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

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> 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 . . ."*
>
> 7 Herb Formula "*purifies the blood, promotes cell repair, fights tumor formation, and fights pathogenic bacteria"*
>
> 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. . ."*
>
> 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."*

1. Respondents Make And Substantiate Structure And Function Claims That The Products In Question Assist The Body By Reinforcing Its Natural Innate Capacity To Correct Imbalance And Help The Body Diminish Disease

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INTRODUCTION

Respondent James Feijo is overseer of Respondent Daniel Chapter One (DCO), a Christian ministry organized as a Washington State Corporation Sole devoted to body, mind and spirit health. Contrary to Complaint Counsel's assertion, Respondents have controverted every point in Complaint Counsels' case. Respondents deny that they claimed that their products were effective in preventing, treating, or curing cancer. They deny that they sell products. They deny that they advertise. They deny that the FTC had legal jurisdiction over their non-profit religious activities. They deny that they lacked competent and reliable scientific evidence to support the statements they made about their product. They deny that their activities are substantially, if at all, in commerce. And they deny that their actions violated Sections 5 and 12 of the Federal Trade Commission Act.

In fact, Complaint Counsel has failed to present evidence on key elements of their case. They have provided no expert testimony on either the proper scientific evidence to support statements or claims about the effects of herbs or the standard that should be applied to evidence that supports statements about the effects of herbs. Nor have they provided any expert testimony on how the net impression of the set of statements made by Respondents should be determined, relying instead on the "common sense" of the person responsible for the Internet surf that identified 130 organizations as violating FTC laws without distinguishing among any of them.

Complaint Counsel have failed to present persuasive evidence that Respondents made the alleged claims and lacked adequate substantiation. For these reasons Complaint Counsel's motion for summary decision on its behalf should be denied. Indeed the failure of Complaint

Counsel to provide any evidence on herbal science, or the factual status of "net impression" in this case, as spelled out in Respondents' Motion for Summary Decision should cause Respondents' Motion for Summary Decision to be granted.

I. STATEMENT OF FACTS

A. DCO and the Feijos Have Not Advertised or Sold Products to Consumers

In 1986, James Feijo and his wife Patricia started DCO as a nonprofit ministry which among its projects began a small health food store. Ex. 1. At this time the Feijos were engaged in home church missionary work in Communist countries including Poland, East Germany and China. They took Bibles to Christian communities that met in homes of their members as part of their "home church" missionary work. As a result of the missionary travels, the Feijos were in East Germany when the Berlin wall fell on November 9, 1989 and in Tiananmen Square during the summer Democracy protests of 1989.

In 2002, James Feijo organized DCO as a corporation sole under Washington state laws. Ex. 1. DCO currently offers consumers 150 to 200 products. Ex. 1. James Feijo serves as DCO's Overseer, trustee for all DCO assets, and custodian of DCO's financial records. Ex. 1. Patricia Feijo is DCO's Secretary. Ex. 1. James Feijo was a high school science teacher and coach, including fitness coach, to high school students and amateur and professional athletes. Patricia Feijo is a trained Homeopath and worked for several years as a bench technician as part of a team doing cancer research on animals at a major

Worcester research center, working in conjunction with a major Worcester Hospital using the experimental chemotherapy on people.

Respondents' principal office and place of business is located in Portsmouth, Rhode Island, where the Feijos live. Ex. 1. Messiah Y'Shua Shalom, a second Washington Corporation Sole established by James Feijo, owns two Rhode Island buildings that house an Order Center, offices and a house (neither DCO nor Messiah Y'Shua Shalom owns a warehouse) used by DCO as offices and a residence. Ex. 1. DCO also owns a three-bedroom property in Deerfield Beach, Florida, where the Feijos and other individuals who are part of the DCO community and guests stay. DCO also owns two Cadillac cars—one used and one bought at a last-year's model sale—which together cost DCO $56,000 or an average of $28,000 each—which the Feijos and other persons associated with DCO use. Ex. 1. DCO pays the Feijos' expenses but does not pay them salaries. Ex. 1.

DCO has never purchased, bartered or otherwise arranged for an advertisement of the herbs or other products it provides to its followers. All its communications are on its web site, in its rarely published news letters and handbooks which it provides for free or small donations, or on its daily radio program which are all directed to individuals who are part of the DCO audience and which are outspokenly clear that they are not selling drugs but rather providing a critique of current health practices, a campaign for "health freedom" and complementary and alternative approaches to conventional attitudes about wellness—including products—as a concrete expression of their campaign for more health choice. The program for well being pursued by Daniel Chapter One is grounded in the Bible.

B. Daniel Chapter One Maintains A Non Profit Charitable Program That Allows Any User Of DCO Products To Obtain Free DCO Products And Accepts Donations From Other DCO Product Users

At its origination Daniel Chapter One offered free products to any individual who wanted them. When this turned out to be an unmanageable program DCO created a new program that informed individuals who desired and needed free nutritional products to go a church and seek the support of a minister who could inform DCO of the need and desire. The minister would then act as a reference for the individual to Daniel Chapter One. As a result of this effort a number of churches have received herbal and nutritional products for distribution to individuals both for free and for donations from the individuals able to make donations and also have shared in the monetary donations made for the herbal and nutritional products provided by DCO.

1. The Feijos Developed The Formulas For The DCO Products And Contracted With FDA Regulated Laboratories To Ensure The Quality Of Those Products And The Accuracy And Legality Of The Product Labels.

As a coach, including fitness coaching, James Feijo observed the relationship between various nutritional products, herbs and other dietary supplements and athletic performance. He also noted, as a devout Christian, that a number of Bible verses created dietary information that paralleled his observations of the athletes he coached. For example, Daniel Chapter One in the Bible tells the story of a group of individuals who resisted eating the King's prescribed diet. They talked the authorities into letting them eat a special, and they thought healthier, diet than that prescribed by the King's government.

While eating this diet, which was essentially vegetarian, the Bible reports they indeed did have improved heath over the King's men.

Based on his readings of the Bible and his observations of the athletes he coached James Feijo developed, created, and arranged for the production of various DCO Products. Ex. 1. He contracted with various FDA regulated manufacturing facilities for them to ensure the safety of the products, the quality and proper amounts of ingredients to meet the dosage requirement of his formulations, and the accuracy and legal compliance of the labels on the products and to ensure that the identity and amount of each ingredient is contained on the product labels. Ex. 1. The companies provided the services to ensure that the dietary supplements met quality and labeling requirements. Universal Nutrition, a respected regulated manufacturer of dietary supplement products, is one firm that DCO contracts with to manufacture approximately 35-40 products, including Bio*Shark, GDU, and BioMixx. Ex. 1 The tea like drink 7 Herb Formula, the fourth product singled out by the FTC, is manufactured and provided to DCO in the same manner by a different company after the formulation was developed, based on a well known previously existing product, by that company's herbal consultant. Ex. 2.

Patricia Feijo, drawing on her research technician background and training as a homeopath, reviewed all DCO products' directions, recommended usages and statements made about the DCO products for the express purpose of ensuring that they contained no health claims, that they properly stated the structure and function nature of the product effects and that no statements were made for the products which were not substantiated in

the scientific literature that supports the use of dietary supplements that are herbs and nutritional products. Ex. 1.

2. Respondents Do Not Sell Products To Consumers

From time to time James Feijo establishes a recommended donation amount for the DCO products. However he does not "price" to the market as a for profit business would but rather leaves the recommended donations in place long after the market prices on similar products sold by for profit businesses have been raised by their sellers. Ex. 1.

The fact that about a thousand consumers have purchased DCO's products supports the assertion of Respondents that DCO, which has been in existence for 24 years, is something other than a business. Ex. 1. DCO generates approximately $2 million in annual sales annually as shown by its records for 2006, 2007, and 2008. Ex. 1. This too suggests that it is something other than a business, since the products it makes available are dietary supplements which are part of a market that sell about $24 billion worth of product a year. Daniel Chapter one is not organized or run to make, and does not make, a profit.

The recommended donation for DCO products is comparable to or lower than similar dietary supplement product prices for products available in the for profit dietary supplement market. If individuals are unable to make the recommended donation they can make a lower donation or no donation at all by contacting a minister who will inform DCO of their needs. During its twenty four years of activity DCO has received virtually no complaints, about quality, value, or nature of the information supplied. During the same

time it has received dozens if not hundreds of testimonials to the value and usefulness of both the DCO products and its various informational programs.

The testimonials received both in writing and on a daily basis from listeners to their radio program underscore the existence of a community of individuals involved with the message of "health freedom" and "health choice" that is the backbone of the DCO health ministry. The testimonials tend to be spontaneous and heart felt. For example ,one user of DCO products and believer in the DCO message created the 7Herb Formula web site and donated it to the DCO ministry.

The message that DCO is sharing with the individuals in its community create what the Supreme Court calls an Expressive Association.

3. The DCO Products

a. Bio*Shark

As a very successful high school athletic coach, Jim Feijo designed a computer program to track his athletes. He expanded to internationally competitive amateur athletes and then to professionals. He noted that the stress on an extreme athlete created nutritional and physiological effects similar to those experienced by diseased individuals. This led him to design a program for extreme athletes and ill individuals to strengthen the natural structures and functions for the body that build endurance, strength, balance and the ability to withstand disease.

He applied the term "BioMolecular Nutritional Health" to the integrated ideas based on his experience and built into his program measured nutritional factors in relation to the structure and function of the body. He used these ideas to design the products that

he had made especially for DCO. Thus he formulated Bio*Shark out of shark cartilage and several herbs. Ex. 1.

Each Bio*Shark label directs users to take 2-3 capsules three times a day or as directed by a physician or by a "BioMolecular Nutrition health care professional." Ex. 1. BioMolecular nutrition also includes and draws on the intangible—spiritual—components of performance, integrating "the spiritual and physical" aspects of Respondents' system and products. Expert report and deposition of Jay Lehr who is a scientific expert, a triathlon racer and a user of DCO products. Ex. 1. Respondents recommend a donation for one bottle of Bio*Shark, as they do for all their products, that is an amount comparable to the price paid for similar products in the dietary supplement industry. Ex. 1. Respondents estimate that approximately 50% of the mark up on all their products goes to support churches and the five health food stores and health professional offices that have asked to carry DCO products and the support of the DCO free and reduced donation programs.

Respondents' expert Dr. Lamont concluded that "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." Ex. 3.

b. 7 Herb Formula

7 Herb Formula is a tea made of four herbs that have been used for decades in herbal healing with three additional herbs added by DCO after review and evaluation by an herbal professional in conjunction with an herbal manufacturer. Ex. 2. Both Respondents' herbal experts Dr. Duke and Dr. Lamont concluded "There is a reasonable basis for the claims that the ingredients of 7 Herb Formula '..., fights tumor formation, and fights pathogenic bacteria.'"

Ex. 4 and Ex. 3.

c. GDU

"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. . .'" Ex. 4

"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 quercetin, 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." Ex. 3.

d. BioMixx

"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.'" Ex. 4.

"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." Ex. 3.

C. Respondents Disseminate Accurate, Substantiated Structure and Functions Claims for DCO Products...

1. Respondents Say:

a. 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 . . ."*

b. The tea 7 Herb Formula *"purifies the blood, promotes cell repair, fights tumor formation, and fights pathogenic bacteria"*

c..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. . ."*

d. 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."*

e. On each product label: "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

f. Each of Respondents'' web sites says "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."

2. Respondents do not say that "the DCO Products were effective in preventing, treating, or curing cancer."

Respondents not only did not say that their products are "effective" in preventing, treating or curing cancer," they do not believe it. They believe that the body has mechanisms to heal itself. They present their message, in the language set out about each of the products above, that says their products affect these mechanisms, assisting them to

perform their function or enhance their structure. Dr. Lamont and Dr. Duke explicitly said that herbal science supports the claims made by DCO. Ex. 3 and Ex. 4.

Respondents clearly and unequivocally offer a different, natural, choice to their followers. It is a choice that interested individuals can make separate from or in conjunction with standard chemotherapeutic or radiation treatments. In her deposition, Dr. Lamont described the mindset of someone who might share Respondents' view of this set of alternatives. She said:

> Occasionally there will be a person who, for maybe religious purposes or they just live in a different mindset, that there is no way they're going to subject themselves to the traumas and poisoning effect of chemotherapy and radiation. And let's face it. It is poisoning.
>
> I mean, these are cytotoxic agents and not in the sense of, you know, curcumin could kill a cancer cell, but these go in and kill all rapidly reproducing cells in the body. And you lose muscle mass and you lose multiple organ function, and it drives many people to the brink of death just from the therapy. And if they're lucky, they recuperate and can live with that five-year survival rate and be proclaimed a success. Lots don't. And I think -- what are we up to --65 percent now of people can live five years past their -- concluding their treatment. Ex. 5.

3.. Respondents make and substantiate structure and function claims, as set out for the products above, that the products in question assist the body by reinforcing its natural innate capacity to correct imbalance and help the body diminish disease by

strengthening the body's natural healing functions,
to assist it in maintaining coherence and wellness, and

assisting the body in achieving and maintaining the structural balance that helps it diminish the effects of cancer and other disease including for those taking chemotherapy.

Respondents assert that the statement or claims made about the products they provide to members of their community were intended to be in support of Normal Structure and Function Claims permitted under the *Dietary Supplement Health and Education Act of 1994* and the regulations thereunder. The Respondents further assert that

they do in fact have reasonable evidence for their claims, including, in addition to the testimony and reports of their expert witnesses which explicitly state that herbal science supports the DCO statements for each product, Traditional Use and Biblical substantiation which Respondents assert are valid and lawful substantiation for claims made particularly in an Expressive Association context.

Respondents assert that they and their communicants are engaging in Expressive Association as a private association, protected by the First Amendment to the Constitution for the United States of America. See: *Boy Scouts Of America V. Dale* (99-699) 530 U.S. 640 (2000) 160 N. J. 562, 734 A. 2d 1196. The relatively small number of users of DCO products, the high ratio of information to product use—two hours a day on the radio, several web sites, news letters and various manuals—all of which repeat the structure-function message of the statements presented for the products above, and five small stores that asked to make DCO products available to their communities all reinforce the fact that DCO is in a community of people with shared beliefs involved in an Expressive Association rather than a business organized to make a profit.

Complaint Counsel misread the nature of the dispute in this case. There is here a paradigm clash. Counsel and the FTC assert and apparently believe that the only legitimate proper evidence for a party to rely on in making claims about dietary supplements such as herbs is the classical testing of dangerous single chemical entities. As Respondents' expert Dr. Rustum Roy made clear, this is not an appropriate approach to testing natural products that pose no inherent risk, have been around for centuries—maybe as long as the Bible—and have traditional use profiles.

As Respondents' herbal expert Dr. James Duke pointed out, it is estimated that there are as many as five thousand single chemical entitles in turmeric, one herb used by Respondents. It is patently obvious that the classical testing of herbal ingredients in the way dangerous single chemical entities are tested is impractical, unwise and dangerous—depriving individuals of herbs useful to their health. The fact of the matter is that the herbal world has accepted scientific norms—which by the way Dr. Miller, Complaint Counsel's cancer expert, acknowledged that he was unfamiliar with--with which Respondents have complied.

The fact that Complaint Counsel has chosen to argue that the only way to comply with the law is to subject herbs to the same standard as single chemical entities means that Counsel has failed to meet the FTC's responsibility to address the nature of the herbal claims made—Counsel has not provided evidence on the net impression of the claims, the nature of the audience to which they are addressed, substantiation, the state interest being vindicated or the existence of herbal science that supports Respondents'. Their failure to address these issues means that Complaint Counsel is not entitled to a summary decision. In fact, their failure to address these issues entitles Respondents to a summary decision as set out in Respondents' Motion for Summary Decision.

Citizens Have the Right to Seek Alternatives to Standard Medicine

The Respondents assert the right of consumers to intentionally forgo standard treatment and engage in other methods to achieve and maintain a healthy status. This interest of citizens is especially significant in the context of a private association for religious dietary and nutritional expressive activities.

In the case of *State v Biggs* (46 SE Reporter 401, 1903) the North Carolina Supreme Court dealt with a person who was advising people as to diet, and administering massage, baths and physical culture. In the Biggs case, the defendant "advertised himself as a 'nonmedical physician'... [and] held himself out to the public to cure disease by 'a system of drugless healing'..." p.401.

That Court held that there could be no "state system of healing" p.402 and while "Those who wish to be treated by practitioners of medicine and surgery had the guaranty that such practitioners had been duly examined...those who had faith in treatment by methods not included in the 'practice of medicine and surgery' as usually understood, had reserved to them the right to practice their faith and be treated, if they chose, by those who openly and avowedly did not use either surgery or drugs in the treatment of diseases..." p.402. Biggs was acquitted.

"The state has not restricted the cure of the body to the practice of medicine and surgery -- allopath, as it is termed, -- nor required that, before anyone can be treated for any bodily ill, the physician must have acquired a competent knowledge of allopath and be licensed by those skilled therein. To do that would be to limit progress by establishing allopathy as the state system of healing, and forbidding all others. This would be as foreign to our system as a state church for the cure of souls. All the state has done has been to enact that, when one wished to practice medicine or surgery, he must, as a protection to the public [not to the doctor], be examined and licensed by those skilled in surgery and medicine. To restrict all healing to that one kind -- to allopath, excluding homeopathy, osteopathy, and all other treatments -- might be a protection to doctors in surgery and medicine; but that is not the object of the act, and might make it unconstitutional, because

creating a monopoly." North Carolina's Supreme Court in *State v MacKnight*, 42 S.E. 580, 1902 at p 582.

In *Hillman/Kohan Eyeglasses, Inc v New Jersey State Board*, 169 NJ Super 259, the Court observed that, absent compelling health reasons, consumers should have choices in the competitive marketplace, and further, that if the legislature had intended to create a monopoly, it would have done so by specific grant of monopoly, which it did not do in the case of optometry, nor, we assert, in the case of nutritional support for persons concerned with diagnosed diseases such as cancer.

People have the right to obtain unlicensed, private professional health care services. The Southern District of Texas case of *Andrews v. Ballard* (498 F Supp 1038, 1980) is cited as a leading authority for the propositions that (1) a decision to obtain (in this case) acupuncture needle treatments from one not licensed as a medical doctor is a constitutional right encompassed by the right of privacy (p.1048) and (2) the provisions of the medical practices act, insofar as they limit the use of acupuncture needles to licensed physicians, are unconstitutional (p.1051, et seq.).

The North Carolina Supreme Court concluded, nearly a century ago in *State v. Biggs*, supra., at p.405: "Medicine is an experimental, not an exact science. All the law can do is to regulate and safeguard the use of powerful and dangerous remedies, like the knife and drugs, but it cannot forbid dispensing with them. When the Master, who was himself called the Good Physician, was told that other than his followers were casting out devils and curing diseases, he said, 'Forbid them not.'" p.405.

Traditional Use Claims and the FTC

Based upon the FTC's own Internet postings, Complaint Counsel has ignored a significant basis for the substantiation of the nutritional claims made by the Respondents.

"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." http://www.ftc.gov/bcp/conline/pubs/buspubs/dietsupp.htm FTC - Dietary Supplements: An Advertising Guide for Industry.

FTC continues - "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.

One can see from the above FTC analysis that RISK and BENEFIT will be weighed on a spectrum of risk – at one end are products that support natural structure and function and at the other end are products that claim to treat life-threatening diseases.

The distinction between "treat" life-threatening diseases and offering "therapies" that may benefit normal structure and function for persons facing such diseases is well founded in law. Let us therefore consider the use of the terms "therapy" and "therapeutic" with reference to alternative health practices. It compares those terms to the term-of-art, "treatment of disease." Alternative health practices can be generally defined as traditional

or other practices that are used by individuals, often for self-help, to achieve and maintain a healthy status, either on their own or complementary to standard medical care. These practices do not include the potentially dangerous use of invasive techniques and toxic drugs that are the province of licensed medicine. They do, however, include developing therapies and nonstandard approaches that are outside the scope of licensed medicine. These are sometimes referred to as "Complementary and Alternative Modalities" (CAM).

CAM health practices can be generally defined as traditional or other practices that are used by individuals, often for self-help, to achieve and maintain a healthy status, either on their own or complementary to standard medical care. These practices do not include the potentially dangerous use of invasive techniques and toxic drugs that are the sole province of licensed medicine. They do, however, include developing therapies and nonstandard approaches that are outside the scope of licensed medicine. Such approaches as Nutrition, Homeopathy, Hands-on-Healing, Magnetics, Sound Health, Energy Therapies, Biofeedback, Meditation, Breath Work, Reiki, Chi Gong, Tai Chi and Herbology are examples of complementary and alternative therapeutic practices. Traditional Chinese, Ayurvedic medicine or folk remedies and "Dr. Mom" home remedies are also examples of CAM practices.

The terms “therapy” and “therapeutic” do not occur, for example, in the context of the Dietary Supplement Health and Education Act of 1994 (DSHEA). Rather, that statute, passed unanimously by Congress, tells us that Dietary Supplements may not “diagnose, treat, cure or prevent” any disease. It does not specifically forbid the use of the word “therapy” (or “therapeutic”). Under the Supreme Court’s rule in the *Thompson v Western*

Medical 535 U. S. 357 (2002) 238 F.3d 1090, affirmed. case, we should expect that these words would not be forbidden by the Courts.

Further, the Code of Medical Ethics of the American Medical Association has also begun to acknowledge an independent use of the term "therapy." The original Hippocratic Oath, with its injunction to "Do no harm." has been replaced by a complex Code detailing the relationship between physician and patient and alternative practitioner. Changes made during the early 1990's were inspired by anti-trust lawsuits brought during the 1980's by chiropractors and others. These changes are just now becoming recognized by regulators and courts.

While "treatment which has no scientific basis" remains condemned (Opinion 3.01), under Opinion 3.04, physicians are free to "refer" a patient "for therapeutic or diagnostic services to another physician, limited practitioner or any other provider of health care services permitted by law to furnish such services, whenever he or she believes that this may benefit the patient." Thus, unscientific "treatment" is distinguished from "health care services permitted by law."

"Treatment" -- which means the use of standard medicine and surgery to "cure" disease -- is distinguished from other health care services (therapies) which need only meet the lesser "may benefit" standard. While physicians "prescribe" treatments for disease, therapies that may benefit may be subject to "referral" thereby further indicating the distinction. Thus, for example, Dietary Supplements that support normal structure and function to support therapeutic outcomes can be seen to complement licensed medicine, but not to be held to its strictures, nor limited in its practice to licensed physicians. Since

such therapies are not prescription services, members of the public may choose such services without the permission of their physician.

The claims made for Therapeutic Nutritionals must, of course, be allowed Structure and Function Claims. Thus, for example, one cannot claim that a nutrient (except for plant sterols) lowers cholesterol levels – since there is now a "disease" of hypercholesterolemia – but can claim that a nutrient maintains normal cholesterol levels for persons with normal cholesterol. A purveyor may say that a certain combination of multivitamins was designed to maintain normal structure and function for a person with diabetes, but not that the combination treats diabetes or affects the blood sugar level. Similarly, any claim made for any alternative practice must meet the FTC standard of "truthful and not misleading" and must be based on reasonable substantiation. Telling people what an alternative practitioner does NOT do is as important as telling what is done. It is therefore important to include the proper Disclaimers for any use of alternative practices.

As the High Court said in *Thompson*, "We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information. * * * Even if the Government did argue that it had an interest in preventing misleading advertisements, this interest could be satisfied by the far less restrictive alternative of requiring ... a warning..."

What is the proper level of substantiation for alternative practice claims? It is not the "significant scientific agreement" required of drug claims, but rather, the general "competent scientific evidence" standard that applies to all commercial claims. That does not necessarily mean that purveyors need to have multiple double-blind experiments (as