid, ursolic-acid
Cancer-Preventive: (-)-epicatechin, chlorogenic-acid, oleanolic-acid, rutin, ursolic-acid
Chemopreventive: chlorogenic-acid, rutin
Cyclooxygenase-Inhibitor: oleanolic-acid, ursolic-acid
Cytoprotective: rutin
Cytotoxic: (-)-epicatechin, pteropodine, ursolic-acid
Hepatoprotective: chlorogenic-acid, oleanolic-acid, rutin, ursolic-acid
Hypocholesterolemic: (-)-epicatechin, campesterol, rutin
Immunostimulant: (-)-epicatechin, alloisopteropodine, allopteropodine, chlorogenic-acid, isomitraphylline, isopteropodine, isorhynchophylline, mitraphylline
Interferonogenic: chlorogenic-acid
Leucocytogenic: oleanolic-acid, ursolic-acid
Lipoxygenase-Inhibitor: (-)-epicatechin, chlorogenic-acid, rutin, ursolic-acid
Ornithine-Decarboxylase-Inhibitor: chlorogenic-acid, ursolic-acid
Protease-Inhibitor: ursolic-acid
Reverse-Transcriptase-Inhibitor: (-)-epicatechin
Sunscreen: chlorogenic-acid, rutin
Topoisomerase-II-Inhibitor: rutin

APPENDIX III: HERB-DRUG COMPARISONS

Almonds vs. Cardiopathic Drugs for Cardiopathy

Almug (Pterocarpus santalinus) vs. Vioxx for Colon Cancer

Aloe vs. Benzocaine or Lidocaine + Bactine for Burns

Apricot Pits vs. Laetrile for Cancer

Balm of Gilead vs. Benzaepil (Lotensin) for Hypertension (aqueous extract of Commiphora opobalsamum (4 mg/kg iv) depressed systemic arterial blood pressure by 20% ($P < 0.01$) and reduced heart rate of anaesthetised rats by 14%) (X9292417)

Barley bread (w beans, fitches, lentils, millet and wheat) vs. lipitor for hypercholestrolemia

Biblical Mint vs. Cognex for Alzheimer's Disease (AD) (See papers by N. Perry on other mint species)

Biblical Rose (Narcissus) vs. Galanthamine for Alzheimer's

Biblical Wormwood vs. Antimony for Leishmaniasis ess. oil at 2 ug/ml; aqueous extract at 4 ug/ml (X11346978);

Black cumin vs. Claritin for Hay Fever (X14669258)

Black cumin's thymoquinone vs. Pharm.Antiseptics for Sepsis (Lai and Roy, 2004)

Black cumin's thymoquinone for Cancer (Lai and Roy, 2004)

Bramble vs. Aspirin for Pain (X 14522443)

Brier (Solanum incanum) vs. "Curaderm" (solasodine + salicylic acid) for Skin Cancer

Butcher's Broom vs. Preparation H for Hemorrhoids

Capers vs. Tolbutamid for Diabetes (aqueous extracts have potent anti-hyperglycemic activity in rats; without affecting basal plasma insulin concentrations. X15261975)

Carob vs. Imodium (Loperimide) for Diarrhea

Cassia (Saussurea) vs. Antibiotics for Tuberculosis (JNP61:1181)

Chickpea (a/o lentil) vs. HRT for Prevention of Cardiopathy and Osteoporosis

Chicory(Prebiotic) and Lactobacillus (Probiotic) vs. Cipro for Bladder Infections

Cinnamon vs. Avandia or Tolbutamid (Orinase) for Diabetes

Coriander vs. Chelation for Lead and Mercury Overdose (Ess. Oil comparable to sorbic acid at preventing the slimy spoilage of Vienna sausage. (Nakatani, 1994))

Cotton's gossypol vs.. Unknown Pharms as Reversible Male Contraceptive

Cumin vs. Glibenclamide for Diabetes mellitus (X12220968) (antimelanomic farnesol and perillaldehyde; anticancer beta-elemene, eugenol, limonene, alpha-pinene, and linalool)

Dandelion vs. Interferon for Hepatitis

Date Palm vs. Amphotericin B for Candidiasis (" Tackholm and Drar (1973) report that pollen of a male date palm mixed with water is a charm against childlessness.[Pollen contains estrone, like pomegranate fruits)

Dill vs. Simethicone for Gas

Faba Beans vs. Pharm LevaDopa for Parkinson's

Faba Bean, Grape , Garlic, Lentils (Chickpea), Olive Oil, Onion (Biblical Diet) for Cardiopathy,

Fenugreek vs.. Silicone for Micromastia

Fenugreek vs. Lipitor for High Cholesterol

Fenugreek: Fennel (3:1) (Hildegard's suggestion for cancer of the penis) followed by beer barley cakes (Substitute dill with anethole for the fennel)

Fig (and Benzaldehyde) vs. Laetrile for Cancer (Kings ii)

Flax vs. Etoposide for Cancer

Flaxseed vs.. Fluoxetine (Prozac) or Sertraline (Zoloft) for Depression (for vegetarians)

Frankincense vs. Celebrex for Arthritis (In the Bible, Frankincense is mentioned 16 times for worship, 3 times in Solomon's garden, twice as a tribute of honor, and only once as merchandise.

Garlic vs. Chemo for Cancer

Garlic vs. Ciprofloxacin (Cipro) for Bladder Infection (if not Anthrax)

Garlic vs. Zocor for High Cholesterol (and Alzheimer's via antiamyloid activity (X 15277073)

Grapeseed vs. Pharms for cardiopathy, diabetes, enteroparasites, fibromyalgia, gout, parkinsons (See White et al; Herbal Drug Store)

Henna vs. Benadryl for Poison Ivy

Ivyleaf Extract (Prospan) vs. Robitussin for Bronchitis (X12725580) (X12006725:

Juniper vs. Etoposide for Cancer

Laurel vs. Sumatriptan for Migraine

Lentils vs. Zocor for High Cholesterol

Lettuce(seed oil) vs. Diazepam (Valium) for Insomnia (FT67:215)

Madonna Lily vs. Nystatin for Candidiasis (Bulb extract more active than flower extract;e isolated compounds were inactive. X12501491)

Mallows vs. Robitussin for Bronchitis (2 in CR2)

Mandrake (dangerous) vs. Transdermal Scopolamine for Vertigo:

Milkthistle vs. Silymarin Interferon for Hepatosis

Mustard (better horseradish, but not mentioned per se in the Bible) vs. Dristan for Sinusitis

Myrrh vs. Synthroid for Hypothyroidism

Myrtle Oil vs. Glibenclamide for Diabetes mellitus (X15234770)

Nettle vs. Claritin for Hay Fever

Nettle vs. Celebrex for Arthralgia (British clinical studies show improvement)

Olive Oil vs. Zocor for High Cholesterol

Onion vs. Pharms for Diabetes

Pomegranate vs. HRT for Syndome X (Clinical trials for the latter; Herb Clip43832)

Poppy vs. Percoset for Pain

Rocket (Oroth of Kings 2) vs. Lorenzo's Oil for Adrenoleukodystrophy Adrenomyeloneuropathy .

Rue (Homeopathic) vs. Pharms for Neurocysticercosis (X11317525)

Russian olive vs. Pharms for Prostate Cancer Prevention

Saffron vs. Pharms for Cancer Prevention (Lai and Roy, 2004; X15239370)

Spikenard vs. Ritalin for Hyperkiness (Attention Deficit Disorder (MPI)

Sweetcane (Pure sugar) vs. Honey a/oPropolis for Topical Infections

Tares (dangerous ergotized grass) vs. Ergotamine (Ergostat) for Headache

Thorn (Ziziphus) vs. Imodium for Diarrhea (X 11167035; X 12826300)

Turmeric vs. Celebrex for Arthritis and Colon Cancer Prevention

Turmeric vs. Pharms for Cancer Prevention (Lai and Roy, 2004)

Walnut Oil vs. Fish Oil (and Suicidogenic Antidepressants Pharms) for Mania

Walnut Oil vs. Zocor for High Cholesterol (X12934760)

Watercress vs. Celebrex for Colon Cancer

Watermelon's Lycopene vs. Pharms for Prostate Cancer Prevention

Willow vs. Aspirin for Backache (X12017748)

APPENDICES IV & V: ADDITIONAL HERB/DRUG CONTRASTS FOR PLANTS THAT MIGHT BE CONSIDERED SPICES OR CULINARY HERBS

Commiphora myrrha - Myrrh - Hypothyroidism - l-Thyroxine [[Possibly equivalent]]

Coriandrum sativum - Coriander -Mercury Chelation - purified sulfur oxide [[Neither very promising but coriander probably safer]]

** Crocus sativus -Saffron -Moderate Depression - imipramine [[(30 mg saffron = 100 mg/imprimaaine). But walnut oil, saffron, and turmeric a triple Biblical whammy]]

Cuminum cyminum - Cumin - Diabetes - Cuminaldehyde = ½ acarbose (a-glucosidaseinhibitor) [[Probably equivalent]]

* Curcuma longa - Turmeric - Arthritis - Celebrex [[I'd bet on turmeric]]

Eruca sativa - Rocket - Adrenoleukodystrophy - Lorenzo's Oil [[Neither to get excited about]]

Ferula gummosa - Galbanum - Bacterial Sepsis - Antibiotics (X15567258); [[Possibly equivalent]]

Gossypium herbaceum - Levant Cotton - Male Contraceptive (Gossypol) – NAPA [[Works but dangerous]]

* Juniperus communis - Cedar- Condylomata -(Podophyllotoxin) Podophyllin [Juniper contains he same podophyllotoxin that is in mayapple, whose resin is prescribed for condylomata, and though topical and approved, kills a few people]]

Laurus nobilis - Bayleaf - Migraine - Sumatriptan [[Bay contains some of the same parthenolides as the efficacious feverfew, which needs to be compared with sumatriptan]]

Mentha longifolia - Biblical Mint - Alzheimer's -Cognex [[Biblical Mint contains nearly a dozen acetylcholinesterase inhibitors, Cognex and Aricept, the pharmaceuticals, are one AChEI's.]]

Myrtus communis - Myrtle - Edema - Oxyphenylbutazone

Nardostachys jatamansi - Spikenard - Hyperkinesis - D-amphetamine (or chlorpromazine) [[Neither herbal or pharmaceutical seem to be doing much good]]

Nigella sativa -Black Cumin - Asthma - Albuterol [[Probably equivalent]]

Origanum syriacum - Lebanese Oregano - Backache - Percoset [[Possibly equivalent]]

**Papaver somniferum - Poppy - Cough - Contac [[Codeine in the poppy is probably one of the worlds best antitussives]]

Prunus dulcis - Almond - Cancer - Laetrile [[almonds, especially bitter almonds, contain compounds like laetrile]]

Ruta chalepensis - Fringed Rue - Insect Repellent - Deet [[Possibly equivalent]]

**Silybum marianum - Milk Thistle - Hepatitis C - Interferon [[Both have proven useful but never compared to my knowledge]]

Sinapis arvensis - Charlock - Sinusitis - Sudafed [[Probably equivalent]]

*Trigonella foenum-graecum - Fenugreek- Alactea - NAPA [[Fenugreek will increase milk production and even increase the size of the boobs]]

Urtica dioica - Nettle - Hay Fever -Dristan [[Probably equivalent; only one weak trial of nettle]]

Vitis vinifera - Grape - Chemopreventive - Tamoxifen [[Probably equivalent; Biblical Bean, not exactly a spice, might be better]].....

** Biblical Bean [[Vicia faba and fenugreek contains the same pharmaceutical l-dopa prescribed for Parkinsons]]

Appendix 1

In the Matter of
Assessing Consumer Perceptions of Health Claims;
Public Meeting; Request for Comments

Docket No. 2005N-0413

January 17, 2006

Comments of the Staff of
the Bureau of Economics,
the Bureau of Consumer Protection,
and the Office of Policy Planning
of the Federal Trade Commission

BEFORE THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

In the Matter of
Assessing Consumer Perceptions of Health Claims;
Public Meeting; Request for Comments

Docket No. 2005N-0413

Comments of the Staff of
the Bureau of Economics,
the Bureau of Consumer Protection,
and the Office of Policy Planning
of the Federal Trade Commission

January 17, 2006*

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*These comments represent the views of the staff of the Bureau of Economics, the Bureau of Consumer Protection, and the Office of Policy Planning of the Federal Trade Commission. They do not necessarily represent the views of the Federal Trade Commission or any individual Commissioner. The Commission has, however, voted to authorize the staff to submit these comments. Questions or comments concerning this document may be addressed to Dennis Murphy (202-326-3524 or dmurphy@ftc.gov) or Pauline Ippolito (202-326-3447 or pippolito@ftc.gov) in the Bureau of Economics.

I. Introduction

On November 17, 2005, the Food and Drug Administration ("FDA") held a public meeting to present findings of five recent studies of consumer perceptions of qualified and unqualified health claims for conventional foods and dietary supplements. In the meeting announcement, FDA also sought public comment on (1) available research and the implications of the research for further consumer studies and (2) other approaches that might convey effectively to consumers the strength of science supporting health claims.[1] The staff of the Federal Trade Commission's Bureau of Economics, Bureau of Consumer Protection, and Office of Policy Planning ("FTC staff") is pleased to submit this comment in response to FDA's request for public comment.

In this comment, the FTC staff identifies five findings from the studies that may help guide future research in this area. These findings are: (1) Current FDA language for qualified and unqualified claims does not communicate the intended levels of scientific certainty to consumers; (2) The current language the FDA uses to communicate an unqualified Significant Scientific Agreement claim does not convey strong scientific certainty to consumers; (3) The FTC staff's research indicates that language may be crafted that will differentiate clearly among differing levels of scientific certainty; (4) The "report card" formats perform consistently well in ranking scientific certainty; and (5) Consumer interpretation of the individual qualified claims that researchers have tested varies widely. The comment then suggests several ways in which researchers might build on these findings.

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[1] Assessing Consumer Perceptions of Health Claims; Public Meeting; Request for Comments, Docket No. 2005N-0413, 70 Fed. Reg. 60749, 60750-51 (Oct. 19, 2005) (hereinafter "FDA Public Meeting").

A. The FDA Approach to Regulating Qualified Health Claims

The FDA currently evaluates the scientific evidence supporting health claims in food and dietary supplement labeling pursuant to an interim process using a four level system.[2] Level "A" health claims are *unqualified* claims for which there is "significant scientific agreement" ("SSA") that the diet-disease relationship is valid. Levels "B", "C", and "D" claims correspond to *qualified* health claims for which the level of comfort regarding the scientific support for a given diet-disease relationship is progressively weaker.[3]

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[2] FDA statutes and regulations permit health claims on labels for both food and dietary supplements if they are supported by "significant scientific agreement" ("SSA") among qualified experts based on publicly available scientific evidence. 21 U.S.C. 343(r)(1)(B); 21 C.F.R. 101.14(a)(1) and (2). In 1999, the U.S. Court of Appeals for the D.C. Circuit considered a constitutional challenge to the FDA's denial of four health claims for dietary supplements that were not supported by SSA. *See Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999). The FDA asserted that it could prohibit these claims because they had the potential to mislead consumers, but the court rejected this argument. The court held that the FDA had violated the First Amendment by denying these claims without proof that disclosures would not have sufficed to cure the potential for deception. After the *Pearson* decision and another related case, *Whitaker v. Thompson*, 248 F.Supp.2d 1 (D.D.C. 2002)), the FDA adopted an interim process that allows marketers to convey truthful, non-misleading health claims for both foods and dietary supplements that indicate the level of scientific support for the claim.

[3] *Guidance for Industry and FDA: Interim Evidence-based Ranking System for Scientific Data*, 68 Fed. Reg. 41387 (July 11, 2003); *Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements*, 68 Fed. Reg. 41387 (July 11, 2003).

Examples of FDA SSA and Qualified Health Claims

FDA Scientific Ranking[4]	Health Claim Statement
Level A (SSA standard - high level of comfort)	"Diets rich in calcium may reduce the risk of osteoporosis."
Level B (moderate/good level of comfort)	"Omega-3 fatty acids may reduce the risk of heart disease **but the scientific evidence is promising but not conclusive.**"
Level C (low level of comfort)	"A diet high in selenium may reduce the risk of cancer **but the scientific evidence is limited and inconclusive.**"
Level D (extremely low level of comfort)	"The antioxidant lycopene may reduce the risk of certain cancers, including prostate cancer in men, **but the scientific evidence is very limited and preliminary.**"

FDA's recent consumer research tested the "B", "C", and "D" level health claims in the chart above, and a slightly shortened version of the SSA claim.[5]

B. Research Presented at the November Meeting

At the meeting, FDA presented the findings of its copy test of 1,920 consumers, which examined the performance of health claims in labeling for four fictional food products using two language-only formats and two "report card" formats.[6] The International Food Information

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[4] Descriptions of FDA scientific rankings from *Guidance for Industry and FDA: Interim Evidence-based Ranking System for Scientific Data* and *Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements*, *supra* note 3.

[5] Brenda M. Derby & Alan S. Levy, *Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims* 8-10 (U.S. Food and Drug Administration, Working Paper No. 1, 2005).

[6] *Id. See also* Brenda M. Derby & Alan S. Levy, *Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims* (Nov. 17, 2005) (slide presentation at FDA Public Meeting), *available at* http://www.fda.gov/ohrms/dockets/dockets/05n0413/05n-0413-ts00004-Derby.pdf.

Council ("IFIC") Foundation presented findings of an internet-based survey of 5,642 consumers, which tested the same health claim formats as those examined by FDA.[7] Staff of the Federal Trade Commission ("FTC") discussed findings from a series of copy tests dating back to 1998. This research, which involved approximately 1300 consumers, tested qualified health claims in print advertising.[8] Ratapol P. Teratanavat and Neal H. Hooker ("Teratanavat-Hooker"), researchers from The Ohio State University, discussed two computer-based experiments that studied how a sample of 372 college students interpreted qualified and unqualified health claims in food product labeling.[9] Finally, Karen Russo France and Paula Fitzgerald Bone ("France-Bone"), faculty members at West Virginia University, presented findings from copy test research of 359 consumers who examined one unqualified and one qualified "B" level health claim on the labels of two fictional dietary supplements.[10]

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[7] IFIC Foundation, Qualified Health Claims Consumer Research Project Executive Summary (Mar. 2005), *available at* http://www.ific.org/research/qualhealthclaimsres.cfm. *See also* Wendy Reinhardt Kapsak, *Assessing Consumers' Perceptions of Health Claims* (Nov. 17, 2005) (slide presentation at FDA Public Meeting), *available at* http://www.fda.gov/ohrms/dockets/dockets/05n0413/05n-0413-ts00006-kapsak.pdf.

[8] Dennis Murphy *et al.*, *A Generic Copy Test of Food Health Claims in Advertising*, Federal Trade Commission (1998); R. Dennis Murphy, *Consumer Perceptions of Qualified Health Claims in Advertising* (Federal Trade Commission, Working Paper No. 277, 2005). *See also* Pauline M. Ippolito, *Qualified Health Claims* (Nov. 17, 2005) (slide presentation at FDA Public Meeting), *available at* http://www.fda.gov/ohrms/dockets/dockets/05n0413/05n-0413-ts00005-ippolito.pdf.

[9] Neal H. Hooker, *Do People Understand Qualified Health Claims? Evidence from Experimental Studies* (2005) (manuscript on file with Ohio State University). *See also* Neal H. Hooker & Ratapol P. Teratanavat, *Qualified Health Claims: Food for Thought?* (Nov. 17, 2005) (slide presentation at FDA Public Meeting), *available at* http://www.fda.gov/ohrms/dockets/dockets/05n0413/05n-0413-ts00008-hooker.pdf.

[10] Karen Russo France & Paula Fitzgerald Bone, *Policy Makers' Paradigms and Evidence from Consumer Interpretations of Dietary Supplement Labels*, 39 J. CONSUMER

II. FTC Experience

The FTC has significant expertise in food and dietary supplement advertising and labeling issues. The FTC enforces the Federal Trade Commission Act,[11] which prohibits deceptive or unfair acts or practices in or affecting commerce.[12] A high priority of the FTC is bringing law enforcement actions to prevent deceptive claims in health-related advertising.[13] The Commission strives to achieve this goal in a manner that will not impose unduly burdensome

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AFFAIRS 27 (2005). *See also* Karen Russo France & Paula Fitzgerald Bone, *Policy Makers' Paradigms and Evidence from Consumer Interpretations of Dietary Supplement Labels* (Nov. 17, 2005) (slide presentation at FDA Public Meeting), *available at* http://www.fda.gov/ohrms/dockets/dockets/05n0413/05n-0413-ts00007-France.pdf.

[11] 15 U.S.C. § 45 *et seq.*

[12] *Id.* The FTC and the FDA have overlapping jurisdiction to regulate the advertising, labeling, and promotion of foods, over-the-counter drugs, cosmetics, and medical devices. Under a long-standing liaison agreement between the agencies, the FDA exercises primary responsibility for regulating the labeling of these products, and the FTC has primary responsibility for ensuring the advertising of these products is truthful and not misleading. Working Agreement Between FTC and FDA, 4 Trade Reg. Rep. (CCH) ¶ 9,850.01 (1971).

[13] For example, the FTC has brought law enforcement actions against food companies that allegedly made deceptive claims about the health benefits of their products. *See, e.g., Tropicana Products, Inc.*, C-4145 (Aug. 19, 2005) (consent order); *KFC Corp.*, C-4118 (Sept. 17, 2004) (consent order). *See also Comments of the Staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office of Policy Planning of the FTC in the Matter of Request for Comments on Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims; Reopening of the Comment Period*, Docket Nos. 1994P-0390 and 1995P-0241, at 3 (July 27, 2004); *Comments of the Staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office of Policy Planning of the FTC in the Matter of Food Labeling: Health Claims; Dietary Guidance*, Docket No. 2003-0496, at 4 (Jan. 26, 2004).

restrictions that might chill information useful to consumers in making purchasing decisions.[14]

Likewise, FTC staff has studied the effect of advertising regulation on consumers and competition[15] and has examined the role of advertising in communicating health information to consumers.[16] As noted above, since 1998 FTC staff has conducted extensive consumer survey research on qualified health claims, including advertising copy tests on over 1,300 consumers, to study which types of qualifying language most effectively convey limitations in scientific support for diet-disease relationships.

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[14] *See, e.g.*, FTC Policy Statement Regarding Advertising Substantiation, appended to *Thompson Medical Co.*, 104 F.T.C. 648, 839 (1984) (substantiation factors include benefits of a truthful claim and costs of a false claim, thus balancing the goal of preventing deception with the need to ensure access to truthful information and vigorous competition).

[15] *See* Pauline Ippolito & Janis Pappalardo, *Advertising Nutrition & Health: Evidence from Food Advertising 1977-1997*, FTC Staff Report (2002); Pauline Ippolito & Alan Mathios, *Information and Advertising Policy: A Study of Fat and Cholesterol Consumption in the United States, 1977-1990*, FTC Staff Report (1996); Pauline Ippolito & Alan Mathios, *Health Claims in Advertising and Labeling: A Study of the Cereal Market*, FTC Staff Report (1989); John Calfee & Janis Pappalardo, *How Should Health Claims for Foods Be Regulated? An Economic Perspective*, FTC Staff Report (1989).

[16] Murphy *et al.* (1998) and Murphy (2005), *supra* note 8.

Finally, FTC staff has commented on several FDA food advertising and labeling issues[17] and participated on the Task Force on Consumer Health Information for Better Nutrition, which formulated recommendations on FDA's proposed regulatory approach to qualified health claims.

Based on its experience and research in this area, FTC staff submits this comment in response to FDA's request for public comment on the implications of available research for future research on qualified health claims. The comment first presents what we believe to be principal findings of the research presented at the November meeting and then discusses possible ways in which further research on health claims might build on these findings.

III. Principal Findings of Research Presented at the Public Meeting

Our review of the five studies presented at the public meeting has identified at least five findings that may have important implications for future research. Many of these findings are common to most or even all of the studies, and therefore should be considered robust.

Finding #1: The current FDA language for qualified and unqualified claims does not communicate the four intended levels of scientific certainty to consumers.

All of the studies tested examples of language that FDA has approved tentatively for qualified health claims in labeling. Four of the five studies tested FDA claims that spanned more

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[17] *See, e.g., Comments of the Staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office of Policy Planning of the FTC in the Matter of Food Labeling: Health Claims; Dietary Guidance*, Docket No. 2003-0496 (Jan. 26, 2004); *Comments of the Staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office of Policy Planning of the FTC in the Matter of Obesity Working Group; Public Workshop: Exploring the Link Between Weight Management and Food Labels and Packaging*, Docket No. 2003N-0338 (Dec. 12, 2003); *Comments of the Staff of the Bureau of Economics, the Bureau of Consumer Protection, and the Office of Policy Planning of the FTC in the Matter of Food Labeling: Trans Fatty Acids in Nutrition Labeling: Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote on Disclosure Statements*, Docket No. 03N-0076 (Oct. 9, 2003).

than one level of scientific certainty. These "language-only" claims do not employ any symbols or letter grades to describe the level of certainty the claim is intended to communicate. The IFIC and FDA studies tested the largest number and broadest range of these claims.

The IFIC research included a "sorting" exercise that produced strong evidence that the current FDA language does not function as intended. In this experiment, consumers compared four of the FDA claims, one from each of the four levels of scientific certainty ("A" through "D"). Only 22 percent of the participants could sort the four claims in the correct order of scientific certainty.[18]

The more formal copy test portions of the FDA and IFIC studies asked respondents to rate the scientific certainty conveyed by a given claim on a 7-point scale that ranged from (1) "very uncertain" to (7) "very certain." Unlike the IFIC sorting exercise, in these tests different groups of consumers saw different claims and could not compare the language side by side. Neither study found a statistically significant relationship between the average certainty scores that respondents gave the various claims and the level of certainty the claims were intended to convey.[19] That is, consumers who saw a label with a higher level FDA claim did not on average choose scores that were higher than scores chosen by consumers who saw a lower level FDA claim. In the Teratanavat-Hooker research, the average certainty ratings that college students assigned to an FDA unqualified "A" health claim did not differ significantly from the average

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[18] IFIC Foundation (Mar. 2005), *supra* note 7, at 5. Further, one-third of the consumers rated the "D" claim (weakest science) as conveying the highest level of certainty.

[19] Derby & Levy, *supra* note 5, at 21; IFIC Foundation (Mar. 2005), *supra* note 7, at 5-8.

rating given an FDA "D" level claim.[20] Finally, in the France-Bone study, participants did not rate an FDA "A" claim as more certain than an FDA "B" claim.[21] In short, these results suggest that the current FDA language for qualified claims does not distinguish adequately between the levels of science supporting these claims.

Finding #2: Consumers do not perceive the current FDA SSA claim to convey strong scientific certainty.

Research to date has found consistently that consumers believe that SSA claims are supported by less science than is in fact the case.[22] This discounting of what is intended to be the strongest claim available in labeling greatly increases the difficulty of crafting qualified claims that differentiate varying levels of scientific certainty below the level of significant scientific agreement.

Evidence of this discounting can be found in all of the studies that conducted relevant tests. In the FDA study, the average scientific certainty score for the various SSA claims ranged from 3.9 to 4.8 on a 7-point scale.[23] The IFIC study findings are similar.[24] The Teratanavat-Hooker study recorded an average certainty rating of 4.11 out of a possible seven points for the

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[20] Hooker, *supra* note 9, at 19.

[21] France & Bone, *supra* note 10, at 45.

[22] The format for this claim is: "Diets rich in substance X may reduce the risk of disease Y."

[23] Analysis is based on data provided to FTC staff by FDA staff. Removing the "may" from this claim made very little difference in the certainty scores. The maximum average score achieved was still was only about 4.8.

[24] Again, the highest average rating for the SSA claim was 4.8 and the lowest recorded average score was only 2.8 out of a possible seven points. (Analysis is based on data provided to FTC staff by IFIC staff.)

FDA SSA claim.[25] Finally, the average certainty scores in the France-Bone study for the two tested FDA SSA claims were 3.5 and 4.0 on a six-point scale.[26]

In part, these scores may reflect basic consumer skepticism of promotional claims, however worded.[27] As we detail below, however, consumers gave higher certainty ratings to other approaches to unqualified claims, including a strongly worded "proof" claim used in FTC staff's copy test research and a "report card" format claim tested in the IFIC study.

Finding #3: The results of the FTC staff's copy tests indicate that it is possible to craft language that differentiates clearly among differing levels of scientific certainty.

During the past 10 years, the FTC staff has conducted a series of four copy tests of qualified health claims in advertising. These tests incorporated several approaches to measuring consumer perception of the degree of support for a qualified health claim, including a 5-level rating scale in the early tests and a 7-point scale in the most recent research. Over the course of this research, FTC staff tested four levels of health claims – one unqualified claim and three successively more qualified claims – all appearing in print ads for a fictional antioxidant vitamin supplement. The unqualified claim, referenced hereafter as the "proof" claim, used very strong language to convey a high level of scientific certainty for the efficacy of antioxidant vitamins in reducing the risk of cancer. The relevant portion of the text stated:

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[25] Hooker, *supra* note 9, at 35.

[26] France & Bone, *supra* note 10, at 44 (Table 2, Cell 2).

[27] *See, e.g.*., Calfee, J.E., & Ringold, D.J., *The Seventy Percent Majority: Enduring Consumer Beliefs about Advertising,* 13 J. PUBLIC POLICY AND MARKETING: 228-238 (1994).

> Scientists have now proven that supplements containing these same antioxidant vitamins also reduce the risk of cancer. It's a fact!

Although this claim very likely overstates the degree of certainty scientists would accord a diet-disease relationship, it was included for experimental purposes in the early testing to provide a firm basis for determining whether it was feasible to devise qualifying language that could communicate a lower level of certainty to consumers.[28] A "mildly" qualified claim used language intended to convey a "weight-of-the-evidence" level claim similar to FDA's current "B" level claim.[29] The qualifying language stated that the evidence "looks promising, but scientists won't be sure until longer term research is completed." A stronger "qualified" claim cautioned that:

> It's too early to tell for sure. Some studies have failed to show that these vitamins protect against cancer. Longer term research is needed.

Finally, the most recent FTC staff copy tests included a more highly qualified "Box Disclaimer" advertisement that contained the following disclaimer set off inside a box:

> There is much scientific debate about whether antioxidant vitamin supplements reduce the risk of some kinds of cancer. Most studies have failed to show that these vitamin supplements reduce the risk of cancer.

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[28] Had the results shown no significant difference between consumer interpretation of this proof claim and the qualified claims, we could have concluded with some certainty that attempts to qualify health claims are unlikely to be effective.

[29] At the time this claim was first tested in 1998, the science supporting the relationship between antioxidant vitamin supplements and a reduced cancer risk arguably could have been rated at a level "B." Over the course of the FTC's series of copy tests, however, the science weakened to a "C" level.

Figure 1 shows the average certainty scores that respondents assigned to these claims using a 5-point scale.[30] On average, consumers were able to discern clear differences in the level of certainty communicated by these claims. As intended, the average certainty scores decline consistently as the level of intended qualification increases, *i.e.*, as the science becomes less certain. It is also clear from comparing the results for the proof and mildly qualified claim that even a small degree of qualification can reduce consumers' certainty ratings substantially. [31]

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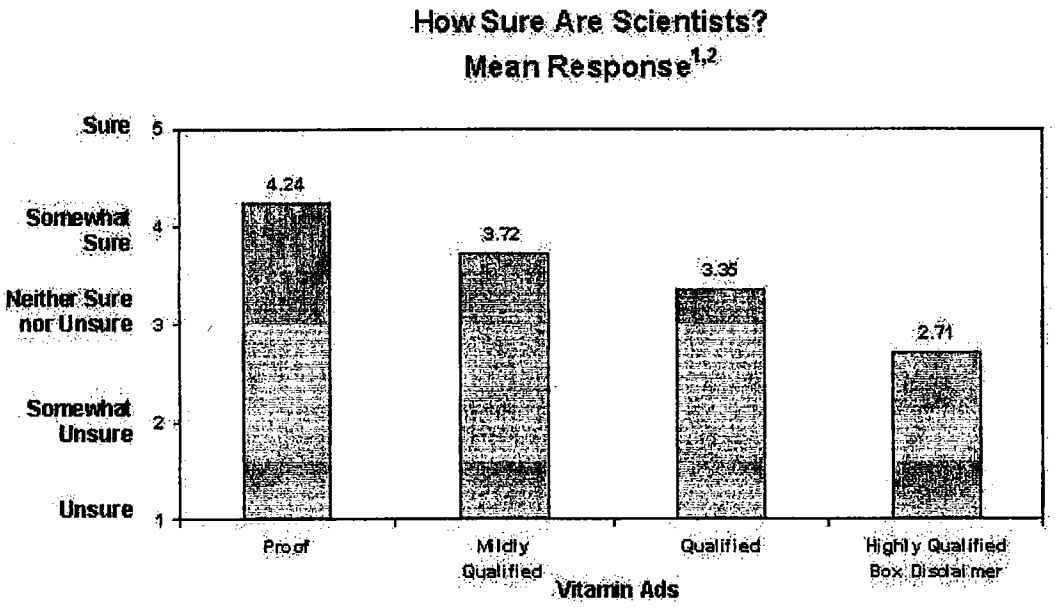
[30] Murphy (2005), *supra* note 8 at 22. The mean score for the Highly Qualified Box Disclaimer is from an earlier unpublished copy test performed in July 2002.

[31] An analysis of the distribution of ratings across the five certainty choices shows that 58 percent of respondents seeing the proof claim thought that scientists were "sure" about the efficacy of antioxidant vitamin supplements, whereas only 22 percent of respondents seeing the mildly qualified claim thought that the science was "sure." For the qualified claim and the highly qualified box disclaimer test ads, the figures for "sure" were, respectively, ten percent and five percent.

Figure 1



[1] All differences are significant in one-tailed tests.

[2] Consumers were asked to rate certainty on a 1-5 scale as shown.

Finding #4: The "report card" formats performed consistently well on the ranking tests.

The report card approach to communicating scientific certainty uses a letter grade (from "A" to "D") rather than a verbal description to describe the certainty of the science supporting a given health claim. The FDA and IFIC studies used two formats to present the letter grade. In the "report card text" version, a health claim supported by, say, a "C" level of science is followed by the statement:

> FDA evaluated the scientific evidence and gave it a "C" rating, based on a scale from A (strongest evidence) to D (weakest evidence).

A second approach, called the "report card graphic," uses four levels of boxes with the appropriate box checked off. These boxes are labeled, from top to bottom: "A: Strong Evidence;" "B: Moderate Evidence;" "C: Some Evidence;" and "D: Little Evidence." Figure 2 presents an example of a "D" level report card graphic label used in the FDA copy test.[32]

In FDA's research, the average certainty scores for both versions of the report card format tracked the intended level of certainty for the "B" through "D" claims. FDA did not test an "A" level report card claim, but instead used a shortened version of the current language-only format for an SSA claim. ("Substance X may reduce the risk of disease Y.") Interestingly, the "B" level report card scores were consistently higher than the SSA claim scores, which may be another indication that the current unqualified language is not communicating a sufficiently high level of scientific certainty.[33]

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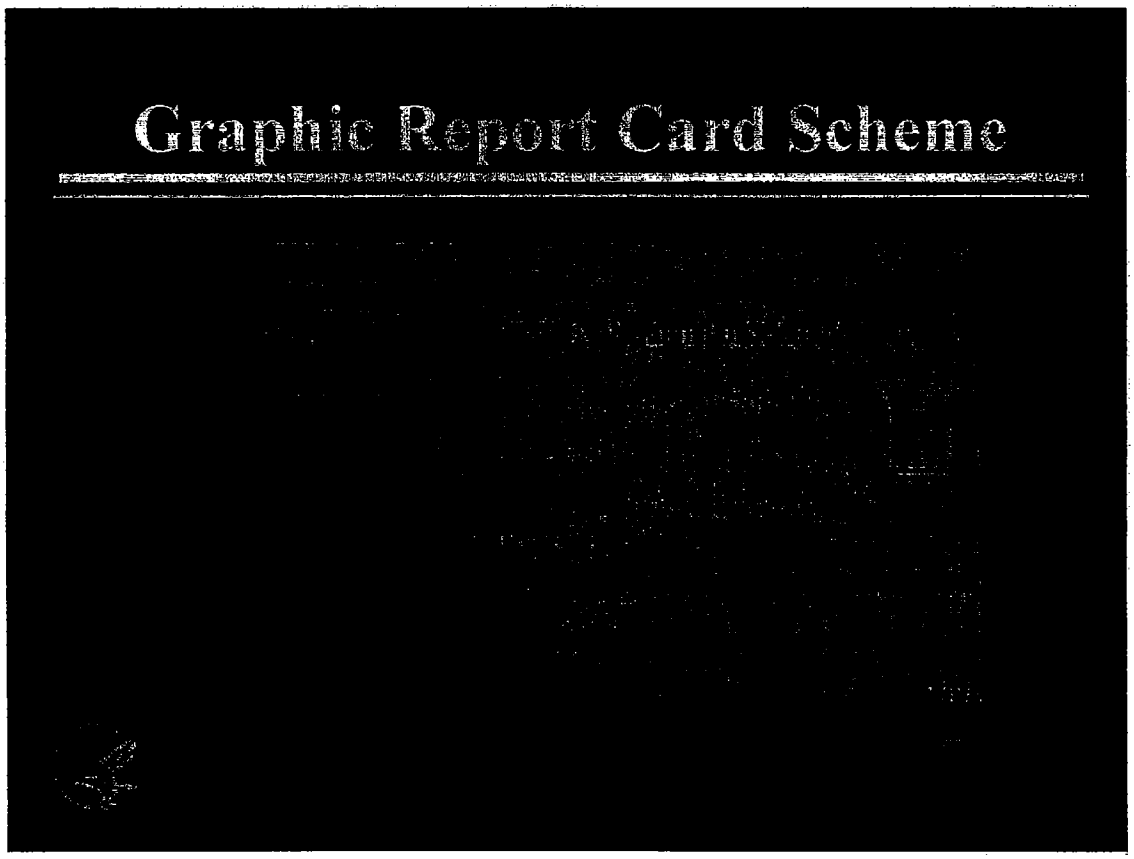
[32] Derby & Levy, *supra* note 6, at 10.

[33] Derby & Levy, *supra* note 5, at 23; Analysis is based on data supplied to FTC staff by FDA staff.

Figure 2



The IFIC research, which, unlike the FDA test, included report card formats for "A" level claims, found that consumers could distinguish reliably among the four levels of qualification when shown labels using the same report card graphic format used by the FDA. With the report card text format, respondents could distinguish between two levels (A-B and C-D).[34] In absolute terms, the Report Card "A" average certainty scores were consistently higher than the corresponding average language-only SSA claims.[35] Finally, the Teratanavat-Hooker study tested an "A" and "D" level report card graphic format in combination with the corresponding current FDA language-only claim, and also tested the current FDA language standing alone. Respondents could distinguish the claims when the report card graphic was included, but could not distinguish when the claim was presented in language form only.[36] Again consistent with the findings of other research, the mean certainty rating for the report card version of the unqualified health claim was significantly higher than for the FDA unqualified claim standing alone (5.02 vs. 4.11 on a 7-point scale).[37]

Finding #5: Consumer interpretation of qualifying language varies widely.

In its most recent research, the FTC staff tested three possible qualified claims for antioxidant vitamin supplements and a reduced risk of cancer, including the very strong "Box Disclaimer" discussed earlier. Consumers were asked "How certain is the evidence?" FTC staff used a 7-point scale for these ads. The average certainty scores for the three ads (3.33 to 4.04 on

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34 IFIC Foundation (Mar. 2005), *supra* note 7, at 6-7.

35 Data provided to FTC staff by IFIC staff.

36 Hooker, *supra* note 9, at 19 and graph at 38.

37 *Id.* at 35.

a 7-point scale) were at or below the midpoint of the scale, values that appear reasonable for a level of science that is below a weight-of-the-evidence standard. For any given claim, however, the scores that individual consumers chose did not cluster tightly around the average score. Instead, the choices were spread out across the scale.

As shown in Figure 3, an approximately equal proportion of consumers seeing the highly qualified Box Disclaimer chose option 1 (The science is "not at all certain"); option 3 (The science is "slightly certain"); and option 5 (The science is "somewhat certain.."). Further, one-third of the respondents rated the certainty of the science above the midpoint.[38] This suggests that these consumers may have overestimated the degree of scientific certainty for the antioxidant vitamin-cancer relationship, which, as indicated, is supported by less than the weight of the evidence.[39]

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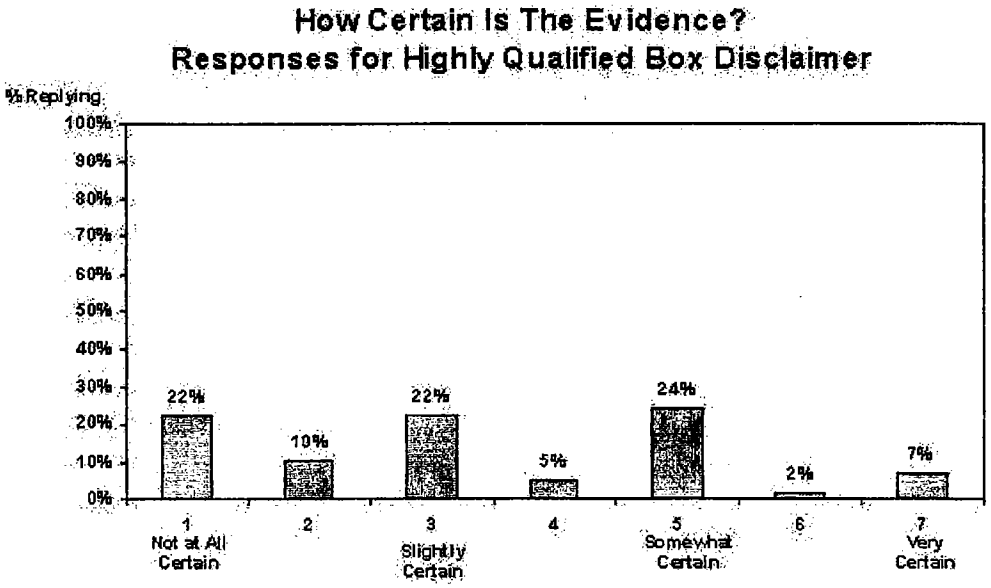
[38] Murphy (2005), *supra* note 8 at 29.

[39] Although some variation in consumer interpretation of qualified health claims is inevitable given what are almost certainly broad differences in respondents' background beliefs, the degree of variation observed in the research is nonetheless surprising, particularly for the heavily qualified claims, such as the Box Disclaimer, that incorporate very strong language intended to communicate a low level of certainty. It is possible that such a "disclaimer" runs counter to the basic efficacy claim being made for the product. Rather than qualifying the claim, the "disclaimer" may contradict it, leaving consumers in a difficult interpretative situation that is reflected in the wide variation in responses. *See* J. Howard Beales, Remarks Before the Food and Drug Law Institute's Conference on Qualified Health Claims, at 8-9 (Jan. 14, 2004), *available at* http://www.ftc.gov/speeches/beales/040114foodanddruglawinstitute.pdf.

Figure 3


How Certain Is The Evidence?
Responses for Highly Qualified Box Disclaimer
% Replying
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
22%
10%
22%
5%
24%
2%
7%
1
Not at All Certain
2
3
Slightly Certain
4
5
Somewhat Certain
6
7
Very Certain

The distributions for the scientific certainty ratings in the FDA's study also show wide variation in choices among consumers seeing the same label claim. This variation is evident for both the claims in language-only and report card format. For example, 40 percent of respondents seeing a Report Card Text "D" claim linking lycopene with a reduced risk of prostate cancer rated the certainty of the science at 5 or higher on the 7-point scale, and thus arguably were misled concerning the true level of scientific support. (Thirty-seven percent gave the science a score of 3 or lower, and the remainder (24%) chose the midpoint score of 4).[40] The results suggest that a qualified claim that, on average, communicates the correct level of scientific certainty may still mislead a substantial number of consumers.

IV. Implications for Future Research

The research findings discussed above have at least four implications for future research efforts on qualified health claims.

Implication #1: Other approaches to language-only claims should be explored.

Although the tested FDA language did not communicate differing levels of scientific support clearly, the results of FTC staff's copy tests suggest that it may be possible to craft language-only claims that do perform satisfactorily. As emphasized above, one difficulty with the FDA's current approach may be an insufficiently strong SSA claim. In particular, the SSA claim makes no mention of the high degree of scientific support for this class of diet-disease relationships.

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[40] We did not have access to the underlying data for the other studies presented at the November 17 meeting and could not determine the degree of variation in the individual scores in that research.

One possible solution to this problem would be to include an explicit description of the quality of the underlying evidence in each claim level. We show below an example of such a format using four levels of qualification. The FTC staff has not tested this language, and we provide the illustration only to stimulate thought on the type of language-only claims that might perform most effectively.

Claim Level	Claim
A.	Very strong evidence shows that a diet rich in substance X reduces the risk of disease Y.
B.	Promising evidence indicates that a diet rich in substance X reduces the risk of disease Y, but the evidence is not definite.
C.	Some evidence suggests that a diet rich in substance X may reduce the risk of disease Y, but the evidence is weak.
D.	Limited evidence suggests that a diet rich in substance X may reduce the risk of disease Y, but the evidence is very weak.

Implication #2: Additional approaches similar to the report card format should be tested.

As discussed, the various studies found that the report card format was largely successful in communicating differing levels of scientific certainty to consumers. One potential difficulty with this approach, however, is that letter grades currently appear on certain product labels as a measure of product quality, *e.g.*, Grade A turkey, eggs, and butter. Marketers might therefore be reluctant to use any scientific certainty score below an "A" for fear consumers would construe the grade too broadly as a negative statement about overall product quality.[41]

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[41] It should be noted, however, that relevant charts included in IFIC's November 17 presentation do not reveal strong evidence of any such undesirable "spillover" effects from the report card reporting system. These charts show, *inter alia*, the average ratings that consumers

The positive results for the report card format suggest that other simple scoring methods that do not rely on letter grades might also be successful and should be targeted for testing in future research projects. For example, certainty might be displayed on a thermometer-type scale, or perhaps using a system of stars, checkmarks, or numerical ratings. (The FDA may wish to consult with consumer education specialists in developing different ratings systems to test.) Alternatively, the letter grades might simply be removed from the report card graphic display, since the level of evidence corresponding to each box is already described in summary fashion (see Figure 2).

Implication #3: IFIC's "sort test" can help allocate research resources

As discussed, IFIC found that FDA's language-only claims could not pass a simple sorting test exercise where consumers saw all of the claims simultaneously and then attempted to rank the claims in the right order of intended scientific certainty. Relative to full copy tests, such a test is relatively inexpensive to perform and can quickly weed out claims that are unlikely to function as intended in subsequent formal copy testing. In particular, the sorting exercise will allow researchers to determine quickly whether other approaches to language-only claims should

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gave for product quality and safety when shown only a nutrient content claim (which is labeled "control" in the charts), and the corresponding ratings for the test conditions where consumers saw an explicit health claim in report card text or graphic format. There are no statistically significant differences between any of the quality or safety ratings in the report card conditions and those in the nutrient content test conditions. This lack of differences suggests that marketers could make an explicit health claim, rather than the less informative nutrient content claim, without any adverse repercussions on consumer perceptions of product quality or safety. *See* IFIC Foundation (Mar. 2005), *supra* note 7, slides 6 and 7, *available at* http://www.ific.org/research/upload/Slides.pdf.

be explored. Accordingly, researchers may wish to include such a sorting exercise as a preliminary component of studies in this area.

Implication #4: Future research should examine the degree of variation in certainty ratings for a given test condition.

It is important that any system for qualifying claims meet the threshold ranking test that requires average ratings of scientific certainty for the various testing conditions to decline as the degree of qualification increases. As we noted in our discussion of the FTC staff and FDA staff copy tests, however, a large proportion of respondents seeing the same claim frequently selected scores that were considerably above or below the average score. Even if the average rating is considered consistent with the actual level of scientific support for the claim, the qualified language might still mislead or confuse a substantial number of consumers.[42] A system of qualified claims that communicates the correct level of scientific certainty to a larger proportion of consumers would reduce this concern. Future researchers may wish, therefore, to address this issue explicitly.

V. Conclusion

The FDA is to be applauded for its important research on consumer interpretation of qualified health claims and for providing the opportunity for other researchers to present their findings in a public forum. The various studies have provided valuable insights into the performance of alternative approaches to conveying levels of scientific certainty in labeling and

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[42] The wide dispersion in ratings could also indicate that consumers were confused by the rating system itself. This issue might be explored in future research by using different rating systems to test the same claims. The degree of variation in responses found for each of the rating systems could then be compared to determine which rating system was easiest for consumers to understand.

advertising. In particular, the research suggests that FDA's current "language only" claims are not clearly communicating differences in scientific certainty. At the same time, certain findings indicate that it may be possible to craft language that will function more successfully in this regard.

Finally, the "report card" format was generally successful in communicating differences in scientific certainty, although a significant degree of disagreement was evident in consumer interpretation of the grades assigned to the claims. As discussed, these findings can help shape the next round of research in this important area of public policy.

Respectfully submitted,

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Michael A. Salinger, Director
Pauline Ippolito, Associate Director for Special Projects
Jesse Leary, Assistant Director, Division of Consumer Protection
Dennis Murphy, Economist, Division of Consumer Protection
Bureau of Economics

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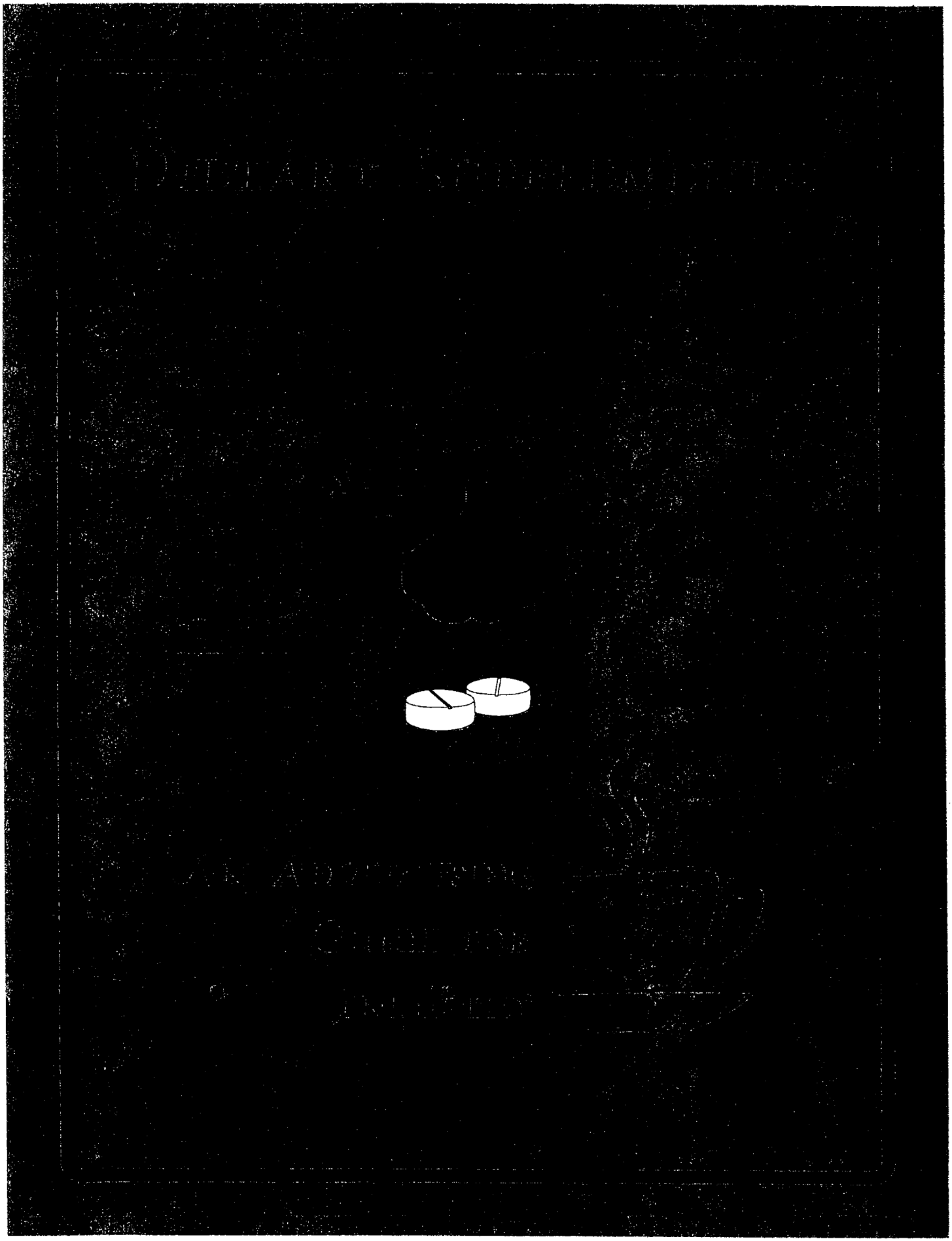
Appendix 2

Dietary Supplements:
An Advertising Guide for Industry

April 2001

Federal Trade Commission
Bureau of Consumer Protection



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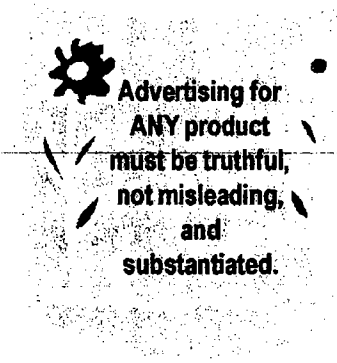
INTRODUCTION

The dietary supplement industry is a dynamic one. Scientific research on the associations between supplements and health is accumulating rapidly. The number of products — and the variety of uses for which they are promoted — have increased significantly in the last few years. The role of the Federal Trade Commission, which enforces laws outlawing "unfair or deceptive acts or practices," is to ensure that consumers get accurate information about dietary supplements so that they can make informed decisions about these products.[1]

The Federal Trade Commission (FTC) and the Food and Drug Administration (FDA) work together under a long-standing liaison agreement governing the division of responsibilities between the two agencies. As applied to dietary supplements, the FDA has primary responsibility for claims on product labeling, including packaging, inserts, and other promotional materials distributed at the point of sale. The FTC has primary responsibility for claims in advertising, including print and broadcast ads, infomercials, catalogs, and similar direct marketing materials. Marketing on the Internet is subject to regulation in the same fashion as promotions through any other media. Because of their shared jurisdiction, the two agencies work closely to ensure that their enforcement efforts are consistent to the fullest extent feasible.

In 1994, the Dietary Supplements Health and Education Act (DSHEA) significantly changed the FDA's role in regulating supplement labeling.[2] These claims are commonly referred to as "structure/function" claims.[3] Although DSHEA does not directly apply to advertising, it has generated many questions about the FTC's approach to dietary supplement advertising. The answer to these questions is that advertising for any product — including dietary supplements — must be truthful, not misleading, and substantiated. Given the dramatic increase in the volume and variety of dietary supplement advertising in recent years, FTC staff is issuing this guide to clarify how long-standing FTC policies and enforcement practices relate to dietary supplement advertising.



The FTC's approach to supplement advertising is best illustrated by its Enforcement Policy Statement on Food Advertising (Food Policy Statement). Although the Food Policy Statement does not specifically refer to supplements, the principles underlying the FTC's regulation of health claims in food advertising are relevant to the agency's approach to health claims in supplement advertising. In general, the FTC gives great deference to an FDA determination of whether there is adequate support for a health claim. Furthermore, the FTC and the FDA will generally arrive at the same conclusion when evaluating unqualified health claims. As the Food Policy Statement notes, however, there may

be certain limited instances when a carefully qualified health claim in advertising may be permissible under FTC law, in circumstances where it has not been authorized for labeling. However, supplement marketers are cautioned that the FTC will require both strong scientific support and careful presentation for such claims.[5]

Supplement marketers should ensure that anyone involved in promoting products is familiar with basic FTC advertising principles. The FTC has taken action not just against supplement manufacturers, but also, in appropriate circumstances, against ad agencies, distributors, retailers, catalog companies, infomercial producers and others involved in deceptive promotions. *Therefore, 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.*

APPLICATION OF FTC LAW TO DIETARY SUPPLEMENT ADVERTISING

The FTC's truth-in-advertising law can be boiled down to two common-sense propositions:

1) advertising must be truthful and not misleading; and
2) before disseminating an ad, advertisers must have adequate substantiation for all objective product claims.[6]

A deceptive ad is one that contains a misrepresentation or omission that is likely to mislead consumers acting reasonably under the circumstances to their detriment. The FTC's substantiation standard is a flexible one that depends on many factors. When evaluating claims about the efficacy and safety of foods, dietary supplements and drugs, the FTC has typically applied a substantiation standard of competent and reliable scientific evidence.

To determine whether an ad complies with FTC law, it is first necessary to identify all express and implied claims that the ad conveys to consumers. Once the claims are identified, the scientific evidence is assessed to determine whether there is adequate support for those claims. The following sections describe this two-step process with examples illustrating how principles of ad interpretation and substantiation apply in the context of dietary supplement advertising. The examples have been simplified to illustrate one or two specific points. Therefore, advertisers should use these examples as general guidance only.[7]

A. Identifying Claims and Interpreting Ad Meaning

1. Identifying Express and Implied Claims

The first step in evaluating the truthfulness and accuracy of advertising is to identify all express and implied claims an ad conveys to consumers. Advertisers must make sure that whatever they say expressly in an ad is accurate. Often, however, an ad conveys other claims beyond those expressly stated. Under FTC law, an advertiser is equally responsible for the accuracy of claims suggested or implied by the ad. Advertisers cannot suggest claims that they could not make directly.

When identifying claims, advertisers should not focus just on individual phrases or statements, but rather should consider the ad as a whole, assessing the "net impression" conveyed by all elements of the ad, including the text, product name, and depictions. When an ad lends itself to more than one reasonable interpretation, the advertiser is responsible for substantiating each

interpretation. Copy tests, or other evidence of how consumers actually interpret an ad, can be valuable. In many cases, however, the implications of the ad are clear enough to determine the existence of the claim by examining the ad alone, without extrinsic evidence.

Example 1

An advertisement claims that "university studies prove" that a mineral supplement can improve athletic performance. The advertiser has expressly stated the level of support for the claimed benefit and is therefore responsible for having "university studies" that document the advertised benefit. Furthermore, the implied reference to scientific evidence likely conveys to consumers the implied claim that the studies are methodologically sound.

Example 2

An advertisement for a vitamin supplement claims that 90% of cardiologists regularly take the product. In addition to the literal claim about the percentage of cardiologists who use the product, the ad likely conveys an implied claim that the product offers some benefit for the heart. Therefore, the advertiser must have adequate support for both representations.

Depending on how it is phrased, or the context in which it is presented, 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.

Example 3

An ad for an herbal supplement makes the claim that the product boosts the immune system to help maintain a healthy nose and throat during the winter season. The ad features the product name "Cold Away" and includes images of people sneezing and coughing. The various elements of the ad — the product name, the depictions of cold sufferers, and the reference to nose and throat health during the winter season — likely convey to consumers that the product helps prevent colds. Therefore, the advertiser must be able to substantiate

that claim. Even without the product name and images, the reference to nose and throat health during the winter season may still convey a cold prevention claim.

Example 4

An ad for a dietary supplement called "Arthricure" claims that the product maintains joint health and mobility into old age. The "before" picture shows an elderly women using a walker. The "after" picture shows her dancing with her husband. The images and product name likely convey implied claims that the product is effective in the treatment of the symptoms of arthritis, and may also imply that the product can cure or mitigate the disease. The advertiser must be able to substantiate these implied claims.

2. When to Disclose Qualifying Information

An advertisement can also be deceptive because of what it fails to say. Section 15 of the FTC Act requires advertisers to disclose information if it is material in light of representations made or suggested by the ad, or material considering how consumers would customarily use the product. Thus, if an ad would be misleading without certain qualifying information, that information must be disclosed. For example, advertisers should disclose information relevant to the limited applicability of an advertised benefit. Similarly, advertising that makes either an express or implied safety representation should include information about any significant safety risks. Even in the absence of affirmative safety representations, advertisers may need to inform consumers of significant safety concerns relating to the use of their product.

Example 5

An advertisement for a multi-vitamin/mineral supplement claims that the product can eliminate a specific mineral deficiency that results in feelings of fatigue. In fact, less than 2% of the general population to which the ad is targeted suffers from this deficiency. The advertiser should disclose this fact so that consumers will understand that only the small percentage of people who suffer from the actual mineral deficiency are likely to experience any reduction in fatigue from using the product.

Example 6

An advertiser for a weight loss supplement cites a placebo-controlled, double-blind clinical study as demonstrating that the product resulted in an average weight loss of fifteen pounds over an eight-week period. The weight loss for the test group is, in fact, significantly greater than for the control subjects. However, both the control and test subjects engaged in regular exercise and followed a restricted-calorie diet as part of the study regimen. The advertisement should make clear that users of the supplement must follow the same diet and exercise regimen to achieve the claimed weight loss results.

Example 7

An advertiser claims that its herbal product is a natural pain reliever "without the side effects of over-the-counter pain relievers." However, there is substantial evidence that the product can cause nausea in some consumers when taken regularly. Because of the reference to the side effects of other pain relievers, consumers would likely understand this ad to mean that the herbal product posed no significant adverse effects. Therefore, the advertiser should disclose information about the adverse effects of the herbal product.

Example 8

An herbal weight loss product contains an ingredient which, when consumed daily over an extended period, can result in a significant increase in blood pressure. Even in the absence of any representation about the product's safety, the advertiser should disclose this potentially serious risk.

3. Clear and Prominent Disclosure

When the disclosure of qualifying information is necessary to prevent an ad from being deceptive, that information should be presented clearly and prominently so that it is actually noticed and understood by consumers. A fine-print disclosure at the bottom of a print ad, a

disclaimer buried in a body of text, a brief video superscript in a television ad, or a disclaimer that is easily missed on an Internet web site, are not likely to be adequate. To ensure that disclosures are effective, marketers should use clear language, avoid small type, place any qualifying information close to the claim being qualified, and avoid making inconsistent statements or distracting elements that could undercut or contradict the disclosure. Because consumers are likely to be confused by ads that include inconsistent or contradictory information, disclosures need to be both direct and unambiguous to be effective.

Example 9

A marketer promotes a supplement as a weight loss aid. There is adequate substantiation to indicate that the product can contribute to weight loss when used in conjunction with a diet and exercise regimen. The banner headline claims "LOSE 5 POUNDS IN 10 DAYS," the ad copy discusses how easy it is to lose weight by simply taking the product 3 times a day, and the ad includes dramatic before-and-after pictures. A fine print disclosure at the bottom of the ad, "Restricted calorie diet and regular exercise required," would not be sufficiently prominent to qualify the banner headline and the overall impression that the product alone will cause weight loss. The ad should be revised to remove any implication that the weight loss can be achieved by use of the product alone. This revision, combined with a prominent indication of the need for diet and exercise, may be sufficient to qualify the claim. However, if the research does not show that the product contributes anything to the weight loss effect caused by diet and exercise, it would be deceptive, even with a disclosure, to promote the product for weight loss.

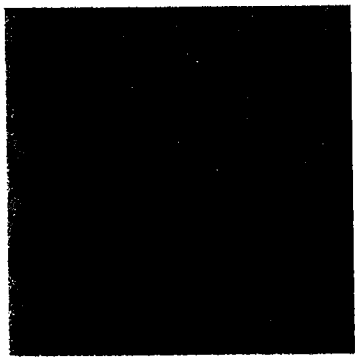
Qualifying information should be sufficiently simple and clear that consumers not only notice it, but also understand its significance. This can be a particular challenge when explaining complicated scientific concepts to a general audience, for example, if an advertiser wants to promote the effect of a supplement where there is an emerging body of science supporting that effect, but the evidence is insufficient to substantiate an unqualified claim. The advertiser should make sure consumers understand both the extent of scientific support and the existence of any significant contrary evidence. Vague qualifying terms — for example, that the product "may" have the claimed benefit or "helps" achieve the claimed benefit — are unlikely to be adequate. Furthermore, advertisers should not make qualified claims where the studies they rely on are contrary to a stronger body of evidence. In such instance, even a qualified claim could mislead consumers.

Example 10

A company has results from two studies suggesting that the main ingredient in its supplement helps to maintain healthy cholesterol levels. There are, however, significant limitations to each of the studies and a better controlled study is necessary to confirm whether the effect is genuine. The company makes a claim in advertising that "scientific studies show that our product may be effective in reducing cholesterol." The use of the word "may" is not likely to be a sufficient disclaimer to convey the limitations of the science. A disclosure that clearly describes the limitations of the research, in language consumers can easily understand, and states directly and unambiguously that additional research is necessary to confirm the preliminary results is more likely to be effective. As discussed in the following section on substantiating claims, the extent to which studies support an unqualified claim will depend largely on what experts in the relevant field would consider to be adequate support.

B. Substantiating Claims

In addition to conveying product claims clearly and accurately, marketers need to verify that there is adequate support for their claims. Under FTC law, before disseminating an ad, advertisers must have a reasonable basis for all express and implied product claims. What constitutes a reasonable basis depends greatly on what claims are being made, how they are presented in the context of the entire ad, and how they are qualified. The FTC's standard for evaluating substantiation is sufficiently flexible to ensure that consumers have access to information about emerging areas of science. At the same time, it is sufficiently rigorous to ensure that consumers can have confidence in the accuracy of information presented in advertising. A number of factors determine the appropriate amount and type of substantiation, including:



- **The Type of Product.** Generally, products related to consumer health or safety require a relatively high level of substantiation.
- **The Type of Claim.** Claims that are difficult for consumers to assess on their own are held to a more exacting standard. Examples include health claims that may be subject to a placebo effect or technical claims that consumers cannot readily verify for themselves.

- **The Benefits of a Truthful Claim** and **The Cost/Feasibility of Developing Substantiation for the Claim.** These factors are often weighed together to ensure that valuable product information is not withheld from consumers because the cost of developing substantiation is prohibitive. This does not mean, however, that an advertiser can make any claim it wishes without substantiation, simply because the cost of research is too high.
- **The Consequences of a False Claim.** This includes physical injury, for example, if a consumer relies on an unsubstantiated claim about the therapeutic benefit of a product and foregoes a proven treatment. Economic injury is also considered.
- **The Amount of Substantiation that Experts in the Field Believe is Reasonable.** In making this determination, the FTC gives great weight to accepted norms in the relevant fields of research and consults with experts from a wide variety of disciplines, including those with experience in botanicals and traditional medicines. Where there is an existing standard for substantiation developed by a government agency or other authoritative body, the FTC accords great deference to that standard.

The FTC typically requires claims about the efficacy or safety of dietary supplements to be supported with "competent and reliable scientific evidence," defined in FTC cases 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 and reliable results." This is the same standard the FTC applies to any industry making health-related claims. There is no fixed formula for the number or type of studies required or for more specific parameters like sample size and study duration. There are, however, a number of considerations to guide an advertiser in assessing the adequacy of the scientific support for a specific advertising claim.

1. Ads that Refer to a Specific Level of Support

If an advertiser asserts that it has a certain level of support for an advertised claim, it must be able to demonstrate that the assertion is accurate. Therefore, as a starting point, advertisers must have the level of support that they claim, expressly or by implication, to have.

Example 11

An ad for a supplement includes the statement "Scientists Now Agree!" in discussing the product's benefit. This statement likely conveys to consumers that the state of science supporting the benefit has reached the level of scientific consensus. Unless the advertiser possesses this level of evidence, the claim is not substantiated.

Example 12

An advertiser claims that its product has been "studied for years abroad" and is now the "subject of U.S. government-sponsored research." In addition to the explicit claim that the product has been studied, such phrases likely convey to consumers an implied claim that there exists a substantial body of competently-conducted scientific research supporting the efficacy of the product. The advertiser would be responsible for substantiating both claims.

2. The Amount and Type of Evidence

When no specific claim about the level of support is made, the evidence needed depends on the nature of the claim. A guiding principle for determining the amount and type of evidence that will be sufficient is what experts in the relevant area of study would generally consider to be adequate. The FTC will consider all forms of competent and reliable scientific research when evaluating substantiation. As a general rule, well-controlled human clinical studies are the most reliable form of evidence. Results obtained in animal and *in vitro* studies will also be examined, particularly where they are widely considered to be acceptable substitutes for human research or where human research is infeasible. Although there is no requirement that a dietary supplement claim be supported by any specific number of studies, the replication of research results in an independently-conducted study adds to the weight of the evidence. In most situations, the quality of studies will be more important than quantity. When a clinical trial is not possible (e.g., in the case of a relationship between a nutrient and a condition that may take decades to develop), epidemiologic evidence may be an acceptable substitute for clinical data, especially when supported by other evidence, such as research explaining the biological mechanism underlying the claimed effect.

Anecdotal evidence about the individual experience of consumers is not sufficient to substantiate claims about the effects of a supplement. Even if those experiences are genuine, they may be attributable to a placebo effect or other factors unrelated to the supplement. Individual experiences are not a substitute for scientific research.[8]

Example 13

An advertiser relies on animal and *in vitro* studies to support a claim that its vitamin supplement is more easily absorbed into the bloodstream than other forms of the vitamin. However, the animal research uses a species of animal that, unlike humans, is able to synthesize the vitamin, and the *in vitro* study uses a different formulation with a higher concentration of the

compound than the product being marketed. In addition, human research is feasible and relatively inexpensive to conduct in light of the potential sales of the product and is the type of research generally accepted in this particular field of study. The substantiation is likely to be inadequate in this case, both because there are significant methodological problems and because, in this particular instance, human research is both feasible and the accepted approach in the field.

Example 14

A company wants to advertise its supplement as helpful in maintaining good vision into old age. There have been two long-term, large-scale epidemiologic studies showing a strong association between life-long high consumption of the principal ingredient in the supplement and better vision in those over 70. Experts have also discovered a plausible biological mechanism that might explain the effect. A clinical intervention trial would be very difficult and costly to conduct. Assuming that experts in the field generally consider epidemiological evidence to be adequate to support the potential for a protective effect, and assuming the absence of any stronger body of contrary evidence, a claim that is qualified to accurately convey the nature and extent of the evidence would be permitted.

Example 15

An advertisement for a supplement claims that the product will cause dramatic improvements in memory and describes the experiences of 10 people who obtained these results. The descriptions of these anecdotal experiences are truthful, but the advertiser has no scientific substantiation for the effect of its product on memory and cannot explain why the product might produce such results. The individual experiences are not adequate to substantiate the claim without confirming scientific research.

3. The Quality of the Evidence

In addition to the amount and type of evidence, the FTC will also examine the internal validity of each piece of evidence. Where the claim is one that would require scientific support, the research should be conducted in a competent and reliable manner to yield meaningful results. The design, implementation, and results of each piece of research are important to assessing the adequacy of the substantiation.

There is no set protocol for how to conduct research that will be acceptable under the FTC substantiation doctrine. There are, however, some principles generally accepted in the scientific community to enhance the validity of test results. For example, a study that is carefully controlled, with blinding of subjects and researchers, is likely to yield more reliable results. A study of longer duration can provide better evidence that the claimed effect will persist and resolve potential safety questions. Other aspects of the research results — such as evidence of a dose-response relationship (*i.e.*, the larger the dose, the greater the effect) or a recognized biological or chemical mechanism to explain the effect — are examples of factors that add weight to the findings. Statistical significance of findings is also important. A study that fails to show a statistically significant difference between test and control group may indicate that the measured effects are merely the result of placebo effect or chance. The results should also translate into a meaningful benefit for consumers. Some results that are statistically significant may still be so small that they would mean only a trivial effect on consumer health.

The nature and quality of the written report of the research are also important. Research cannot be evaluated accurately on the basis of an abstract or an informal summary. In contrast, although the FTC does not require that studies be published and will consider unpublished, proprietary research, the publication of a peer-reviewed study in a reputable journal indicates that the research has received some measure of scrutiny. At the same time, advertisers should not rely simply on the fact that research is published as proof of the efficacy of a supplement. Research may yield results that are of sufficient interest to the scientific community to warrant publication, but publication does not necessarily mean that such research is conclusive evidence of a substance's effect. The FTC considers studies conducted in foreign countries as long as the design and implementation of the study are scientifically sound.[9]

Example 16

An advertiser conducts a literature search and finds several abstracts summarizing research about the association between a nutrient and the ability to perform better on memory tests. The advertiser relies on these summaries to support a claim that its supplement, which contains the same nutrient, aids memory. However, without looking carefully at the specifics of the study design, implementation, and results, there is

no way for an advertiser to ascertain whether the research substantiates the product claims. (For example, did the research use a comparable formulation of the ingredient? Was the study adequately controlled? Did the study yield results that are statistically significant?) The advertiser should carefully review the underlying science, with the assistance of an expert if necessary, before drafting advertising claims.

Example 17

An advertiser makes an unqualified claim about the anti-clotting effect of a supplement that contains a compound extracted from fruit. There are three studies supporting the effect and no contrary evidence. One study consists of subjects tested over a one-week period, with no control group. The second study is well-controlled, of longer duration, but shows only a slight effect that is not statistically significant. The third study administers the compound through injection and shows a significant anti-clotting effect, but there is some question whether the compound would be absorbed into the bloodstream if administered orally. Because the studies all have significant limitations, it would be difficult to draft even a carefully qualified claim that would adequately convey to consumers the limited nature of the evidence. The advertiser should not base a claim on these studies.

Example 18

The marketer of an herbal supplement claims that its product promotes healthy vision and is approved in Germany for this purpose. The product has been used extensively in Europe for years and has obtained approval by the German governmental authorities, through their monograph process, for use to improve vision in healthy people. The company has two abstracts of German trials that were the basis of the German monograph, showing that the ingredient significantly improved the vision of healthy individuals in the test group over the placebo group. Animal trials done by the company suggest a plausible mechanism to explain the

effect. Although approval of the supplement under the German monograph suggests that the supplement is effective, advertisers should still examine the underlying research to confirm that it is relevant to the advertiser's product (for example, that the dosage and formulation are comparable) and to evaluate whether the studies are scientifically sound. Advertisers should also examine any other research that exists, either supporting or contradicting the monograph, especially if it is not possible to identify and review the research on which the monograph is based.

4. The Totality of the Evidence

Studies cannot be evaluated in isolation. The surrounding context of the scientific evidence is just as important as the internal validity of individual studies. Advertisers should consider all relevant research relating to the claimed benefit of their supplement and should not focus only on research that supports the effect, while discounting research that does not. Ideally, the studies relied on by an advertiser would be largely consistent with the surrounding body of evidence. Wide variation in outcomes of studies and inconsistent or conflicting results will raise serious questions about the adequacy of an advertiser's substantiation. Where there are inconsistencies in the evidence, it is important to examine whether there is a plausible explanation for those inconsistencies. In some instances, for example, the differences in results are attributable to differences in dosage, the form of administration (e.g., oral or intravenous), the population tested, or other aspects of study methodology. Advertisers should assess how relevant each piece of research is to the specific claim they wish to make, and also consider the relative strengths and weaknesses of each. If a number of studies of different quality have been conducted on a specific topic, advertisers should look first to the results of the studies with more reliable methodologies.

The surrounding body of evidence will have a significant impact both on what type, amount and quality of evidence is required to substantiate a claim and on how that claim is presented — that is, how carefully the claim is qualified to reflect accurately the strength of the evidence. If a stronger body of surrounding evidence runs contrary to a claimed effect, even a qualified claim is likely to be deceptive.

Example 19

An advertiser wishes to make the claim that a supplement product will substantially reduce body fat. The advertiser has two controlled, double-blind studies showing a modest but statistically significant loss of fat at the end of a six-week period. However, there is an equally well-controlled, blinded 12-week study showing

no statistically significant difference between test and control groups. Assuming other aspects of methodology are similar, the studies taken together suggest that, if the product has any effect on body fat, it would be very small. Given the totality of the evidence on the subject, the claim is likely to be unsubstantiated.

Example 20

Advertisements for a fiber supplement make the claim that the product is "proven" to aid weight loss. Although the company has two published, peer-reviewed studies showing a relationship between fiber and weight loss, neither of these studies used the same proportions of soluble and insoluble fiber or the same total amount of fiber as the supplement product. There are numerous controlled, published human clinical studies, however, using the amount and type of fiber in the supplement product, that provide evidence that the product would not result in measurable weight loss. The totality of the evidence does not support the "proven" claim and, given the stronger body of contrary evidence, even a qualified claim is likely to be deceptive.

Example 21

An advertiser runs an ad in a magazine for retired people, claiming that its supplement product has been found effective in improving joint flexibility. The company sponsored a 6-week study of its supplement, involving 50 subjects over the age of 65, to test the product's effect on improving flexibility. The study was double-blinded and placebo-controlled and has been accepted for publication in a leading medical journal. The study showed dramatic, statistically significant increases in joint flexibility compared to placebo, based on objective measurements. In addition, several large trials have been conducted by European researchers using a similar formulation and dose of the active ingredient in the supplement. These trials also found statistically significant results. The advertiser reviewed the underlying European research and confirmed that it meets accepted research standards. The evidence as a whole likely substantiates the claim.

5. The Relevance of the Evidence to the Specific Claim

A common problem in substantiation of advertising claims is that an advertiser has valid studies, but the studies do not support the claim made in the ad. Advertisers should make sure that the research on which they rely is not just internally valid, but also relevant to the specific product being promoted and to the specific benefit being advertised. Therefore, advertisers should ask questions such as: How does the dosage and formulation of the advertised product compare to what was used in the study? Does the advertised product contain additional ingredients that might alter the effect of the ingredient in the study? Is the advertised product administered in the same manner as the ingredient used in the study? Does the study population reflect the characteristics and lifestyle of the population targeted by the ad? If there are significant discrepancies between the research conditions and the real life use being promoted, advertisers need to evaluate whether it is appropriate to extrapolate from the research to the claimed effect.

In drafting ad copy, the advertiser should take care to make sure that the claims match the underlying support. Claims that do not match the science, no matter how sound that science is, are likely to be unsubstantiated. Advertising should not exaggerate the extent, nature, or permanence of the effects achieved in a study, and should not suggest greater scientific certainty than actually exists. Although emerging science can sometimes be the basis for a carefully qualified claim, advertisers must make consumers aware of any significant limitations or inconsistencies in the scientific literature.

Example 22

An ad for a supplement claims that a particular nutrient helps maintain healthy cholesterol levels. There is a substantial body of epidemiologic evidence suggesting that foods high in that nutrient are associated with lower cholesterol levels. There is no science, however, demonstrating a relationship between the specific nutrient and cholesterol, although it would be feasible to conduct such a study. If there is a basis for believing that the health effect may be attributable to other components of the food, or to a combination of various components, a claim about the cholesterol maintenance benefits of the supplement product is likely not substantiated by this evidence.

Example 23

A number of well-controlled clinical studies have been conducted to suggest that a mineral supplement can improve mental alertness and memory in subjects with significantly impaired blood circulation to the brain. A claim suggesting that the supplement will improve memory or mental alertness in healthy adults may not be adequately substantiated by this evidence. Advertisers should not rely on research based on a specific test population for claims targeted at the general population without first considering whether it is scientifically sound to make such extrapolations.

Example 24

An advertiser wants to make claims that its combination herbal product helps increase alertness and energy safely and naturally. The product contains two herbs known to have a central nervous system stimulant effect. The advertiser compiles competent and reliable scientific research demonstrating that each of the herbs, individually, is safe and causes no significant side effects in the recommended dose. This evidence may be inadequate to substantiate an unqualified safety claim. Where there is reason to suspect that the combination of multiple ingredients might result in interactions that would alter the effect or safety of the individual ingredients, studies showing the effect of the individual ingredients may be insufficient to substantiate the safety of the multiple ingredient product. In this example, the combination of two herbs with similar stimulant properties could produce a stronger cumulative stimulant effect that might present safety hazards. A better approach would be to investigate the safety of the specific combination of ingredients contained in the product.

Example 25

Several clinical trials have been done on a specific botanical extract showing consistently that the extract is effective for supporting the immune system. The studied extract is a complex combination of many constituents and the active constituents that may produce the benefit are still unknown. An advertiser wishes to cite this research in its advertising, as proof that its product will support the immune system. The advertiser's product is made using a different extraction method of the same botanical. An analysis of the extract reveals that it has a significantly different chemical profile from the studied extract. The advertiser should not rely on these clinical trials alone as substantiation because the difference in extracts may result in significant differences in the two products' efficacy.

C. Other Issues Relating to Dietary Supplement Advertising

In addition to the basic principles of ad meaning and substantiation discussed above, a number of other issues commonly arise in the context of dietary supplement advertising. The following sections provide guidance on some of these issues including: the use of consumer or expert endorsements in ads; advertising claims based on traditional uses of supplements; use of the DSHEA disclaimer in advertising; and the application to advertising of the DSHEA exemption for certain categories of publications, commonly referred to as "third party literature."

1. Claims Based on Consumer Testimonials or Expert Endorsements

An overall principle is that advertisers should not make claims either through consumer or expert endorsements that would be deceptive or could not be substantiated if made directly.[10] It is not enough that a testimonial represents the honest opinion of the endorser. Under FTC law, advertisers must also have appropriate scientific evidence to back up the underlying claim.

Consumer testimonials raise additional concerns about which advertisers need to be aware. Ads that include consumer testimonials about the efficacy or safety of a supplement product should be backed by adequate substantiation that the testimonial experience is representative of what consumers will generally achieve when using the product. As discussed earlier, anecdotal evidence of a product's effect, based solely on the experiences of individual consumers, is generally insufficient to substantiate a claim. Further, if the advertiser's substantiation does not demonstrate that the results are representative, then a clear and

conspicuous disclaimer is necessary. The advertiser should either state what the generally expected results would be or indicate that the consumer should not expect to experience the attested results. Vague disclaimers like "results may vary" are likely to be insufficient.

Example 26

An advertisement for a weight loss supplement features a before-and-after photograph of a woman and quotes her as saying that she lost 20 pounds in 8 weeks while using the supplement. An asterisk next to the quotation references a disclaimer in fine print at the bottom of the ad that reads, "Results may vary." The experience of the woman is accurately represented, but the separate, competent research demonstrating the efficacy of the supplement showed an average weight loss of only 6 pounds in 8 weeks. Therefore, the disclosure does not adequately convey to consumers that they would likely see much less dramatic results. The placement and size of the disclaimer is also insufficiently prominent to qualify the claim effectively. One approach to adequate qualification of this testimonial would be to include a disclaimer immediately adjacent to the quote, in equal print size that says, "These results are not typical. Average weight loss achieved in clinical study was 6 pounds."

When an advertiser uses an expert endorser, it should make sure that the endorser has appropriate qualifications to be represented as an expert and has conducted an examination or testing of the product that would be generally recognized in the field as sufficient to support the endorsement. In addition, whenever an expert or consumer endorser is used, the advertiser should disclose any material connection between the endorser and the advertiser of the product. A material connection is one that would affect the weight or credibility of the endorsement, or put another way, a personal, financial, or similar connection that consumers would not reasonably expect.

Example 27

An infomercial for a dietary supplement features an expert referred to as a "Doctor" and a "leading clinician in joint health" discussing the effect of a supplement product on the maintenance of healthy joints. The expert is not licensed to practice medicine, but has a graduate degree and is a trained physical therapist, running a sports clinic. The expert has not conducted

any review of the scientific literature on the active component of the supplement. In return for appearing in the infomercial, she is given a paid position as an officer the company. The ad is likely to be deceptive for several reasons. First, her qualifications as an expert have been overstated and she has not conducted sufficient examination of the product to support the endorsement. In addition, her connection to the company is one that consumers might not expect and may affect the weight and credibility of her endorsement. Even if she is adequately qualified and has conducted an adequate review of the product, her position as an officer of the company should be clearly disclosed.

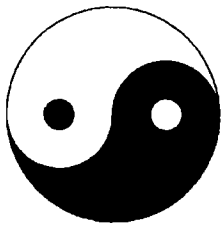
Example 28

A best-selling book about the benefits of a supplement product includes a footnote mentioning the most effective brand of the supplement, by name. The manufacturer of the brand cited in the book has an exclusive promotional agreement with the author and has paid him to reference the product by name. The manufacturer's ad touts the fact that its product is the only brand recommended in this best-selling book. The ad is deceptive since it suggests a neutral endorsement when, in fact, the author has been paid by the manufacturer to promote the product.

2. Claims Based on Traditional Use

Claims based on historical or traditional use should be substantiated by confirming scientific evidence, or should be presented in such a way that consumers understand that the sole basis for the claim is a history of use of the product for a particular purpose. A number of supplements, particularly botanical products, have a long history of use as traditional medicines in the United States or in other countries to treat certain conditions or symptoms. Several European countries have a separate regulatory approach to these traditional medicines, allowing manufacturers to make certain limited claims about their traditional use for treating certain health conditions. Some countries also require accompanying disclosures about the fact that the product has not been scientifically established to be effective, as well as disclosures about potential adverse effects. At this time there is no separate regulatory process for approval of claims for these traditional medicine products under DSHEA and FDA labeling rules.

In assessing claims based on traditional use, the FTC will look closely at consumer perceptions and specifically at whether consumers expect such claims to be backed by supporting scientific evidence. Advertising claims based solely on traditional use should be presented carefully to avoid the implication that the product has been scientifically evaluated for efficacy. The degree of qualification necessary to communicate the absence of scientific substantiation for a traditional use claim will depend in large part on consumer understanding of this category of products. As consumer awareness of and experience with "traditional use" supplements evolve, the extent and type of qualification necessary is also likely to change.



There are some situations, however, where traditional use evidence alone will be inadequate to substantiate a claim, even if that claim is carefully qualified to convey the limited nature of the support. In determining the level of substantiation necessary to substantiate a claim, the FTC assesses, among other things, the consequences of a false claim. Claims that, if unfounded, could present a substantial risk of injury to consumer health or safety will be held to a higher level of scientific proof. For that reason, an advertiser should not suggest, either directly or indirectly, that a supplement product will provide a disease benefit unless there is competent and reliable scientific evidence to substantiate that benefit. The FTC will closely scrutinize the scientific support for such claims, particularly where the claim could lead consumers to forego other treatments that have been validated by scientific evidence, or to self-medicate for potentially serious conditions without medical supervision.

The advertiser should also make sure that it can document the extent and manner of historical use and be careful not to overstate such use. As part of this inquiry, the advertiser should make sure that the product it is marketing is consistent with the product as traditionally administered. If there are significant differences between the traditional use product and the marketed product, in the form of administration, the formulation of ingredients, or the dose, a "traditional use" claim may not be appropriate.

Example 29

The advertiser of an herbal supplement makes the claim, "Ancient folklore remedy used for centuries by Native Americans to aid digestion." The statement about traditional use is accurate and the supplement product is consistent with the formulation of the product as traditionally used. However, if, in the context of the ad, this statement suggests that there is scientific evidence demonstrating that the product is effective for aiding digestion, the advertiser would need to include a clear and prominent disclaimer about the absence of such evidence.

Example 30

A supplement manufacturer wants to market an herbal product that has been used in the same formulation in China as a tonic for improving mental functions. The manufacturer prepares the product in a manner consistent with Chinese preparation methods. The ad claims, "Traditional Chinese Medicine — Used for Thousands of Years to Bring Mental Clarity and Improve Memory." The ad also contains language that clearly conveys that the efficacy of the product has not been confirmed by research, and that traditional use does not establish that the product will achieve the claimed results. The ad is likely to adequately convey the limited nature of support for the claim.

Example 31

A supplement manufacturer markets a capsule containing a concentrated extract of a botanical product that has been used in its raw form in China to brew teas for increasing energy. The advertisement clearly conveys that the energy benefit is based on traditional use and has not been confirmed by scientific research. The ad may still be deceptive, however, because the concentrated extract is not consistent with the traditional use of the botanical in raw form to brew teas and may produce a significantly different effect.

Example 32

A supplement ad claims that a supplement liquid mineral solution has been a popular American folk remedy since early pioneer days for shrinking tumors. The ad is likely to convey to consumers that the product is an effective treatment for cancer. There is no scientific support for this disease benefit. Because 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.

3. Use of the DSHEA Disclaimer in Advertising

Under DSHEA, all statements of nutritional support for dietary supplements must be accompanied by a two-part disclaimer on the product label: that the statement has not been evaluated by FDA and that the product is not intended to "diagnose, treat, cure or prevent any disease." Although DSHEA does not apply to advertising, there are situations where such a disclosure is desirable in advertising as well as in labeling to prevent consumers from being misled about the nature of the product and the extent to which its efficacy and safety have been reviewed by regulatory authorities. For example, a disclosure may be necessary if the text or images in the ad lead consumers to believe that the product has undergone the kind of review for safety and efficacy that the FDA conducts on new drugs and has been found to be beneficial for the treatment of disease. Failure to correct those misperceptions may render the advertising deceptive.

At the same time, the inclusion of a DSHEA disclaimer or similar disclosure will not cure an otherwise deceptive ad, particularly where the deception concerns claims about the disease benefits of a product. In making references to DSHEA and FDA review, advertisers should also be careful not to mischaracterize the extent to which a product or claim has been reviewed or approved by the FDA. Compliance with the notification and disclaimer provisions of DSHEA does not constitute authorization of a claim by FDA and advertisers should not imply that FDA has specifically approved any claim on that basis.

Example 33

A company markets a supplement for "maintaining joint flexibility." The product packaging is similar in color and design to a nonprescription drug used to treat joint pain associated with arthritis and the product name is similar to the drug counterpart. The ad includes statements urging consumers to "ask their pharmacist" and "accept no generic substitute." The various elements of the ad may lead consumers to believe that the supplement is, in fact, an approved drug, or may give consumers more general expectations that the product has been subjected to similar government review for safety and efficacy. A clear and prominent disclaimer may be necessary to indicate that the product has not been evaluated by FDA and is not an approved drug product.

Example 34

An advertisement for an herbal supplement includes strong, unqualified claims that the product will effectively treat or prevent diabetes, heart disease, and various circulatory ailments. The advertiser does not have adequate substantiation for this claim, but includes the DSHEA disclaimer prominently in the ad. In face of the strong contradictory message in the ad, 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.

Example 35

A dietary supplement advertisement makes a number of claims about the benefits of its product for supporting various body functions. The ad also includes the statement, "Complies with FDA notification procedures of the Dietary Supplement Health and Education Act." This statement may suggest to consumers that FDA has authorized the claims made in the ad or that it has reviewed the support for the claims and found the product to be effective. Because there is no review and authorization process for such claims under DSHEA, this would be deceptive.

4. Third Party Literature

Dietary supplement advertisers should be aware that the use of newspaper articles, abstracts of scientific studies, or other "third party literature" to promote a particular brand or product can have an impact on how consumers interpret an advertisement and on what claims the advertiser will be responsible for substantiating. For purposes of dietary supplement labeling, Section 5 of DSHEA provides an exemption from labeling requirements for scientific journal articles, books and other publications used in the sale of dietary supplements, provided these materials are reprinted in their entirety, are not false or misleading, do not promote a specific brand or manufacturer, are presented with other materials to create a balanced view of the scientific information, and are physically separate from the supplements being sold.

The FTC will generally follow an approach consistent with the labeling approach when evaluating the use of such publications in other contexts, such as advertising. Although the FTC does not regulate the content or accuracy of statements made in independently written and published books, articles, or other non-commercial literature, FTC law does prohibit the deceptive use of such materials in marketing products. The determination of whether the

materials will be subject to FTC jurisdiction turns largely on whether the materials have been created or are being used by an advertiser specifically for the purpose of promoting its product. As a practical matter, publications and other materials that comply with the elements of the DSHEA provision, particularly with the requirement that such materials be truthful, not misleading and balanced, are also likely to comply with FTC advertising law.

Example 36

An author publishes a book on the curative properties of an herb. The book title is "The Miracle Cancer Cure." The book does not endorse or otherwise mention any particular supplement brand. The author/publisher does not sell the herbal supplement and does not have any material connection to any marketers of the herb. As non-commercial speech, the book itself would not be subject to the FTC's jurisdiction over advertising. However, if a marketer of the herb referred to the book in advertising materials (for instance, by quoting the title and using excerpts to describe the anti-cancer benefits of its product), such references would likely be considered advertising. The advertiser would be responsible for substantiating any claims about the advertiser's product that are conveyed by these references.

CONCLUSION

Marketers of dietary supplements should be familiar with the requirements under both DSHEA and the FTC Act that labeling and advertising claims be truthful, not misleading and substantiated. The FTC approach generally requires that claims be backed by sound, scientific evidence, but also provides flexibility in the precise amount and type of support necessary. This flexibility allows advertisers to provide truthful information to consumers about the benefits of supplement products, and at the same time, preserves consumer confidence by curbing unsubstantiated, false, and misleading claims. To ensure compliance with FTC law, supplement advertisers should follow two important steps: 1) careful drafting of advertising claims with particular attention to how claims are qualified and what express and implied messages are actually conveyed to consumers; and 2) careful review of the support for a claim to make sure it is scientifically sound, adequate in the context of the surrounding body of evidence, and relevant to the specific product and claim advertised.

Endnotes

[1] The FTC's authority derives from Section 5 of the FTC Act. In addition, supplements have traditionally been regulated under Sections 12 and 15, which prohibit false advertisements, defined as those that are "misleading in a material respect," for foods, drugs, devices or cosmetics.

[2] Under DSHEA, supplement marketers are allowed to make two kinds of claims on labeling: 1) health claims specifically authorized by the FDA; and 2) statements of nutritional support. Health claims — representations about the relationship between a nutrient and a disease or health-related condition — are permitted only if they have been authorized by an FDA finding that there is "significant scientific agreement" to support the claim. The Food and Drug Administration Modernization Act of 1997 (FDAMA) also now allows health claims that are based on "authoritative statements" from certain federal scientific bodies, such as NIH and the National Academy of Sciences. Aside from these authorized claims, supplement marketers are prohibited from making any labeling claim about the diagnosis, mitigation, treatment or cure of a disease. In contrast to health claims, "structure/function" claims, within the broader category of "statements of nutritional support," refer to representations about a dietary supplement's effect on the structure or function of the body for maintenance of good health and nutrition.

[3] Structure/function claims are not subject to FDA pre-authorization. A marketer may make these claims in labeling if it notifies FDA and includes a disclaimer that the claim has not been evaluated by FDA and that the product is not intended to diagnose, mitigate, treat, cure, or prevent disease. DSHEA also requires that structure/function claims in labeling be substantiated and be truthful and not misleading. This requirement is fully consistent with the FTC's standard that advertising claims be truthful, not misleading and substantiated.

[4] FTC policy statements and other information for businesses and consumers are available on the FTC's Internet home page, **www.ftc.gov**.

[5] As indicated in the Food Policy Statement, the FTC will be "especially vigilant in examining whether qualified claims are presented in a manner that ensures that consumers understand both the extent of the support for the claim and the existence of any significant contrary view within the scientific community. In the absence of adequate qualification the Commission will find such claims deceptive."

[6] These principles are articulated in the FTC's Deception Policy Statement and Advertising Substantiation Policy Statement, available at **www.ftc.gov**. The FTC also has authority to challenge unfair trade practices. An unfair practice is one that causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or competition. The majority of advertising cases are brought pursuant to the FTC's deception authority.

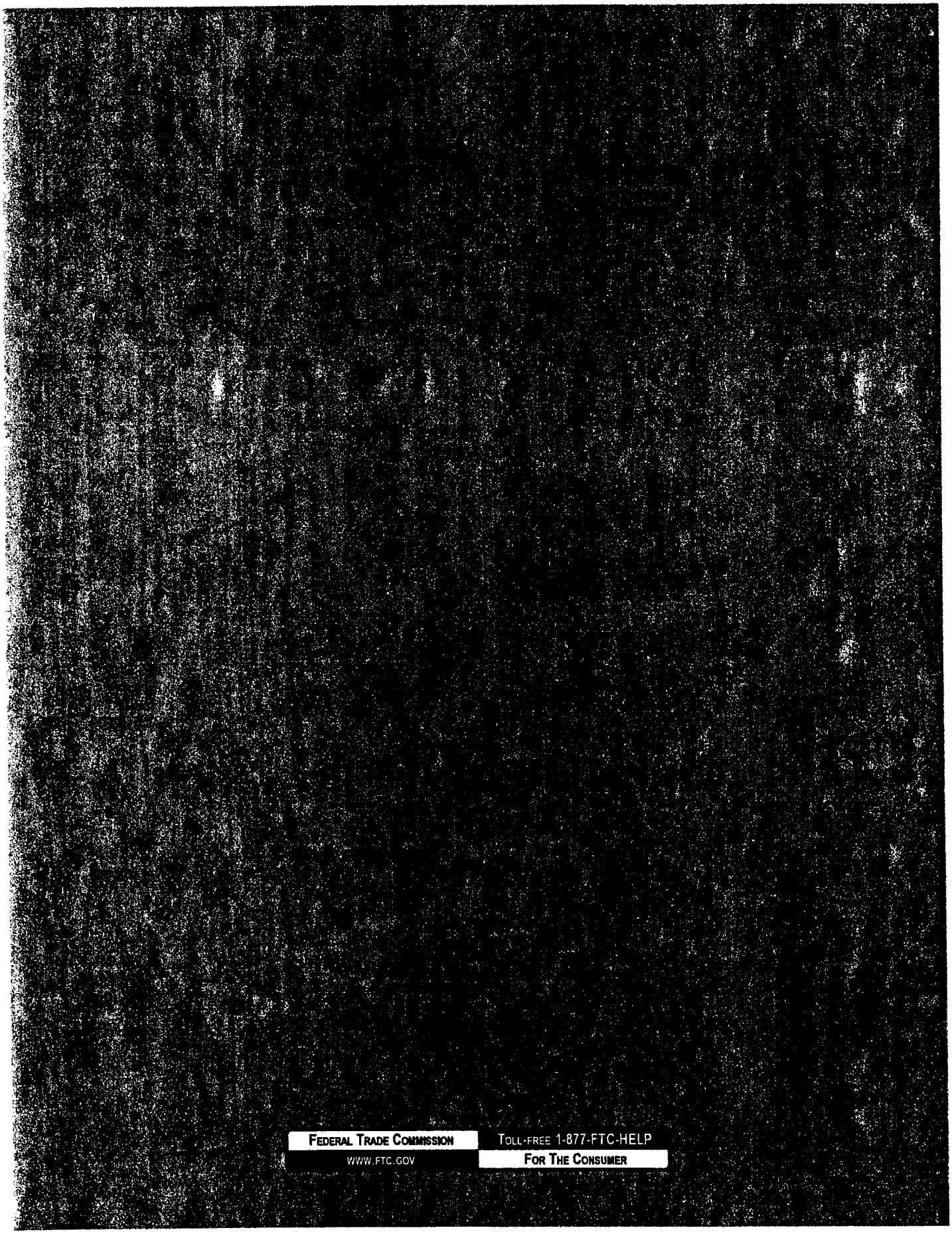
[7] Throughout these examples the terms "advertiser," "marketer," "supplement manufacturer" and "company" are used interchangeably.

[8] Additional guidance on the use of consumer testimonials is provided in Part C.1.

[9] Any foreign research submitted to the FTC in the course of an investigation should be presented in English translation and with sufficient detail to allow the agency to evaluate the study.

[10] The FTC has provided detailed guidance on this subject in its Guides Concerning Use of Endorsements and Testimonials in Advertising, available at **www.ftc.gov**.

Federal Trade Commission
Bureau of Consumer Protection
April 2001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IN THE UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

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

[PROPOSED] ORDER GRANTING RESPONDENTS' MOTION FOR SUMMARY DECISION

Based on the Motion of Respondents' for Summary Decision supported by the Sworn Declaration of Michael McCormack and related documents, and based upon the Response of Complaint Counsel, the Court makes the following Findings of Fact and Conclusions of Law.

1. Respondent Daniel Chapter One (DCO) is a religious ministry founded pursuant to the "corporation sole" laws of Washington State.

2. Respondent's primary purpose is to serve constituents of its ministry.

3. One means by which Respondent serves the constituents of its ministry is by providing dietary supplements through sale and/or donation.

4. Respondent makes claims about four of their dietary supplements as follows:

About Bioshark:

> *"Bioshark is pure skeletal tissue of sharks which provides a protein that inhibits angiogenesis -- the formation of new blood vessels. This can stop tumor growth and halt the progression of eye diseases . . ."*

About 7 Herb Formula:

> *"purifies the blood, promotes cell repair, fights tumor formation, and fights pathogenic bacteria"*

About GDU:

> *"contains natural proteolytic enzymes (from pineapple source bromelain to help digest protein --even that of unwanted tumors and cysts. This formula also helps to relieve pain and heal inflammation. . .GDU is also used for. . .and as an adjunct to cancer therapy. GDU possesses a wide range of actions including anti-inflammatory and antispasmodic activity. . ."*

About BioMixx:

> *"boosts the immune system, cleanses the blood and feeds the endocrine system to allow for natural healing. It is used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatments."*

5. The claims identified in Finding of Fact #4 contain no express claims about the diagnosis, mitigation, treatment, cure or prevention of any disease. These claims are structure/function claims as defined by 21 USC §343(r)(6).

6. The Respondents' structure/function claims are substantiated by adequate scientific evidence.

7. The Commission must meet its burden of proof by clear, cogent and convincing evidence.

8. Complaint Counsel has the burden to prove that Respondents lacked a reasonable basis for their claims.

9. Complaint Counsel provided insufficient evidence to meet the burden of proving that that Respondents lacked a reasonable basis for their claims.

10. Complaint Counsel has the burden to the standards of proof required by 15 USC §45(n).

11. Complaint Counsel provided no evidence to meet the standard of proof required by 15 USC §45(n).

12. Complaint Counsel has the burden to prove with extrinsic evidence the overall net impression of Respondents' claims. That extrinsic evidence must include evidence about consumer perceptions of a reasonable member of Respondents' constituency.

13. Complaint Counsel provided no extrinsic evidence to prove the overall net impression of Respondents' claims.

14 Complaint Counsel had the burden to prove with extrinsic evidence that Respondents lacked adequate substantiation for their claims. That extrinsic evidence must include expert testimony from an expert specifically qualified in the fields of herbal medicine, phyto-nutrition and/or dietary supplement effect on structure and function of the human body.

15. Complaint Counsel provided no qualified extrinsic evidence that Respondents lacked adequate substantiation for their claims.

Based on the foregoing, IT IS ORDERED that Respondents' Motion for Summary Decision is granted. The Commission's Complaint is dismissed with prejudice.

Dated _____, 2009.

_____

D. Michael Chappell
Chief Administrative Law Judge

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

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

CERTIFICATE OF SERVICE

I certify that on February 24, 2009, I served or caused to be served the following document on the individuals listed below by electronic mail, followed by Federal Express delivery:

Respondents' Motion for Summary Decision and Memorandum in Support
Respondents' Motion to Dismiss for Lack of Jurisdiction and Violation of Respondents Constitutional Rights and Memorandum in Support
Respondents' Second Motion to Amend Answer & Memorandum in Support

Service to:

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

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Federal Trade Commission – Northeast Region
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Courtesy Copies:

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