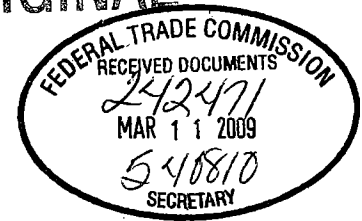


ORIGINAL



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

<p>In the Matter of DANIEL CHAPTER ONE, a corporation, and JAMES FEIJO, individually, and as an officer of Daniel Chapter One</p> <hr/>	<p>) Docket No.: 9329))) PUBLIC DOCUMENT))))))</p>
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**MEMORANDUM IN OPPOSITION TO
COMPLAINT COUNSEL'S MOTION
FOR SUMMARY DECISION**

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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."

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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 health 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. 2.

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 entities 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/online/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

may be required for drug approval). Such substantiation just needs to be competent and scientific.

This means research studies (which is when scientists review the work of others and apply it to specific questions) and clinical trials (which can be as formal as double-blind, placebo controlled investigations) as well as traditional knowledge and clinical experience all have a role to play, but ultimately, such substantiation must rest on the informed professional opinion of some credentialed person who can (in the case of Dietary Supplements, for example) sign onto the Structure and Function Claims Notice to the FDA, attesting that "the notifying firm has substantiation that the Statement to which this Notice applies is truthful and not misleading." (Regulations under 21 U.S.C. 403(r) (6)).

Many times people seek to make claims based on Traditional Uses. This is what the FTC says, "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. * * * 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."

Throughout the world today people are looking to traditional methodologies and leading-edge CAM techniques because they offer alternatives to toxic, expensive drugs with their dangerous side effects, un-manageable and unreasonable costs and other invasive technologies of modern medicine. This search for alternatives is protected by the fundamental right of individuals to communicate and learn; to heal and be healed.

This has been settled law for over a hundred years.

"The state has not restricted the cure of the body to the practice of medicine and surgery -- allopathy, 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 allopathy 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 allopathy, 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.

The problem raised by these examples and the issues they address is not how they should be resolved. The problem is that Complaint Counsel has comely ignored they existence and ;owe ahead arguing the only answer the atsupplied by their cancer expert as appropriate for single entity inherently dangerous chemicals that might have some benefit that outweighs there harm. Cjompnat

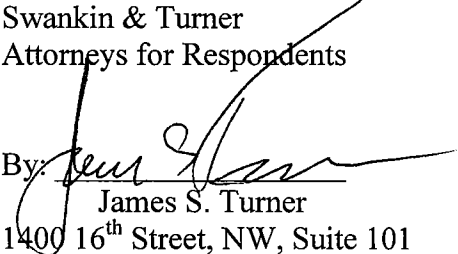
Counsel filed to address the issues that are at the heart of the case. Respondent has presented evidence that they complied with the standards that govern herbal claims. Complaint counsel has presented no evidence they have not.

CONCLUSION

Complaint Counsel's motion for Summary Decision should be denied.

Dated this 10th day of March, 2009.

Swankin & Turner
Attorneys for Respondents

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Exhibit

1

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

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

**COMPLAINT COUNSEL’S STATEMENT OF MATERIAL FACTS
AS TO WHICH THERE IS NO GENUINE ISSUE**

Pursuant to Commission Rule of Practice 3.24, 16 C.F.R. § 3.24, and in support of their motion for summary decision, Complaint Counsel submit this Statement of Material Facts as to Which There is No Genuine Issue.

A. DANIEL CHAPTER ONE AND THE FEIJOS

1. Respondent Daniel Chapter One (“DCO”) is a corporation sole organized in 2002 under the laws of the state of Washington. Respondents’ Answer to FTC’s Compl., dated Oct. 14, 2008 (hereinafter referred to as the “Answer”) at ¶ 1; *see also* Complaint Counsel’s Summary Decision Exhibit (hereinafter referred to as S.D. Ex. ___) 3 (Declaration of FTC Investigator Michael Marino, dated Feb. 23, 2009, (hereinafter referred to as “Marino Dec.”) at ¶ 23, Exhibit L).
2. Respondent James Feijo is responsible for the activities of Respondent DCO as its Overseer. Answer ¶ 2.
3. Patricia Feijo, Respondent James Feijo’s wife, is the secretary for DCO. Deposition of Patricia Feijo, January 14, 2009, (hereinafter referred to as *P. Feijo Dep. Tr.*) at 10, l. 17-21; 52, l. 3-16.
4. Respondent James Feijo and his wife, Patricia, originally started DCO as a health food store in 1986. *P. Feijo Dep. Tr.* at 39, l. 14-25 - 40, l. 1-20.

5. Respondents' principal office and place of business is located at 1028 East Main Road, Portsmouth, Rhode Island 02871. Answer ¶ 1; Deposition of James D. Feijo, January 13, 2009, (hereinafter referred to as *J. Feijo Dep. Tr.*) at 99, l. 10-18.
6. James Feijo sold DCO products prior to registering as a corporation sole. *J. Feijo Dep. Tr.* at 224, l. 4-6.
7. DCO offers 150 to 200 products today. *J. Feijo Dep. Tr.* at 37, l. 11-13.
8. Respondent James Feijo is responsible for the development, creation, and production of Bio*Shark, 7 Herb Formula, GDU, and BioMixx (collectively, the "DCO Products"). S.D. Ex. 4 (*J. Feijo Dep. Ex. 7 - Respondents' Responses to Complaint Counsel's First Set of Interrogs., Resp. to Interrog. No. 2*); *J. Feijo Dep. Tr.* at 116, l. 17-21.
9. Respondent James Feijo is the trustee for all Daniel Chapter One assets, including all funds which are held in trust. S.D. Ex. 4 (*J. Feijo Dep. Ex. 7 - Respondents' Responses to Complaint Counsel's First Set of Interrogs., Resp. to Interrog. No. 9*).
10. Daniel Chapter One has a bank account with Citizens Bank. Deposition of Jill Susan Feijo, January 22, 2009, (hereinafter referred to as *Jill Feijo Dep. Tr.*) at 33, l. 19-23.
11. Patricia Feijo is a signatory to DCO's bank account and writes checks on behalf of the DCO account. *P. Feijo Dep. Tr.* at 54, l. 8-19.
12. Jill Feijo, James Feijo's daughter and Respondents' corporate representative, also has authority to write checks on behalf of the DCO account. *Jill Feijo Dep. Tr.* at 34, l. 15-17.
13. Respondent James Feijo receives all the bank statements for the DCO account. *Jill Feijo Dep. Tr.* at 34, l. 10-11.
14. Respondent James Feijo maintains the financial records for DCO. *Jill Feijo Dep. Tr.* at 47, l. 6-8.
15. Respondent DCO defrays James Feijo's expenses as Overseer and provides for his support. S.D. Ex. 4 (*J. Feijo Dep. Ex. 7 - Respondents' Responses to Complaint Counsel's First Set of Interrogs., Resp. to Interrog. No. 3*).
16. Respondent James Feijo pays his daughter Jill \$700 per week cash for her work at Daniel Chapter One. *Jill Feijo Dep. Tr.* at 13, l. 3-9.
17. DCO has two buildings in Portsmouth, Rhode Island – one contains the office with the Order Center and the other contains the products that DCO offers to the public. *Jill Feijo Dep. Tr.* at 20, l. 9-24.

18. DCO is not registered with the Internal Revenue Service as a charity. *J. Feijo Dep. Tr.* at 45, l. 11-13.
19. Messiah Y'Shua Shalom, a Washington corporation sole, owns the property that Respondents use in Rhode Island. *J. Feijo Dep. Tr.* at 72, l. 7-25 - 73, l. 1-3; *see generally* S.D. Ex. 3 (Marino Dec. at ¶ 23, Exhibit M).
20. Respondent James Feijo is the overseer for Messiah Y'Shua Shalom. *J. Feijo Dep. Tr.* at 72, l. 7-25 - 73, l. 1-3; *see also* S.D. Ex. 3 (Marino Dec. at ¶ 23, Exhibit M).
21. Messiah Y'Shua Shalom houses the buildings where Respondents perform their ministry of Daniel Chapter One. *J. Feijo Dep. Tr.* at 72, l. 7-25 - 73, l. 1-3.
22. Daniel Chapter One owns a three-bedroom property in Deerfield Beach, Florida. *J. Feijo Dep. Tr.* at 70, l. 22-25 - 71, l. 1-15.
23. James and Patricia Feijo live in the properties owned by Messiah Y'Shua Shalom and DCO. *J. Feijo Dep. Tr.* at 70, l. 25 - 71, l. 1-2; 78, l. 20-25 - 79, l. 1.
24. Daniel Chapter One owns two cars - a 2003 Cadillac and a 2004 Cadillac. DCO purchased one Cadillac new and the other Cadillac used. *J. Feijo Dep. Tr.* at 71, l. 16-23.
25. Respondent James Feijo uses the two Cadillacs owned by DCO. *J. Feijo Dep. Tr.* at 96, l. 9-10, 14-16; 97, l. 7-13.
26. Respondents practice a science they call BioMolecular Nutrition. S.D. Ex. 5 (*J. Feijo Dep. Ex. 12 - BioGuide: The BioMolecular Nutrition Guide to Natural Health 3* at FTC-DCO 0307).
27. According to Respondents, “[t]here are two aspects of BioMolecular Nutrition, the spiritual and the physical.” S.D. Ex. 5 (*J. Feijo Dep. Ex. 12 - BioGuide: The BioMolecular Nutrition Guide to Natural Health 3* at FTC-DCO 0307).
28. “The principles of BioMolecular Nutrition were those missing principles needed to bind together those of the nutritionists and the biochemists.” S.D. Ex. 5 (*J. Feijo Dep. Ex. 12 - BioGuide: The BioMolecular Nutrition Guide to Natural Health 3* at FTC-DCO 0309).
29. According to Respondents, “[b]ecause of BioMolecular nutritional products developed at that time, we’ve been able to support other naturopathic disciplines – chiropractic, acupuncture, herbology, and homeopathy – and using the principles of BioMolecular Nutrition has allowed many natural health practitioners to be complete.” S.D. Ex. 5 (*J. Feijo Dep. Ex. 12 - BioGuide: The BioMolecular Nutrition Guide to Natural Health 3* at FTC-DCO 0308).

B. RESPONDENTS DISTRIBUTE THEIR PRODUCTS IN COMMERCE TO CONSUMERS

30. Respondents distribute the DCO Products in commerce. Answer ¶ 4; *J. Feijo Dep. Tr.* at 102, l. 13-16.
31. Respondent DCO has an 800 number and a call center for consumers to purchase the DCO Products. *P. Feijo Dep. Tr.* at 67, l. 7-13; *Jill Feijo Dep. Tr.* at 15, l. 5-14.
32. Respondent James Feijo created, managed, and maintained the toll-free telephone number, designed so that consumers can order the DCO Products. S.D. Ex. 4 (*J. Feijo Dep. Ex. 7 - Respondents' Responses to Complaint Counsel's First Set of Interrogs., Resp. to Interrog. No. 33*).
33. On the front page of their BioMolecular Nutrition Product Catalog, Respondents inform consumers to "Call Toll FREE 1-800-504-5511 or shop online at www.danielchapterone.com." S.D. Ex. 6 (*J. Feijo Dep. Ex. 6 - BioMolecular Nutrition Product Catalog at FTC-DCO 0060*).
34. Respondents operate the website www.danielchapterone.com. Answer ¶ 5; *J. Feijo Dep. Tr.* at 62, l. 10-13.
35. DCO also operates the Web sites dclpages.com and dcstore.com. *J. Feijo Dep. Tr.* at 232, l. 21-25 - 233, l. 1-19.
36. Consumers learn of DCO's 800 number from the DCO Web site, the BioGuide, and the radio program. *Jill Feijo Dep. Tr.* at 15, l. 15-25.
37. Respondent James Feijo established the price of the DCO Products. S.D. Ex. 4 (*J. Feijo Dep. Ex. 7 - Respondents' Responses to Complaint Counsel's First Set of Interrogs., Resp. to Interrog. No. 25*); *P. Feijo Dep. Tr.* at 77, l. 13-16.
38. Jill Feijo has supervised Respondent DCO's Order Center for the past nine years and has taken telephone orders. S.D. Ex. 4 (*J. Feijo Dep. Ex. 7 - Respondents' Responses to Complaint Counsel's First Set of Interrogs., Resp. to Interrog. No. 30*).
39. DCO employs Kevin Vandeburg, Axel Busche, and Jay Butler to work in the building that contains the DCO Products and to ship the DCO Products ordered by consumers. *Jill Feijo Dep. Tr.* at 21, l. 7-22.
40. DCO's Order Center is open Monday through Friday from 9:00 a.m. to 8:00 p.m. *Jill Feijo Dep. Tr.* at 16, l. 5-10.
41. DCO receives payments through its Order Center through credit card and COD. *Jill Feijo Dep. Tr.* at 18, l. 6-10.

42. DCO also accepts consumers' orders on the Internet. *Jill Feijo Dep. Tr.* at 18, l. 11-13.
43. DCO's Web site contains a tab inviting consumers to shop at DCO's "On-Line Store." S.D. Ex. 7 (*J. Feijo Dep. Ex. 4 - Exhibits A - D to Administrative Complaint* at FTC-DCO 0011); S.D. Ex. 8 (*Respondents' Responses and Objections to Complaint Counsel's Request for Admissions, Respondents' Answer to Complaint Counsel's Req. for Admis. Regarding Authenticity and Admissibility ¶ 1*).
44. DCO's Web site contains an icon inviting consumers to "Buy Now." S.D. Ex. 7 (*J. Feijo Dep. Ex. 4 - Exhibits A - D to Administrative Complaint* at FTC-DCO 0011); S.D. Ex. 8 (*Respondents' Responses and Objections to Complaint Counsel's Request for Admissions, Respondents' Answer to Complaint Counsel's Req. for Admis. Regarding Authenticity and Admissibility ¶ 1*).
45. Respondents' acquisition costs for the products they sell is 30 percent of the price Respondents charge to consumers for products such as 7 Herb Formula. *J. Feijo Dep. Tr.* at 232, l. 3-8.
46. Over a thousand consumers have purchased DCO's products. *P. Feijo Dep. Tr.* at 57, l. 13-18.
47. Respondents have generated approximately \$2 million in annual sales for the years 2006, 2007, and 2008 for all of DCO's two-hundred products. *J. Feijo Dep. Tr.* at 206, l. 18-20; 212, l. 14-24; S.D. Ex. 9 (*J. Feijo Dep. Ex. 9 - Daniel Chapter One Monthly Gross Sales*).
48. There is no indication in the BioMolecular Nutrition Product Catalog that the price listed is for a donation. *J. Feijo Dep. Tr.* at 158, l. 11-17; *P. Feijo Dep. Tr.* at 76, l. 11-17; 77, l. 5-12.
49. There is no mention of the DCO ministry in the BioMolecular Nutrition Product Catalog. *J. Feijo Dep. Tr.* at 161, l. 4-10.
50. Jill Feijo does not recall whether there is anything in writing regarding any alleged "donation policy." *Jill Feijo Dep. Tr.* at 22, l. 25 - 23, l. 1-3.
51. Most consumers pay DCO's alleged "suggested donation" price and "not many" people per day ask Jill Feijo to pay a lowered amount. *Jill Feijo Dep. Tr.* at 23, l. 14-21.
52. On January 3, 2008, FTC investigator Michael Marino ("Marino") purchased the DCO Products from Respondents' Web site. S.D. Ex. 3 (*Marino Dec.* at ¶ 9-10, Exhibit C).
53. Prior to making the purchase, Marino created an undercover e-mail account to confirm and monitor the progress of the purchase and received four emails from Respondents

relating to the purchase of the DCO Products. S.D. Ex. 3 (Marino Dec. at ¶ 11, Exhibit D).

54. On or about January 24, 2008, Marino received the DCO Products. S.D. Ex. 3 (Marino Dec. at ¶ 12).
55. Included in the shipment of the DCO Products ordered by Marino were the following: (a) BioGuide 3: The BioMolecular Nutrition Guide to Natural Health 3; (b) “BioMolecular Nutrition Product Catalog;” (c) a blank purchase order form; and (d) an invoice form. S.D. Ex. 3 (Marino Dec. at ¶ 12, Exhibits E-H).
56. According to the UPS Ground shipping label attached to the package containing the DCO Products and the DCO materials, the shipment originated from Daniel Chapter One, 822 Anthony Road, Portsmouth Rhode Island 02871-5604 and was sent to an FTC undercover address in a state other than Rhode Island in the United States. S.D. Ex. 3 (Marino Dec. at ¶ 12).
57. Marino inspected the contents of the shipment of the DCO Products and did not observe a separate document indicating that the purchase was a “donation” or thanking the purchaser for making a “donation” to Daniel Chapter One. S.D. Ex. 3 (Marino Dec. at ¶ 13).
58. According to Commission records, the amount charged to the undercover credit card used for the purchase of the DCO Products was \$175.75. These records also indicate that this charged was made by “DANIEL CHAPTER ONE.” S.D. Ex. 3 (Marino Dec. at ¶ 14).
59. DCO’s shipping and handling fees for its products are \$20.95. *J. Feijo Dep. Tr.* at 152, l. 22-25 - 153, l. 1-3.
60. DCO offers coupons to consumers for their next online store order. *J. Feijo Dep. Tr.* at 154, l. 2-7.
61. Respondents run promotions from time to time to “give [consumers] more of an opportunity to . . . get things at a lower rate.” *J. Feijo Dep. Tr.* at 154, l. 8-24.
62. For example, consumers can buy multiple bottles and get a bottle free. *J. Feijo Dep. Tr.* at 232, l. 16-20.
63. A number of stores nationally sell DCO’s products, including stores in Georgia and a store in Pennsylvania. *P. Feijo Dep. Tr.* at 72, l. 16-24.
64. Doctors and stores that carry DCO’s product line get the product at a lesser price because they are going to be selling it. *P. Feijo Dep. Tr.* at 71, l. 3-9.

65. Respondents' Cancer Newsletter, entitled How to Fight Cancer is Your Choice!!!, costs \$5.95. S.D. Ex. 10 (*DCO's Cancer Newsletter, Millenium [sic] Edition, 2002 - "How to Fight Cancer is Your Choice!!!"* at FTC-DCO 0405).
66. In their Cancer Newsletter, Respondents instruct consumers to call "1-800-504-5511" to order their products. S.D. Ex. 10 (*DCO's Cancer Newsletter, Millenium [sic] Edition, 2002 - "How to Fight Cancer is Your Choice!!!"* at FTC-DCO 0405).
67. In their Cancer Newsletter, entitled How to Fight Cancer is Your Choice!!!, Respondents state that their "[l]atest Bioguide" is "[o]nly \$9.95." S.D. Ex. 10 (*DCO's Cancer Newsletter, Millenium [sic] Edition, 2002 - "How to Fight Cancer is Your Choice!!!"* at FTC-DCO 0397).
68. Respondents' publication entitled The Most Simple Guide to the Most Difficult Diseases: The Doctors' How-To Quick Reference Guide costs \$12.95. S.D. Ex. 3 (Marino Dec. at ¶ 24, Exhibit N at FTC-DCO 2825).
69. On their Web site dc1store.com, Respondents state: "For Information on Special offers for **purchasing** multiple bottles of 7-Herb call 1-800-504-5511 between 9-6 EST Mon-Fri." S.D. Ex. 11 (*Pages from Respondents' Web site dc1store.com listing contact information, dated Mar. 31, 2008, at FTC-DCO 0084*) (emphasis added) .
70. On their Web site dc1store.com, Respondents state the following regarding their affiliate program: "**Welcome to the DC1 Affiliate Program!** Our program is free to join, it's easy to sign-up and requires no technical knowledge. Affiliate programs are common throughout the Internet *and offer website owners a means of profiting from their websites. Affiliates generate sales for commercial websites* and in return receive a percentage of the value of those sales. **How Does It Work?** When you join the DC1 Affiliate Program, you will be supplied with a range of banners and textual links that you place within your site. When a user clicks on one of your links to the DC1 Affiliate Program, their activity will be tracked by our affiliate software. You will earn a commission based on your commission type. **Real-Time Statistics and Reporting!** Login 24 hours a day to check your sales, traffic, account balance and see how your banners are performing. You can even test conversion performance by creating your own custom links! Affiliate Program Details. Pay-Per-Sale: 10% of all sales you deliver. \$100.00 USD - Minimum balance required Payments are made on the 1st of each month, for the previous month." S.D. Ex. 12 (*Pages from Respondents' Web site dc1store.com discussing "DC1 Affiliate Program," dated Dec. 12, 2007 at FTC-DCO 0461 - 0462*) (emphasis in bold in original; emphasis in italics supplied) .
71. When discussing the cost of DCO's products generally, Terry Brotherton, a consumer whose testimonial was provided by Respondents in discovery, stated "*[i]t wasn't cheap but it was the best money I ever spent.*" S.D. Ex. 13 (*Terry Brotherton Statement produced by Respondents as DCO 0156*) (emphasis added).

72. When discussing the cost of 7 Herb Formula specifically, Charlotte Rice, a consumer whose testimonial was provided by Respondents in discovery, stated, "I then proceeded to reduce my 7 Herb Formula to a maintenance dosage. Tricia & Jim Feijo did not agree with my decision. They felt I should stay on the maximum dosage to be safe, **but I was having financial problems, and could not afford the cost.**" S.D. Ex. 14 (*Charlotte Rice Statement produced by Respondents as DCO 0170 - 0171* at DCO 0170) (emphasis added).
73. When discussing the cost of 7 Herb Formula, GDU, Bio*Shark, and other DCO products, Earl Davis, a consumer whose testimonial was provided by Respondents in discovery, stated, "[t]he only drawback that we've experienced is the pricing of the products. There should be discounts for customers who have referred lots of people and for those customers who consume lots of product monthly because alternative therapy is expensive. . . ." S.D. Ex. 15 (*Earl Davis Statement produced by Respondents as DCO 0187*) (emphasis added).
74. When discussing the cost of 7 Herb Formula, Ernie Jensen, a consumer whose testimonial was provided by Respondents in discovery, stated "I could not afford the 7 Herb [Formula]." S.D. Ex. 16 (*Ernie Jensen Statement produced by Respondents as DCO 0189 - 0193* at DCO 0189).
75. The trademark symbol appears next to Respondents' term "BioMolecular Nutrition" and Respondents' products 7 Herb Formula, GDU, and BioMixx. S.D. Ex. 6 (*J. Feijo Dep. Ex. 6 - BioMolecular Nutrition Product Catalog* at FTC-DCO 0060 - 0061).

BioShark

76. Bio*Shark is a product that contains, among other ingredients, Shark Cartilage. Answer ¶ 6.
77. Respondents offer one bottle of Bio*Shark for \$65.95 (300 of the 800 mg capsules) and \$30.95 (100 of the 800 mg capsules). Answer ¶ 6.
78. Respondents pay Universal Nutrition \$3.15 per unit for the 100 capsule bottle of Bio*Shark and \$8.75 per unit for the 300 capsule bottle of Bio*Shark. Deposition of Claudia Petra Bauhoffer-Kinney, January 15, 2009, (hereinafter referred to as *Kinney Dep. Tr.*) at 44, l. 15-19.
79. During 2008, Respondents paid Universal Nutrition approximately \$1,437 to manufacture 479 units of the 100 capsule bottle of Bio*Shark and approximately \$6,256 to manufacture 782 units of the 300 capsule bottle of Bio*Shark. *Kinney Dep. Tr.* at 45, l. 3-10.
80. Universal Nutrition does two things - it has its own brand of products, and it also is a private label manufacturer. *Kinney Dep. Tr.* at 17, l. 10-23.

81. DCO falls under the private label part of Universal Nutrition. *Kinney Dep. Tr.* at 17, 1. 24-25.
82. Universal Nutrition makes approximately 35-40 products for DCO, including Bio*Shark, GDU, and BioMixx. *Kinney Dep. Tr.* at 21, 1. 1-19.
83. Universal Nutrition started manufacturing Bio*Shark for Respondents approximately eight to ten years ago. *Kinney Dep. Tr.* at 42, 1. 23-25 - 43, 1. 1.

7 Herb Formula

84. 7 Herb Formula is a liquid tea concentrate product that contains, among other ingredients, distilled water, Cat's Claw, Burdock Root, Siberian Ginseng, Sheep Sorrel, Slippery Elm, Watercress, and Turkey Rhubarb Root. Answer ¶ 8.
85. Respondents offer one 32-ounce bottle of 7 Herb Formula for \$70.95. Answer ¶ 8.
86. On their Web sites danielchapterone.com and dc1pages.com, Respondents state the following regarding 7 Herb Formula: "I think it costs too much: Essiac formulas normally retail for \$45 to \$69 per bottle. If you compare that to the cost of a hospital stay and drug treatment, this is cheap! ***Daniel Chapter One's 7 Herb Formula is equally priced with most other brands but with ours you get a great deal more.*** Remember you are not only getting 32 ounces per bottle, when some of the other brands are only 16 ounces; you are also getting 2 more expensive herbs (Cat's Claw and Siberian Ginseng). We use 3 times the herbs and prepare each individually using a double water filtering process. If that is the case you must at least double the price they are asking to get equal price comparison." S.D. Ex. 17 (*Pages from Respondents' Web sites dc1pages.com, dated April 2, 2008, at FTC-DCO 0159 - 0160, and danielchapterone.com, dated November 7, 2008, at FTC-DCO 0495, stating "I think it costs too much"*) (emphasis added).

GDU

87. GDU is a product that contains, among other ingredients, Bromelain, Turmeric, Quercetin, Feverfew, and Boron. Answer ¶ 10.
88. Respondents offer GDU for \$45.95 (300 capsules) and \$29.95 (120 capsules). Answer ¶ 10.
89. Respondents pay Universal Nutrition \$3.28 per unit for the 120 tablet [sic] bottle of GDU and \$7.07 per unit for the 300 tablet [sic] bottle of GDU. *Kinney Dep. Tr.* at 34, 1. 21-25 - 35, 1. 1-4.

90. During 2008, Respondents paid Universal Nutrition approximately \$5,127 to manufacture 1,709 units of the 120 tablet [sic] bottle of GDU and approximately \$52,661 to manufacture 7,523 units of the 300 tablet [sic] bottle of GDU. *Kinney Dep. Tr.* at 34, l. 5-25 - 35, l. 1-4.

BioMixx

91. BioMixx is a product that contains, among other ingredients, Goldenseal, Echinacea, and Ginseng. Answer ¶ 12.
92. Respondents offer BioMixx for \$40.95 (3 lb. powder) and \$22.95 (1 lb. powder). Answer ¶ 12.
93. Respondents pay Universal Nutrition \$11.50 per unit for the 3 pound bottle of BioMixx. *Kinney Dep. Tr.* at 46, l. 8-16.
94. During 2008, Respondents paid Universal Nutrition approximately \$8,778 to manufacture 798 units of the 3 pound bottle of BioMixx. *Kinney Dep. Tr.* at 46, l. 8-16.

C. RESPONDENTS DIRECT CONSUMERS ON HOW TO TAKE THEIR PRODUCTS

95. Respondent James Feijo and his wife, Patricia Feijo, have been solely responsible for creating, drafting, and approving the directions for usage and the recommended usages of the DCO Products. S.D. Ex. 4 (*J. Feijo Dep. Ex. 7 - Respondents' Responses to Complaint Counsel's First Set of Interrogs., Resp. to Interrog. No. 16*).
96. There only has been one version of each of the DCO Products, and the information relating to the identity of each ingredient and the amount of each ingredient is contained on the labels for the DCO Products. S.D. Ex. 4 (*J. Feijo Dep. Ex. 7 - Respondents' Responses to Complaint Counsel's First Set of Interrogs., Resp. to Interrog. No. 17*).
97. Each Bio*Shark product 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. Answer ¶ 6; S.D. Ex. 18 (*P. Feijo Dep. Ex. 14 - Bio*Shark Labels at FTC-DCO 0065 - 0066, 0122 - 0123*).
98. Respondent James Feijo and his wife developed the suggested dosage for Bio*Shark, and the suggested dosage was based on their "reading and from experience." *P. Feijo Dep. Tr.* at 166, l. 19-25 - 167, l. 1-4.
99. Respondents' product label directs users to take 1-2 ounces of 7 Herb Formula with 2-4 ounces of hot or cold filtered or distilled water. The label further directs users to take 7 Herb Formula twice daily or as directed by a BioMolecular Nutrition Health care

professional. Answer ¶ 8; S.D. Ex. 19 (*P. Feijo Dep. Ex. 15 - 7 Herb Formula Labels at FTC-DCO 0064, 0124*).

100. Respondent James Feijo and his wife developed the suggested dosage for 7 Herb Formula. *P. Feijo Dep. Tr.* at 175, l. 13-16.
101. Respondents' GDU product label directs users to take 3-6 capsules 2 to 4 times per day or as directed by a physician or by a BioMolecular Nutrition health care professional. Answer ¶ 10; S.D. Ex. 20 (*P. Feijo Dep. Ex. 16 - GDU Caps Labels at FTC-DCO 0125 - 0126, 0067 - 0068*).
102. Respondent James Feijo and his wife developed the suggested dosage for GDU. *P. Feijo Dep. Tr.* at 192, l. 20-23.
103. Respondents' product label for BioMixx directs users to take five scoops daily. Answer ¶ 12; S.D. Ex. 21 (*P. Feijo Dep. Ex. 17 - BioMixx Labels at FTC-DCO 0127 - 0128*).

D. RESPONDENTS CLAIM THAT THEIR PRODUCTS CURE, MITIGATE, TREAT, OR PREVENT CANCER OR TUMORS.

104. DCO's Web site depicts pictures of the DCO Products next to the statement "Daniel Chapter One's Cancer Solutions." *P. Feijo Dep. Tr.* at 176, l. 20-25 - 177, l. 1-19; S.D. Ex. 7 (*J. Feijo Dep. Ex. 4 - Exhibits A - D to Administrative Complaint at FTC-DCO 0014*); S.D. Ex. 8 (*Respondents' Responses and Objections to Complaint Counsel's Request for Admissions, Respondents' Answer to Complaint Counsel's Req. for Admis. Regarding Authenticity and Admissibility* ¶ 2).
105. On their Web site dc1pages.com, Respondents publish information about the DCO Products, including, but not limited to, the following:

Supporting Products

To enhance 7 Herb Formula's healing quantities Daniel Chapter One advises [sic] to get familiar with the supporting products below:

**CANCER
TREATMENT:**

**7Herb Formula
Bio*Shark
BioMixx
GDU Caps**

also

Ezekiel Oil
topically

S.D. Ex. 22 (*Pages from Respondents' Web site dclpages.com regarding "Supporting Products," dated April 2, 2008 at FTC-DCO 0190*).

106. In DCO's The Most Simple Guide to the Most Difficult Diseases: The Doctors' How-To Quick Reference Guide, DCO recommends the following products for cancer:

CANCER

All types of Cancer

7*Herb Formula™

2 ounces in juice or water
(minimum intake)
2 times daily

Bio*Shark™**(for tumors only)**

2 - 4 capsules
3 times daily with meals

BioMixx™ (Boosts immune system)

4 - 5 scoops in soy milk
2 times daily

GDU Caps™

3 - 6 capsules
3 times daily; ½ hr.
BEFORE meals

S.D. Ex. 3 (M. Marino Dec. at ¶ 24, Exhibit N at FTC-DCO 2739).

107. Through the "Testimonies" tab on the danielchapterone.com Web site, Respondents provide the following titles for testimonials from their customers, who claim that DCO's Products were effective in the cure, mitigation, treatment, or prevention of cancer or tumors:

Cancer, Bladder (Drew Dellinger)
Cancer, Breast Mass (Deloris Winter)
Cancer, Cancerous Lung Tumor (Douglas Meeks)
Cancer, Cancerous Tumor (Joe Rocha)
Cancer, Leukemia, Brain Tumor (Tracey Kulikowski)
Cancer, Prostate (Jim Givens)
Cancer, Prostate Cancer (Joe)
Special Forces Officer Overcomes Prostate Cancer

Cancer, Prostate (Sherman “Red” Smith)
Cancer, Renal Cell (Jim Hatfield)
Cancer, Skin (Pastor Wayne Harms)
Cancer, Stage 4 (Joseph Jungles)

S.D. Ex. 23 (*Testimonials from Respondents’ Web site at FTC-DCO 0100 - 0119*).

108. In Respondents’ BioGuide: The BioMolecular Nutrition Guide to Natural Health 3, Respondents published the following testimonial from Tracey Kulikowski that states: “I had contracted leukemia and had three inoperable tumors. When I decided not to do chemotherapy or radiation, my father sent me **BIOMIXX** 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, Siberian Ginseng, and **Bio*Shark**. I am now in complete remission. The cancer cell count has dropped, the doctors tell me. I had a tumor just above the brain stem in my brain that has completely disappeared. The tumor on my liver is shrinking and the tumor behind my heart has shrunk over 50%. . . . There are alternatives besides chemo and radiation!” S.D. Ex. 5 (*J. Feijo Dep. Ex. 12 - BioGuide: The BioMolecular Nutrition Guide to Natural Health 3 at FTC-DCO 0353*)(emphasis in bold added).
109. Respondent James Feijo was responsible for putting together BioGuide 3. *J. Feijo Dep. Tr.* at 243, l. 12-21.
110. Patricia Feijo was responsible for writing the BioGuide. *P. Feijo Dep. Tr.* at 20, l. 15-25.
111. Bio*Shark, 7 Herb Formula, GDU, and BioMixx all appear in Respondents’ Cancer Newsletter, entitled How to Fight Cancer is Your Choice!!!. S.D. Ex. 10 (*DCO’s Cancer Newsletter, Millenium [sic] Edition, 2002 - “How to Fight Cancer is Your Choice!!! at FTC-DCO 0390 - 405*).
112. The Cancer Newsletter is “strictly all about the products for cancer.” *J. Feijo Dep. Tr.* at 143, l. 17-22.
113. Patricia Feijo was responsible for writing the Cancer Newsletter. *P. Feijo Dep. Tr.* at 26, l. 23-25 - 27, l. 1-19; 28, l. 5-10.
114. James and Patricia Feijo are not doctors. *P. Feijo Dep. Tr.* at 114, l. 15-16.
115. James Feijo never held a position where he had to use any skills involving medicine. *J. Feijo Dep. Tr.* at 47, l. 12-17.
116. James and Patricia Feijo are not research scientists. *P. Feijo Dep. Tr.* at 114, l. 16.
117. During the July 8, 2008 DCO Healthwatch radio program, James Feijo stated that “the FTC, the FDA, the Canadian Government don’t like the fact that we’ve told people about

what to do about natural methods of health and healing, especially cancer.” S.D. Ex. 3 (Marino Dec. at ¶ 22, Exhibit J at 7, l. 16-19 (FTC-DCO 0506)).

118. During the July 14, 2008 DCO Healthwatch radio program, Patricia Feijo stated the following: “And while the FTC does not want us saying that anything natural can be used to treat cancer and that nothing certainly can cure cancer, we know that the truth is different than what they want us to say. The truth is God has given us herbs in His creation and nutrients that can heal cancer, even cure cancer.” S.D. Ex. 3 (Marino Dec. at ¶ 22, Exhibit K at 4, l. 17-23 (FTC-DCO 0612)).

BioShark

119. Respondents publish information about Bio*Shark, including, but not limited to, the following:

PRODUCTS

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, and halt the progression of eye diseases such as diabetic retinopathy and macular degeneration. . .

Answer ¶ 7; S.D. Ex. 8 (*Respondents’ Responses and Objections to Complaint Counsel’s Request for Admissions, Respondents’ Answer to Complaint Counsel’s Req. for Admis. Regarding Authenticity and Admissibility ¶ 1*); see also *J. Feijo Dep. Tr.* at 61, l. 11-14; 100, l. 24-25 - 101, l. 1; 107, l. 15-18; *P. Feijo Dep. Tr.* at 156, l. 14-25 - 157, l. 1-7.

120. Respondents publish information about Bio*Shark, including, but not limited to the following:

If you suffer from any type of cancer, Daniel Chapter One suggests taking this products [sic], to fight it: [emphasis added]

7*Herb Formula™ . . .

Bio*Shark™ . . . [emphasis added]

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! . . . [emphasis added]

Answer ¶ 9; S.D. Ex. 8 (*Respondents’ Responses and Objections to Complaint Counsel’s Request for Admissions, Respondents’ Answer to Complaint Counsel’s Req. for Admis. Regarding Authenticity and Admissibility ¶ 2*); see also *J. Feijo Dep. Tr.* at 61, l. 11-14; 100, l. 24-25 - 101, l.1; 110, l. 23-25 - 111, l. 13-20.

121. In their BioMolecular Nutrition Product Catalog, next to the pictures of the BioShark bottles, Respondents state that “Shark Cartilage protein inhibits angiogenesis, stops tumor growth, and halts eye disease.” S.D. Ex. 6 (*J. Feijo Dep. Ex. 6 - BioMolecular Nutrition Product Catalog* at FTC-DCO 0061).
122. On a prior Daniel Chapter One Web site, Respondents stated “**Bio*Shark Shark Cartilage** Stops tumor growth in its tracks.” S.D. Ex. 24 (*Respondents’ “Web Pages from prior Daniel Chapter One Web sites” at FTC-DCO 2032*) (emphasis in original).

7 Herb Formula

123. 7 Herb Formula is a product that can be used by a person who is suffering from cancer. *P. Feijo Dep. Tr.* at 171, l. 4-8.
124. Respondents publish information about 7 Herb Formula, including, but not limited to, the following:

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: [emphasis added]

7*Herb Formula™... [emphasis added]

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!... [emphasis added]

Answer ¶ 9; S.D. Ex. 8 (*Respondents’ Responses and Objections to Complaint Counsel’s Request for Admissions, Respondents’ Answer to Complaint Counsel’s Req. for Admis. Regarding Authenticity and Admissibility* ¶ 2); see also *J. Feijo Dep. Tr.* at 60, l. 17-22; 101, l. 2-6; 110, l. 23-25; 111, l. 13-20.

125. Respondents publish information about 7 Herb Formula, including, but not limited to, the following:

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. . .'

Answer ¶ 9; S.D. Ex. 8 (*Respondents' Responses and Objections to Complaint Counsel's Request for Admissions, Respondents' Answer to Complaint Counsel's Req. for Admis. Regarding Authenticity and Admissibility* ¶ 2); see also *J. Feijo Dep. Tr.* at 60, l. 17-22; 101, l. 2-6; 110, l. 23-25; 111, l. 13-20.

126. In their BioMolecular Nutrition Product Catalog, next to the picture of the 7 Herb Formula bottle, Respondents state that the herbs in 7 Herb Formula "purify the blood and promote cell repair, clear skin, cleanse the liver, decrease cell mutation, fight pathogenic bacteria and **tumor formation.**" S.D. Ex. 6 (*J. Feijo Dep. Ex. 6 - BioMolecular Nutrition Product Catalog* at FTC-DCO 0061) (emphasis added).
127. In Respondents' BioGuide: The BioMolecular Nutrition Guide to Natural Health 3, Respondents published the following testimonial from Buzz McKay: "I had beam radiation for **prostate cancer**. I also took 7 Herb Formula, 6 ounces a day, and BioMixx; I never had a bad day, never felt sick. When my PSA went from 7.6 to 0.5 in the month after I finished radiation, my doctor was surprised. Several months later, it was down to 0.16! 7 Herb Formula is extremely well done - fantastic. I still take 2 ounces of **7 Herb Formula** every morning; I plan to stay on that forever! **I figure 6 ounces (2 morning, 2 afternoon, 2 evening) did such a good job fighting cancer**, 2 ounces is a good prophylaxis!" S.D. Ex. 5 (*J. Feijo Dep. Ex. 12 - BioGuide: The BioMolecular Nutrition Guide to Natural Health 3* at FTC-DCO 0330) (emphasis added).
128. On their Web sites danielchapterone.com and dc1pages.com, Respondents publish information about 7 Herb Formula, including, but not limited to, the following: "With Jim Feijo's addition to the [7 Herb] formula, we now have the most effective and potent formula available in the battle against tumors." S.D. Ex. 25 (*Pages from Respondents' Web sites dc1pages.com, dated April 2, 2008, at FTC-DCO 0142, and danielchapterone.com, dated November 7, 2008, at FTC-DCO 0493, regarding "I want the Original Essiac Formula, not some knock off brand"*).
129. On their Web site dc1pages.com, Respondents publish information about 7 Herb Formula, including, but not limited to, the following: "The 7 Herb Formula has been used by patients involved in clinical studies in cancer clinics and sold in doctor's offices around the country." S.D. Ex. 26 (*Pages from Respondents' Web site dc1pages.com regarding "I use Brand X," dated April 2, 2008, at FTC-DCO 0157*).

130. During the July 8, 2008 DCO Healthwatch radio program, James Feijo stated the following: “Here’s a testimony from Pastor Wayne Hamm, Henderson, Nevada. He had the Gulf War illness. He was told that he needed surgery and radiation treatment for his cancer, that he developed skin cancer because of the Gulf War, he was exposed out there. He didn’t take it. He decided to use Daniel Chapter One 7 Herb Formula, internally and topically. He also used Ezekiel Oil topically, BioShark and GDU. My skin cleared up after a few months in the late 1980s, early ‘99, I was told there was no trace of cancer. The FDA does not want us to let you know about this.” S.D. Ex. 3 (Marino Dec. at ¶ 22, Exhibit J at 104, l. 13-24 (FTC-DCO 0603)).
131. During the July 14, 2008 DCO Healthwatch radio program, Patricia Feijo stated that 7 Herb Formula is “great for cancer.” S.D. Ex. 3 (Marino Dec. at ¶ 22, Exhibit K at 83, l. 8-13 (FTC-DCO 0691)).

GDU

132. Respondents publish information about GDU, including, but not limited to, the following:

PRODUCTS

...

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. [emphasis added]

Answer ¶ 11; S.D. Ex. 8 (*Respondents’ Responses and Objections to Complaint Counsel’s Request for Admissions, Respondents’ Answer to Complaint Counsel’s Req. for Admis. Regarding Authenticity and Admissibility ¶ 3*); see also *J. Feijo Dep. Tr.* at 101, l. 7-9; 138 l. 22-25 - 139, l. 1-2; *P. Feijo Dep. Tr.* at 185, l. 24-25 - 186, l. 1-16.

133. Respondents publish information about GDU, including, but not limited to, the following:

If you suffer from any type of cancer, Daniel Chapter One suggests taking this products [sic], to fight it: [emphasis added]

7*Herb Formula™ . . .

Bio*Shark™ . . .

BioMixx™ . . .

GDU Caps™ . . . [emphasis added]

[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! . . . [emphasis added]

Answer ¶ 9; S.D. Ex. 8 (*Respondents' Responses and Objections to Complaint Counsel's Request for Admissions, Respondents' Answer to Complaint Counsel's Req. for Admis. Regarding Authenticity and Admissibility* ¶ 2); see also *J. Feijo Dep. Tr.* at 101, l. 7-9; 110, l. 23-25; 111, l. 13-20.

134. In their BioMolecular Nutrition Product Catalog, next to the pictures of the GDU bottles, Respondents state that GDU “[c]ontains natural proteolytic enzymes (from pineapple source bromelain) to help digest protein, *even that of unwanted tumors* and cysts. Helps to relieve pain, inflammation, and as *an adjunct to cancer therapy*.” S.D. Ex. 6 (*J. Feijo Dep. Ex. 6 - BioMolecular Nutrition Product Catalog* at FTC-DCO 0062)(emphasis added).
135. In Respondents' BioGuide: The BioMolecular Nutrition Guide to Natural Health 3, Respondents published the following testimonial from Deloris Winter: “I went in for a breast examination by mammography. On 10/8/01 they said they found a mass that they believed was not cancerous, but benign. I began taking GDU six times a day: 2 before breakfast, 2 before lunch, and 2 before dinner, and in a month I went to my doctor for the breast examination, and he found nothing on either breast.” S.D. Ex. 5 (*J. Feijo Dep. Ex. 12 - BioGuide: The BioMolecular Nutrition Guide to Natural Health 3* at FTC-DCO 0331); see also *P. Feijo Dep. Tr.* at 190, l. 5-19.
136. During the July 14, 2008 DCO Healthwatch radio program, Patricia Feijo advised a consumer whose father was diagnosed with colon cancer that she should get her father “on . . . GDU, BioShark and 7 Herb Formula. And if you can get him to, you know, go right now to the website, *How To Fight Cancer Is Your Choice*, or you can get him a hard copy from our order center, while we have them. It's what the FTC wants to shut us down over and they certainly want us to, you know, crash the website and they want to, you know, burn our material. They don't want us circulating *How To Fight Cancer Is Your Choice*.” S.D. Ex. 3 (*Marino Dec.* at ¶ 22, Exhibit K at 85, l. 13-25 - 86, l. 1-25 (FTC-DCO 0693 - 0694)).

BioMixx

137. Respondents publish information about BioMixx, including, but not limited to, the following:

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. [emphasis added]

Answer ¶ 13; S.D. Ex. 8 (*Respondents' Responses and Objections to Complaint Counsel's Request for Admissions, Respondents' Answer to Complaint Counsel's Req. for Admis. Regarding Authenticity and Admissibility* ¶ 4); see also *J. Feijo Dep. Tr.* at 101, l. 10-11.

138. Respondents publish information about BioMixx, including, but not limited to the following:

If you suffer from any type of cancer, Daniel Chapter One suggests taking this products [sic], to fight it: [emphasis added]

7*Herb Formula™ . . .

Bio*Shark™ . . .

BioMixx™ . . . [emphasis added]

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! . . . [emphasis added]

Answer ¶ 9; S.D. Ex. 8 (*Respondents' Responses and Objections to Complaint Counsel's Request for Admissions, Respondents' Answer to Complaint Counsel's Req. for Admis. Regarding Authenticity and Admissibility* ¶ 2); see also *J. Feijo Dep. Tr.* at 101, l. 10-11; 110, l. 23-25; 111, l. 13-20.

139. In Respondents' BioGuide: The BioMolecular Nutrition Guide to Natural Health 3, Respondents state the following regarding BioMixx: "What separates BioMixx is that it was developed specifically to maximize the immune system, particularly for those individuals whose immune systems were compromised through chemotherapy and radiation." S.D. Ex. 5 (*J. Feijo Dep. Ex. 12 - BioGuide: The BioMolecular Nutrition Guide to Natural Health 3* at FTC-DCO 0334).
140. In their Cancer Newsletter, entitled How To Fight Cancer is Your Choice!!!, Respondents state that BioMixx "is used to assist the body in **fighting cancer** and in healing the destructive effects of **radiation** and **chemotherapy** treatments." S.D. Ex. 10 (*DCO's Cancer Newsletter, Millenium [sic] Edition, 2002 - "How to Fight Cancer is Your Choice!!!"* at FTC-DCO 0400) (emphasis added).

E. RESPONDENTS DISSEMINATE CLAIMS ABOUT THEIR PRODUCTS TO CONSUMERS

141. Respondents operate the Web sites www.danielchapterone.com, dc1pages.com, and dcstore.com that provide information on the DCO Products. Answer ¶ 5; *J. Feijo Dep. Tr.* at 62, l. 10-13; see also *J. Feijo Dep. Tr.* at 232, l. 21-25 - 233, l. 1-19.
142. Respondents disseminate information about the DCO Products through written materials, including, but not limited to, the BioGuide, the Cancer Newsletter, the websites www.danielchapterone.com, www.7herbformula.com, www.gdu2000.com, and the radio program, "Daniel Chapter One Health Watch." S.D. Ex. 4 (*J. Feijo Dep. Ex. 7 - Respondents' Responses to Complaint Counsel's First Set of Interrogs., Resp. to Interrog. No. 11*); see also *J. Feijo Dep. Tr.* at 103, l. 19-21.

143. Respondent James Feijo and his wife, Patricia Feijo, are responsible for the information contained in the written materials, including the BioGuide, the Cancer Newsletter, the websites www.danielchapterone.com, www.7herbformula.com, www.gdu2000.com, and the radio program, "Daniel Chapter One Health Watch," that describe the DCO Products. S.D. Ex. 4 (*J. Feijo Dep. Ex. 7 - Respondents' Responses to Complaint Counsel's First Set of Interrogs., Resp. to Interrog. No. 12*); *J. Feijo Dep. Tr.* at 62, l. 10-13.
144. Consumers can locate Respondents' Web site by entering the term "cancer" in a Google search. *J. Feijo Dep. Tr.* at 136, l. 12-17.
145. FTC Investigator Michael Marino found and accessed DCO's Web site www.danielchapterone.com through Microsoft Internet Explorer. S.D. Ex. 3 (Marino Dec. at ¶ 3).
146. Respondent James Feijo and his wife, Patricia Feijo, co-host the Daniel Chapter One radio program for two hours a day, Monday through Friday. S.D. Ex. 4 (*J. Feijo Dep. Ex. 7 - Respondents' Responses to Complaint Counsel's First Set of Interrogs., Resp. to Interrog. No. 5*); *J. Feijo Dep. Tr.* at 16, l. 25 - 17, l. 4.
147. Respondents have counseled cancer patients who have called into the Daniel Chapter One radio program about taking the DCO Products. *P. Feijo Dep. Tr.* at 96, l. 10-25 - 97, l. 1-8.
148. The DCO radio program and the DCO Web site were the natural vehicle for Respondents to reach out to people in other states. *P. Feijo Dep. Tr.* at 62, l. 3-8.

F. RESPONDENTS DID NOT POSSESS SUBSTANTIATION FOR SUCH CLAIMS AT THE TIME THEY WERE MADE.

149. Respondents conducted no scientific testing on any of the DCO Products. *P. Feijo Dep. Tr.* at 161, l. 12-16; *see also J. Feijo Dep. Tr.* at 201, l. 22-25 - 201, l. 1-3.
150. Respondents have not conducted any double-blind studies on the DCO Products. *J. Feijo Dep. Tr.* at 58, l. 17-22; *see also J. Feijo Dep. Tr.* at 205, l. 25 - 206, l. 1-10.
151. Respondents' have not conducted any controlled studies on any of the DCO Products. *J. Feijo Dep. Tr.* at 54, l. 23-25; 55, l. 11.
152. No person has been involved in the scientific testing, research, substantiation, or clinical trials of the DCO Products. S.D. Ex. 4 (*J. Feijo Dep. Ex. 7 - Respondents' Responses to Complaint Counsel's First Set of Interrogs., Resp. to Interrog. No. 15*).
153. Respondents have no documents relating to their policies, procedures, or requirements for evaluating or reviewing each safety, efficacy, or bioavailability representation made

for the DCO Products. S.D. Ex. 27 (*Respondents' Responses to Complaint Counsel's First Req. For Produc. of Documentary Materials and Tangible Things, Resp. to Req. No. 6*).

154. It was not Respondents' practice to obtain scientific studies about any of the components in their products. *P. Feijo Dep. Tr.* at 120, l. 9-19.
155. Respondents did not search for scientific studies regarding the components in their products because "[w]e're working with people, and again, it's experiential and it's working with the whole person." *P. Feijo Dep. Tr.* at 120, l. 20-22.
156. James Feijo agrees that individual results may vary and that what one person says in her testimonial may not apply to other people. *J. Feijo Dep. Tr.* at 141, l. 19-25 - 142, l. 1-8.
157. According to Patricia Feijo, "only God can cure cancer." *P. Feijo Dep. Tr.* at 115, l. 19-20.
158. According to Patricia Feijo, "We [James and Patricia Feijo] do have knowledge that is experiential. We have seen how these products work. God has shown us [James and Patricia Feijo] and given us a wealth of knowledge and information that - - and we felt it is very truthful and actually our duty to share with people." *P. Feijo Dep. Tr.* at 116, l. 12-26.

BioShark

159. Respondents conducted no scientific testing on Bio*Shark. *P. Feijo Dep. Tr.* at 161, l. 12-16.
160. Respondents' substantiation for the statement that "[p]ure skeletal tissue of sharks . . . can stop tumor growth" is "from the material that [they] had read that shark cartilage provides a protein that inhibits angiogenesis and the information [they] have that [they] have . . . read and complied for many years now." *P. Feijo Dep. Tr.* at 157, l. 16-20.
161. Patricia Feijo is not aware of any other studies that might have been done on Bio*Shark or shark cartilage other than Dr. Lane's studies. *P. Feijo Dep. Tr.* at 162, l. 5-16.
162. Universal Nutrition did not conduct any testing, quality or otherwise, on Bio*Shark. *Kinney Dep. Tr.* at 45, l. 19-25 - 46, l. 1.

7 Herb Formula

163. Respondents never had an outside lab study the components of 7 Herb Formula to see whether its components actually have the effect that Respondents believe it has. *P. Feijo Dep. Tr.* at 132, l. 11-15.

164. Rather than having an outside lab study the components of 7 Herb Formula to determine whether its components were actually having the effect Respondents believe, Respondents have “experiential information [and] many testimonies, many hundreds if not thousands of testimonies.” *P. Feijo Dep. Tr.* at 132, l. 16-18.
165. Respondents’ basis for asserting that using 7 Herb Formula will help someone with any type of cancer is “their knowledge about the structure/function of the separate ingredients and the history of the herbal formally, so experientially . . . [they] can say generally that if you suffer from any type of cancer that [Respondents] suggest taking [7 Herb Formula].” *P. Feijo Dep. Tr.* at 175, l. 23-25 - 176, l. 1-7.

GDU

166. GDU was never subjected to clinical trials. *P. Feijo Dep. Tr.* at 190, l. 20-21.
167. Respondents have not done any studies to know whether GDU would counteract with any conventional cancer medicine someone was taking. *P. Feijo Dep. Tr.* at 194, l. 11-14.

BioMixx

168. Respondents did not conduct any tests or clinical studies on BioMixx. *P. Feijo Dep. Tr.* at 199, l. 15-18.
169. Respondents did not engage anybody else to do any kind of clinical tests on BioMixx. *P. Feijo Dep. Tr.* at 199, l. 19-21.
170. Respondents’ basis for asserting that BioMixx fights cancer is “[b]ased on the structure of the ingredients, what we know that to be, and based on the function of those ingredients, what we know that to be, and based on the experiential evidence, the witness of many.” *P. Feijo Dep. Tr.* at 199, l. 22-25 - 200, l. 1-4.
171. Universal Nutrition has not conducted any testing on BioMixx. *Kinney Dep. Tr.* at 50, l. 8-9.

G. DR. MILLER CONFIRMS THAT THERE IS NO COMPETENT AND RELIABLE SCIENTIFIC EVIDENCE TO SUBSTANTIATE THE CLAIMS THAT DCO’S PRODUCTS TREAT, CURE, OR PREVENT CANCER

Introduction

172. Denis R. Miller, M.D. is a board-certified pediatric hematologist/oncologist. S.D. Ex. 1 (Declaration of Complaint Counsel’s Expert Denis R. Miller, M.D., dated February 18, 2009, attaching Denis R. Miller, M.D. Expert Report (hereinafter referred to as *D. Miller Expert Report*) at 1).

173. For over 40 years, Dr. Miller has directed clinical care, education, laboratory and clinical research, and administration, heading divisions or departments at University of Rochester Medical Center, New York Hospital-Cornell Medical Center, Memorial Sloan Kettering Cancer Center, and Northwestern University Medical School. S.D. Ex. 1 (*D. Miller Expert Report* at 1).
174. Dr. Miller also has served as Associate Medical Director of Cancer Treatment Centers of America (“CTCA”) as well as Scientific Director of CTCA’s Cancer Treatment Research Foundations. S.D. Ex. 1 (*D. Miller Expert Report* at 1).
175. As Scientific Director, Dr. Miller supervised the clinical research program and was principal investigator for a number of Phase I/II clinical studies involving treatments for hematological malignancies and cancers of the head and neck, lung, breast, pancreas, and colon. S.D. Ex. 1 (*D. Miller Expert Report* at 1-2).
176. Dr. Miller has authored or co-authored over 300 book chapters, peer-reviewed articles, and abstracts, and has served on the editorial boards of the British Journal of Hematology and the American Journal of Clinical Oncology. S.D. Ex. 1 (*D. Miller Expert Report* at 3).
177. Dr. Miller currently is the Oncology/Hematology Therapeutic Area Leader at PAREXEL International, a leading contract research organization, where he manages clinical trials for the pharmaceutical industry. S.D. Ex. 1 (*D. Miller Expert Report* at 2).
178. To constitute competent and reliable scientific evidence, a product that purports to treat, cure, or prevent cancer must have its efficacy and safety demonstrated through controlled clinical studies. S.D. Ex. 1 (*D. Miller Expert Report* at 7).
179. Only data from well-designed, controlled, clinical trials will substantiate claims that a new therapy is safe and effective to treat, cure, or prevent cancer. S.D. Ex. 1 (*D. Miller Expert Report* at 30).
180. Anecdotal reports of product efficacy are the weakest form of evidence supporting the anticancer activity of a new agent. S.D. Ex. 1 (*D. Miller Expert Report* at 12).
181. Testimonials do not substitute for a well-designed clinical trial in proving the efficacy of a supposed cancer fighting product. S.D. Ex. 1 (*D. Miller Expert Report* at 30).
182. Dr. Miller’s thorough review of peer-reviewed literature and all of the documents produced by DCO indicates that there is no competent and reliable scientific evidence that the DCO Products are effective either alone or in combination with other DCO products in the treatment or cure of cancer, in inhibiting tumor formation, and in preventing the destructive effects of radiation and chemotherapy. S.D. Ex. 1 (*D. Miller Expert Report* at 31).

Bio*Shark

183. Dr. Miller's review of the peer-reviewed literature and all of the documents Respondents submitted as substantiation indicates that there was no competent and reliable scientific evidence that Bio*Shark inhibits tumor growth in humans or that it is effective in the treatment of cancer in humans. S.D. Ex. 1 (*D. Miller Expert Report* at 13).
184. Dr. Miller found that there were no adequate and well-controlled studies demonstrating that Bio*Shark is antiangiogenic or is effective in the treatment of cancer, and even supporting non-clinical studies of crude or partially-purified shark cartilage products were extremely limited, particularly with regard to mechanisms of action, pharmacokinetics, pharmacodynamics, and dose response. S.D. Ex. 1 (*D. Miller Expert Report* at 17).
185. Dr. Miller observed that Respondents' reliance on Dr. I. William Lane's book, "Sharks Don't Get Cancer" was misplaced, as studies at Johns Hopkins University indicate that sharks do indeed get cancer. S.D. Ex. 1 (*D. Miller Expert Report* at 16).

7 Herb Formula

186. Dr. Miller's review of the peer-reviewed literature and all of the documents Respondents submitted as substantiation indicates that there was no competent and reliable scientific evidence that 7 Herb Formula inhibits tumor formation and is effective in the treatment or cure of cancer in humans. S.D. Ex. 1 (*D. Miller Expert Report* at 18).
187. Dr. Miller found neither non-clinical nor clinical studies supporting claims that 7 Herb Formula or any of its individual ingredients are effective anticancer agents or inhibit tumor formation. S.D. Ex. 1 (*D. Miller Expert Report* at 19).
188. Any relevant studies on the ingredients Burdock root, Cat's Claw, sheep sorrel, slippery elm bark, turkish rhubarb root, Siberian ginseng, and watercress were performed either in vitro or on animals, not on humans with cancer. S.D. Ex. 1 (*D. Miller Expert Report* at 19-22).

GDU

189. Dr. Miller's review of the peer-reviewed literature and all of the documents Respondents submitted as substantiation indicates that there was no competent and reliable scientific evidence that GDU eliminates tumors and is effective in the treatment of cancer in humans. S.D. Ex. 1 (*D. Miller Expert Report* at 22).
190. Dr. Miller found no randomized, controlled clinical trials of any of the individual components of GDU or of GDU itself in patients with cancer. S.D. Ex. 1 (*D. Miller Expert Report* at 27).

191. Dr. Miller, however, did note that curcumin (tumeric), one of GDU's ingredients, is currently being evaluated in controlled clinical trials to determine its potential as a chemoprotective and cancer preventive agent. S.D. Ex. 1 (*D. Miller Expert Report* at 22).
192. Animal studies have suggested that curcumin may have activity as a cancer preventive and therapeutic agent. S.D. Ex. 1 (*D. Miller Expert Report* at 23).
193. Nevertheless, Dr. Miller cautioned that some studies have suggested that curcumin may actually inhibit the anticancer activity of some approved anticancer agents as well as exacerbate iron deficiency. S.D. Ex. 1 (*D. Miller Expert Report* at 27).
194. Thus, Dr. Miller advised that further research on curcumin was necessary. S.D. Ex. 1 (*D. Miller Expert Report* at 27).

BioMixx

195. Dr. Miller's review of the peer-reviewed literature and all of the documents Respondents submitted as substantiation indicates that there was no competent and reliable scientific evidence that BioMixx is effective in the treatment of cancer and heals the destructive effects of radiation and chemotherapy. S.D. Ex. 1 (*D. Miller Expert Report* at 27).
196. Dr. Miller found that there are no reported studies of either BioMixx or its constituent ingredients being effective in the treatment of cancer. S.D. Ex. 1 (*D. Miller Expert Report* at 27-28).
197. Dr. Miller also found "absolutely no data" to support the claim that BioMixx is used to heal the destructive effects of radiation and chemotherapy treatments. S.D. Ex. 1 (*D. Miller Expert Report* at 29).

H. RESPONDENTS' EXPERTS DO NOT POSSESS ANY INFORMATION SUBSTANTIATING RESPONDENTS' CLAIMS

Introduction

James Duke, Ph.D.

198. James Duke, Ph.D. ("Duke") has never met Jim and Patricia Feijo. Deposition of James Duke, Ph.D. (hereinafter referred to as *Duke Dep. Tr.*) at 8, l. 6-9.
199. Duke is not a medical doctor. *Duke Dep. Tr.* at 56, l. 3-5.
200. Duke is not licensed to practice medicine in any state. *Duke Dep. Tr.* at 56, l. 6-8.
201. Duke is not a board-certified oncologist. *Duke Dep. Tr.* at 56, l. 9-10.

202. Duke does not recall ever publishing any articles in any peer-reviewed medical journals. *Duke Dep. Tr.* at 56, l. 11-14.
203. Duke has never practiced medicine. *Duke Dep. Tr.* at 18, l. 8.
204. Duke would not recommend that people self-medicate with herbal remedies in treating cancer. *Duke Dep. Tr.* at 135, l. 17-22.
205. Duke is sure that there is a risk that some people will pursue herbal medications instead of effective pharmaceutical medications and thereby die. *Duke Dep. Tr.* at 136, l. 20-23.
206. Duke does not recall any holistic physicians who have consulted with him on the treatment of cancer. *Duke Dep. Tr.* at 19, l. 10-13.
207. Duke does not recall any homeopaths who have consulted with him on the treatment of cancer. *Duke Dep. Tr.* at 19, l. 14-17.
208. Duke has never managed or participated in any studies to measure the efficacy of an herb in treating cancer. *Duke Dep. Tr.* at 29, l. 15-22.
209. Duke does not remember ever being a consultant on a study where the anticancer effects of an herb were being measured on a group of patients. *Duke Dep. Tr.* at 29, l. 23-25 - 30, l. 1-2.
210. Duke does not remember seeing the FTC's Complaint against Respondents. *Duke Dep. Tr.* at 36, l. 19-22.
211. Duke has no knowledge of any of the advertisements that the FTC has challenged as the predicate for the Complaint. *Duke Dep. Tr.* at 36, l. 23-25 - 37, l. 1-2.
212. Duke was not sent any of Respondents' products. *Duke Dep. Tr.* at 37, l. 3-5.
213. Duke has not spoken to any persons who have taken DCO products for the treatment of cancer. *Duke Dep. Tr.* at 38, l. 23-25.
214. Duke has not reviewed the medical records of anyone who claims to have taken DCO products for the treatment of cancer. *Duke Dep. Tr.* at 39, l. 1-4.
215. Duke had never heard of DCO until this case. *Duke Dep. Tr.* at 39, l. 9-10.
216. Duke has never listened to the DCO Radio program. *Duke Dep. Tr.* at 39, l. 11-14.

217. Duke knows of no tests where the patient prays and one group of patients gets a Biblically referenced herb and the other group of patient prays and gets an allopathic treatment. *Duke Dep. Tr.* at 41, l. 20-25 - 42, l. 1-2.
218. Duke does not think that “the FDA permits advertising for cancer unless clinically proven.” *Duke Dep. Tr.* at 46, l. 19-22.
219. Duke’s “Multiple Activity Menus” (“MAMs”) are an attempt to identify herbs that show promise in fighting disease. *Duke Dep. Tr.* at 91, l. 20-23.
220. The MAM and the ratio that it yields does not prove that any one of these herbs is effective in fighting or treating cancer. Rather, “[i]t adds a listing of the chemicals in that herb that have been shown or assumed to help with cancer.” *Duke Dep. Tr.* at 92, l. 5-11.
221. When entering in the MAM an activity for an herb, Duke only enters references to that source “as it may be a good source [or] it may be a bad source.” *Duke Dep. Tr.* at 93, l. 8-13.
222. Duke acknowledged that it is a “gut feeling” on how he makes sure that the studies he references in the MAMs are reliable. *Duke Dep. Tr.* at 108, l. 17-21.
223. Duke acknowledged that his MAMs have not been cited in any peer-reviewed journal. *Duke Dep. Tr.* at 113, l. 2-4.
224. Duke explained that his Indication Evaluations (“IE”) is where he has “gone through all these abstracts over the years [and] I’ve scored for a given indication. If it’s folklore and that’s all I have, it would receive an ‘f’; if it has a chemical or an epidemiological or an animal or an in vitro evidence, I’ve given it a 1; and then the 2, as we mentioned earlier, that means it’s either been clinically approved - - an extract of the plant has been clinically approved or it’s been approved by the Commission E or the Tramil Commission for that indication. These are lines of evidence that point to me which ones are most important and should be studied for cancer.” *Duke Dep. Tr.* at 59, l. 7-21; 118, l. 10-13; 119, l. 7-9.
225. The IE is a “compendium of information.” *Duke Dep. Tr.* at 109, l. 8-10.
226. There is no relationship between the MAMs and the IE. *Duke Dep. Tr.* at 92, l. 12-20.
227. Neither the MAMs nor the IE reflect information that indicates that turmeric, for example, is effective in the treatment of cancer. *Duke Dep. Tr.* at 109, l. 25 - 110, l. 1-6.
228. Duke has never measured the efficacy of herbs as a treatment for cancer in a controlled patient population. *Duke Dep. Tr.* at 55, l. 21-24.

229. Duke is not able to express opinions on what the minimum dosage would be necessary to achieve cancer-fighting. *Duke Dep. Tr.* at 67, l. 24-25 - 68, l. 1.
230. Duke recognizes the difference between something being efficacious in an in vitro study and something being efficacious in human beings. *Duke Dep. Tr.* at 71, l. 20-24.
231. As a matter of science, Duke does not believe that the herbal extract working in vitro proves that it would work in a human. *Duke Dep. Tr.* at 77, l. 10-24.
232. Rather than relying solely on in vitro studies, Duke recommends “the third arm-trial where the whole plant or an extract thereof is compared with a competing pharmaceutical.” *Duke Dep. Tr.* at 77, l. 17-24.
233. According to Duke, “[t]he third arm would compare a given herb with a given pharmaceutical and placebo.” *Duke Dep. Tr.* at 81, l. 17-23.
234. Other than the St. John’s Wort trial that used a placebo and Zoloft, Duke is not aware of any other studies where an herb, a pharmaceutical, and a placebo were studied in a side-by-side manner. *Duke Dep. Tr.* at 82, l. 1-17.
235. Duke does not think of black cohosh as a major anticancer herb. *Duke Dep. Tr.* at 123, l. 5-13.
236. Duke stated that there is no reference to cancer in eleuthero because “that’s not one of the major things that are said about it.” *Duke Dep. Tr.* at 125, l. 23-25 - 126, l. 1-2.
237. Most of the studies Duke has seen have been for preventing cancer. *Duke Dep. Tr.* at 128, l. 22-24.
238. Duke does not remember any studies specifically about treating cancer. *Duke Dep. Tr.* at 128, l. 25 - 129, l. 1-3.
239. Duke testified that anecdotal reports are “even below . . . my lines of evidence.” *Duke Dep. Tr.* at 131, l. 15-20.
240. Duke attributes the increase in life expectancy in the 150 years that pharmaceuticals have been around to pharmaceuticals themselves. *Duke Dep. Tr.* at 133, l. 9-15.
241. Duke does not believe that homeostatic balancing has been the subject of any peer-reviewed articles in connection with the treatment or cure of cancer. *Duke Dep. Tr.* at 133, l. 25 - 134, l. 1-12.
242. In Duke’s IE, there have been no clinical trials as to the efficacy of black cohosh for cancer. *Duke Dep. Tr.* at 147, l. 8-25.

243. There are no clinical trials regarding garlic's efficacy as to cancer in Duke's IE. *Duke Dep. Tr.* at 148, l. 1-5.
244. There are no clinical trials regarding Yellow Root's efficacy as to cancer in Duke's IE. *Duke Dep. Tr.* at 149, l. 1-5.
245. There are no clinical trials regarding eleuthero's efficacy as to cancer in Duke's IE. *Duke Dep. Tr.* at 153, l. 3-7.
246. There are no clinical trials regarding soybean's efficacy as to cancer in Duke's IE. *Duke Dep. Tr.* at 153, l. 24-25 - 154, l. 1-7.
247. There are no entries for sarsaparilla in Duke's IE indicating that it has been evaluated for its efficacy in treating cancer in clinical trials. *Duke Dep. Tr.* at 156, l. 21-24.
248. The editors of Duke's book, The Green Pharmacy Guide to Healing Foods, advised Duke to "shy away from" a section on cancer treatment. *Duke Dep. Tr.* at 178, l. 6-18.
249. Duke does not recall seeing any articles that Mr. and Mrs. Feijo believe substantiated the claims that they made regarding the particular DCO Products. *Duke Dep. Tr.* at 185, l. 7-11.
250. Duke has made no effort to evaluate whether the combination of the ingredients in each of the products that DCO sells - GDU, 7 Herb Formula, and BioMixx - has any synergistic effects. *Duke Dep. Tr.* at 190, l. 10-21.
251. Duke made no effort to see whether there were any studies of any sort regarding the particular products that DCO sells - GDU, 7 Herb Formula, and BioMixx. *Duke Dep. Tr.* at 190, l. 22-25 - 191, l. 1-4.

James K. Dews

252. Respondents offer James K. Dews ("Dews") as an expert in "[h]erbal formulations, specifically 7 Herb Formula." Deposition of James K. Dews (hereinafter referred to as *J. Dews Dep. Tr.*) at 4, l. 25 - 5, l. 1.
253. Dews attended the University of Texas at Arlington and Texas Wesleyan, but he did not finish college degrees at either institution. *J. Dews Dep. Tr.* at 11, l. 2-15.
254. According to Dews, nutraceuticals involves the merging of food supplements and pharmaceuticals. *J. Dews Dep. Tr.* at 17, l. 25.
255. Nutraceuticals involves the extraction of certain chemical compounds that are in many foods or herbs. *J. Dews Dep. Tr.* at 18, l. 14-18.

256. Consumers ingest nutraceuticals. *J. Dews Dep. Tr.* at 18, l. 6.
257. The difference between a pharmaceutical and a nutraceutical is that one can make a disease-curing claim with a pharmaceutical; one cannot make a disease-curing claim with a nutraceutical. *J. Dews Dep. Tr.* at 62, l. 17-18; *see also* 15, l. 12-13.
258. According to Dews, animal studies cannot be extrapolated to humans. *J. Dews Dep. Tr.* at 63, l. 18-25 - 64, l. 1-8.

Rustum Roy, Ph.D.

259. Respondents offer Rustum Roy, Ph.D. (“Roy”) as “an expert in the conduct of scientific research and with the focus on health and materials.” Deposition of Rustum Roy, Ph.D. (hereinafter referred to as *R. Roy Dep. Tr.*) at 7, l. 5-10.
260. Roy did not review the complaint that the FTC filed against Respondents. *R. Roy Dep. Tr.* at 7, l. 17-21.
261. Roy did not review any of the advertisements on which the FTC’s complaint is predicated. *R. Roy Dep. Tr.* at 7, l. 22-24.
262. Roy did not review or obtain any of the product or product labels for the products at issue in the litigation. *R. Roy Dep. Tr.* at 7, l. 25 - 8, l. 1-3.
263. Roy did not conduct any work or tests on any product made by Respondents. *R. Roy Dep. Tr.* at 8, l. 15-22.
264. Roy is not an expert in homeopathy. *R. Roy Dep. Tr.* at 12, l. 11.
265. Roy and his laboratory do “zero clinical trials.” *R. Roy Dep. Tr.* at 13, l. 20.
266. Roy and his laboratory “have nothing to do with causing healing or not in a human being.” *R. Roy Dep. Tr.* at 13, l. 20-21.
267. Roy has not measured the efficacy of the DCO Products. *R. Roy Dep. Tr.* at 14, l. 2-5.
268. Roy has never done any experiments to measure the efficacy of any medical treatments “at the human level.” *R. Roy Dep. Tr.* at 14, l. 6-9.
269. Roy has no idea what the DCO Products contain. *R. Roy Dep. Tr.* at 24, l. 21-25.
270. Roy has not done any literature searches or any literature research concerning any of the ingredients in DCO’s products. *R. Roy Dep. Tr.* at 25, l. 3-7.
271. Roy does not have any formal training in medicine. *R. Roy Dep. Tr.* at 26, l. 9-11.

272. Roy has never treated or consulted with healers who were treating particular patients. *R. Roy Dep. Tr.* at 28, l. 9-11.
273. Roy does not know what Daniel Chapter One sells. *R. Roy Dep. Tr.* at 43, l. 6-8.
274. The practice of Daniel Chapter One selling products over the Internet to people that it had never seen, met, or examined the medical records for “obviously limits” homeopathy. *R. Roy Dep. Tr.* at 50, l. 5-19.
275. Roy’s ideal description of homeopathy would not include selling products over the Internet to persons that the seller has not met. *R. Roy Dep. Tr.* at 51, l. 11-14.
276. It is not Roy’s view that all herbal remedies are effective. *R. Roy Dep. Tr.* at 60, l. 60, l. 23-25 - 61, l. 1.
277. Roy has never been involved in trying to secure FDA approval for some medication. *R. Roy Dep. Tr.* at 79, l. 14-16.

Jay Lehr

278. No one has ever consulted Jay Lehr (“Lehr”) about using herbs in connection with cancer. Deposition of Jay Lehr (hereinafter referred to as *J. Lehr Dep. Tr.*) at 10, l. 24-25 - 11, l. 1.
279. Lehr is not a cancer expert. *J. Lehr Dep. Tr.* at 15, l. 11.
280. Lehr would not speculate on whether Respondents’ products could cure cancer; “that’s now outside my area of expertise.” *J. Lehr Dep. Tr.* at 33, l. 19-22.
281. Lehr has never spoken to Jim Feijo about his products that supposedly treat cancer or tumors. *J. Lehr Dep. Tr.* at 34, l. 2-5.
282. The only testing of pharmaceutical drugs and herbal supplements that Lehr has been involved in involves testing on himself. *J. Lehr Dep. Tr.* at 15, l. 18-25 - 16, l. 1-6.
283. Lehr takes three DCO products every day - Endurosine, Mito/ATP, and Electrocarb. *J. Lehr Dep. Tr.* at 17, l. 18-25 - 18, l. 1-14.
284. The label for PrePost speaks to athletic training. *J. Lehr Dep. Tr.* at 38, l. 1-5.
285. Endorosine increases the oxygen-carrying capacity of the blood. *J. Lehr Dep. Tr.* at 38, l. 9-12.
286. Mito/ATP is a pure energy distillate. *J. Lehr Dep. Tr.* at 38, l. 13-14.

287. Lehr has not spoken to any person who has taken DCO products to treat cancer. *J. Lehr Dep. Tr.* at 19, l. 14-17.
288. Lehr has never reviewed any of the medical claims of someone who stated that DCO's products have helped them to cure their cancer. *J. Lehr Dep. Tr.* at 19, l. 18-21.
289. Beyond his own personal study, Lehr has not conducted any studies on the four DCO Products. *J. Lehr Dep. Tr.* at 23, l. 2-5.
290. Respondent James Feijo has never suggested that Lehr take Bio*Shark, 7 Herb Formula, or BioMixx. *J. Lehr Dep. Tr.* at 25, l. 5-6.
291. The products that Respondent James Feijo has suggested to Lehr "have entirely been to improve [his] athletic performance." *J. Lehr Dep. Tr.* at 25, l. 6-8.
292. Lehr "can only substantiate the claims that [Respondents] have made on the three products [Endurosine, Mito/ATP, and Electrocarb] that [he has] taken regularly now for ten years." *J. Lehr Dep. Tr.* at 25, l. 9-17.
293. Lehr has not reviewed Respondents' Web site. *J. Lehr Dep. Tr.* at 27, l. 7-10.
294. Lehr does not have any familiarity with Respondents' products that are being sold to help people in the treatment of cancer. *J. Lehr Dep. Tr.* at 28, l. 3-6.
295. The only testing that Lehr is aware of that Respondent James Feijo conducted is that which he has done on PrePost and the other products that Respondent James Feijo has shared with him. *J. Lehr Dep. Tr.* at 28, l. 20-22.
296. Lehr's opinion is that because PrePost works so well on him that Respondents' other products should be as effective. *J. Lehr Dep. Tr.* at 32, l. 21-25 - 33, l. 1-18.
297. Lehr is familiar with radiation therapy and chemotherapy. *J. Lehr Dep. Tr.* at 34, l. 6-9.
298. Lehr has seen people positively impacted by conventional cancer treatments like radiation therapy and chemotherapy. *J. Lehr Dep. Tr.* at 34, l. 16-19.
299. Lehr has not been involved in any kinds of studies regarding the prevention, cure, or treatment of cancer in humans. *J. Lehr Dep. Tr.* at 35, l. 1-4.
300. Lehr did not have the opportunity to read any of the scientific studies that Daniel Chapter One has about its products. *J. Lehr Dep. Tr.* at 35, l. 18-21.
301. Lehr has had no need for any other supplements from DCO for any medical problems. *J. Lehr Dep. Tr.* at 40, l. 3-4.

302. Lehr's interests in DCO's products have "strictly been athletic." *J. Lehr Dep. Tr.* at 40, l. 4-5.
303. In preparing for giving expert testimony in this case, Lehr did not talk with Respondent James Feijo about the DCO Products that are the subject of this action. *J. Lehr Dep. Tr.* at 40, l. 6-15.
304. Lehr is not aware of what Daniel Chapter One has done in the double-blind type of study. *J. Lehr Dep. Tr.* at 47, l. 12-13.
305. Lehr is not aware of any studies done in connection with the DCO products that he takes. *J. Lehr Dep. Tr.* at 47, l. 14-17.
306. Lehr is not aware of Jim Feijo's background in science. *J. Lehr Dep. Tr.* at 52, l. 16-18.

Sally B. LaMont, N.D.

307. Respondents offer Sally B. LaMont, N.D. ("LaMont") as "an expert in naturopathic medical, herbal medicine, functional medicine . . . [and] as an expert on nutritional supplements and botanical medicines in the prevention and treatment of illness and as an expert in reviewing the evidence that supports the functional issues of the four products that are the challenged products." Deposition of Sally B. LaMont, N.D. (hereinafter referred to as *LaMont Dep. Tr.*) at 7, l. 20-25 - 8, l. 1-2.
308. LaMont has never previously been asked to be an expert. *LaMont Dep. Tr.* at 54, l. 9-12.
309. Lamont's charge from Respondents is "to provide opinions on the use of nutritional supplements and botanical medicines in the prevention and treatment of illness, including but not limited to cancer, and to review the evidence that exists regarding the mechanisms of action of the major constituents of Daniel Chapter One's products." *LaMont Dep. Tr.* at 33, l. 13-22.
310. LaMont is a naturopathic doctor. *LaMont Dep. Tr.* at 9, l. 9-11, 15, l. 23-25 - 16, l. 1.
311. According to LaMont, naturopathic medicine "is a primary healthcare practice that focuses on health promotion and disease prevention and the treatment of disease with an array of natural therapies that strengthen the body's innate healing capacities." *LaMont Dep. Tr.* at 9, l. 14-18.
312. Naturopathic doctors "provide patient-centered care and practice what would be termed functional medicine, which addresses the unique genetic, environmental and lifestyle factors that contribute to chronic disease and . . . influence our health." *LaMont Dep. Tr.* at 9, l. 19-24.

313. While engaged in naturopathic medicine, LaMont has worked in conjunction with traditional physicians. *LaMont Dep. Tr.* at 10, l. 2-5.
314. In the course of doing a workup on a patient, if LaMont finds “a diagnosis that looks like it could be cancer,” she absolutely would refer the patient to a traditional physician and would comanage that patient’s care with the physician. *LaMont Dep. Tr.* at 10, l. 16-22.
315. LaMont has not focused her naturopathic practice on naturopathic oncology; rather, she “ha[s] kept [her] practice very general.” *LaMont Dep. Tr.* at 11, l. 20-25 - 12, l. 1-2.
316. LaMont does not know what additional specialized training naturopathic oncologists take. *LaMont Dep. Tr.* at 12, l. 7-11.
317. LaMont has not done the specialized training for naturopathic oncology. *LaMont Dep. Tr.* at 12, l. 9-10.
318. After LaMont’s first husband passed away from non-Hodgkin’s lymphoma, she “chose to step back from [dealing with cancer patients] for several years.” *LaMont Dep. Tr.* at 12, l. 12-22.
319. LaMont started practicing naturopathic medicine in 1981 and stopped in 2000 to raise her daughter and to lead the campaign to license naturopathic doctors in California. *LaMont Dep. Tr.* at 13, l. 8-19.
320. LaMont returned to the private practice of naturopathic medicine almost a year ago by working part-time, practicing one day a week and beginning to add a second day. *LaMont Dep. Tr.* at 13, l. 20-25.
321. If LaMont ever found, for example, an abnormal pap smear with carcinoma inside, then she “would refer that patient to a gynecologist for a comprehensive workup and recommend that [her] patients follow the advice of their oncologist.” *LaMont Dep. Tr.* at 14, l. 11-17.
322. LaMont’s understanding is that “cancer must be treated with conventional therapies.” *LaMont Dep. Tr.* at 15, l. 1-4.
323. LaMont has seen conventional cancer therapies helpful in sometimes resolving the condition. *LaMont Dep. Tr.* at 15, l. 1-6.
324. LaMont would always make a referral to a cancer specialist because “it’s an important part of the treatment of cancer at this point.” *LaMont Dep. Tr.* at 15, l. 12-17.
325. Fourteen states license N.D.s. *LaMont Dep. Tr.* at 17, l. 3-8.

326. A licensed naturopathic doctor's responsibilities are "to diagnose and to treat disease and to promote health, which is honestly the focus of our practice, to really strengthen our body's ability to heal itself." *LaMont Dep. Tr.* at 17, l. 17-24.
327. The core of LaMont's practice is "[w]orking with diet and nutrition [and] nutritional supplements." *LaMont Dep. Tr.* at 20, l. 1-2.
328. LaMont also uses botanical medicine. *LaMont Dep. Tr.* at 20, l. 7.
329. LaMont works with mind-body therapies and regularly suggests meditation, qigong, yoga, and other biofeedback-type of therapies that would strengthen the person's connection between their mind and their immune system. *LaMont Dep. Tr.* at 20, l. 7-12.
330. LaMont does acupuncture on most patients. *LaMont Dep. Tr.* at 20, l. 15.
331. Nutritional supplements come from food and are an extension of food. *LaMont Dep. Tr.* at 20, l. 22-23.
332. Botanical medicine "comes from the plant world, and so there are phytochemicals in plants and then there's the whole plant." *LaMont Dep. Tr.* at 20, l. 24-25 - 21, l. 1.
333. Almost all the patients who come to LaMont who have been diagnosed with cancer come to her with that diagnosis and are looking for supportive care. *LaMont Dep. Tr.* at 23, l. 5-10.
334. LaMont thinks that the amount of dosage is important to the individual taking it and their health regimen. *LaMont Dep. Tr.* at 28, l. 11-15.
335. For someone who is in the "throes of chemotherapy," LaMont would have them not to use many of their nutritional supplements the week that they are on chemotherapy. *LaMont Dep. Tr.* at 31, l. 5-9.
336. The reason why LaMont would advise someone not to use nutritional supplements during chemotherapy is because "we don't fully understand yet all of the different ways in which this and other natural therapies may interact with chemotherapy." *LaMont Dep. Tr.* at 31, l. 10-20.
337. LaMont only became familiar with DCO at the end of December 2008. *LaMont Dep. Tr.* at 22, l. 23-25 - 23, l. 1-4.
338. Prior to LaMont's work on this case, she had never come across Bio*Shark, 7 Herb Formula, GDU, and BioMixx. *LaMont Dep. Tr.* at 34, l. 5-7.
339. LaMont looked at the labels for the DCO Products and did literature search on the main constituents of each of the products. *LaMont Dep. Tr.* at 34, l. 11-18.

340. LaMont acknowledged that since they have not been tested, we do not know the effectiveness of GDU, BioMixx, Bio*Shark, and 7 Herb Formula in the prevention, treatment or cure of cancer. *LaMont Dep. Tr.* at 47, l. 25 - 48, l. 1-11.
341. LaMont acknowledged that there have been no clinical studies performed on the DCO Products. *LaMont Dep. Tr.* at 48, l. 21-23.
342. The DCO products “are not silver bullets.” *LaMont Dep. Tr.* at 127, l. 3-5.
343. LaMont does not know the Feijos. *LaMont Dep. Tr.* at 49, l. 2-5.
344. LaMont thinks that it is “best that people follow the recommendations of their oncologist and utilize protocols that are proven to be most effective for their cancer and that they should be well-informed of the potential value of the array of other therapies.” *LaMont Dep. Tr.* at 49, l. 19-25.
345. LaMont testified that “as a doctor, if I’m working with a patient, I’m going to insist that they work with their oncologist and follow their advice and I’m going to comanage their care.” *LaMont Dep. Tr.* at 51, l. 24-25 - 52, l. 1-2.
346. LaMont believes that “[t]he 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.” *LaMont Dep. Tr.* at 52, l. 11-20.
347. LaMont would not be comfortable with the Feijos saying that the DCO products are going to cure cancer. *LaMont Dep. Tr.* at 53, l. 4-19.
348. LaMont can see why the Federal Trade Commission would have concerns about the statement that DCO’s products are cancer solutions. *LaMont Dep. Tr.* at 127, l. 15-24.
349. LaMont would not have written the text that way to include “cancer solutions” next to the DCO products. *LaMont Dep. Tr.* at 128, l. 2-4.
350. LaMont does not “believe that on their own across the board these [DCO] products are going to effectively treat cancer.” *LaMont Dep. Tr.* at 53, l. 20-24.
351. LaMont did not listen to the Feijo’s radio show nor did she have the interest in listening to their show. *LaMont Dep. Tr.* at 77, l. 1-8.
352. LaMont did not say that she would defend the DCO products because she has limited knowledge of their products. *LaMont Dep. Tr.* at 78, l. 16-18.
353. LaMont has never used the DCO products. *LaMont Dep. Tr.* at 78, l. 18.

354. LaMont has not studied the DCO products specifically. *LaMont Dep. Tr.* at 87, l. 25 - 88, l. 1-5.
355. LaMont acknowledges that traditional use evidence does not replace human clinical trials. *LaMont Dep. Tr.* at 89, l. 19-22.
356. LaMont acknowledges that it is not a common occurrence in the industry to make cancer cure or cancer treatment claims. *LaMont Dep. Tr.* at 144, l. 20-25 - 145, l. 1-2.
357. LaMont does not know of other companies that make claims that their products treat or cure cancer. *LaMont Dep. Tr.* at 145, l. 3-5.
358. Until there are clinical trials, LaMont agrees that “we don’t know” whether DCO’s products would effective in battling cancer. *LaMont Dep. Tr.* at 147, l. 20-24.
359. LaMont “wouldn’t want to have anybody say, [t]ake this, it’s going to cure your colon cancer.” *LaMont Dep. Tr.* at 161, l. 12-15.
360. LaMont thinks the approach of referring to some doctors as Dr. Dumb-Dumb, as James Feijo does on his radio show, is disrespectful. *LaMont Dep. Tr.* at 166, l. 7-10.
361. LaMont agrees that there is a danger if consumers do not continue with traditional cancer therapy. *LaMont Dep. Tr.* at 166, l. 20-22.
362. LaMont personally does not think that the Feijos should be suggesting that people should not get colonoscopies, as they suggest on their radio show. *LaMont Dep. Tr.* at 182, l. 8-17.
363. LaMont recognizes that there’s always that danger that people will take DCO products and not go and see their physicians. *LaMont Dep. Tr.* at 183, l. 12-15.
364. LaMont has never conducted a scientific controlled study of any sort. *LaMont Dep. Tr.* at 184, l. 12-14.
365. LaMont does not take any DCO products. *LaMont Dep. Tr.* at 184, l. 25 - 185, l. 1-2.
366. LaMont has not reviewed the medical records of anyone who has taken DCO products. *LaMont Dep. Tr.* at 185, l. 3-5.

BioShark

James Duke, Ph.D.

367. Duke is not offering opinions on BioShark “[b]ecause the major ingredient is an animal, and I don’t deal in animals.” *Duke Dep. Tr.* at 63, l. 19-25.
368. Duke was not asked to provide an opinion on BioShark. *Duke Dep. Tr.* at 64, l. 1.
369. Duke does not think highly of the studies that have been published on shark cartilage. *Duke Dep. Tr.* at 64, l. 2-9.
370. Duke “was not convinced of the efficacy of shark cartilage in the studies that [he] read.” *Duke Dep. Tr.* at 64, l. 13-15.

James K. Dews

371. Dews never has heard of Bio*Shark. *J. Dews Dep. Tr.* at 53, l. 10-12.
372. Dews is not familiar with the use of shark cartilage in the treatment of cancer, and he has never seen any data relating to the use of shark cartilage in the treatment of cancer. He only has heard of this. *J. Dews Dep. Tr.* at 54, l. 4-7.

Jay Lehr

373. Lehr is not familiar with the product called Bio*Shark. *J. Lehr Dep. Tr.* at 21, l. 20-22.
374. Lehr has never spoken to Respondent James Feijo about Bio*Shark. *J. Lehr Dep. Tr.* at 25, l. 23-24.
375. Lehr has not done any literature searches on Bio*Shark. *J. Lehr Dep. Tr.* at 25, l. 24-25 - 26, l. 1.
376. Lehr is not aware whether Jim Feijo has ever done any testing on Bio*Shark. *J. Lehr Dep. Tr.* at 28, l. 13-15.
377. Lehr is not aware of any double-blind studies done in connection with Bio*Shark. *J. Lehr Dep. Tr.* at 47, l. 18-22.

Sally B. LaMont, N.D.

378. LaMont does not know whether the product Bio*Shark inhibits tumor growth. *LaMont Dep. Tr.* at 91, l. 15-19.
379. LaMont does not know whether Bio*Shark is effective in the treatment of cancer. *LaMont Dep. Tr.* at 92, l. 6-8.
380. LaMont acknowledged that there are no well-controlled studies demonstrating that the product Bio*Shark is antiangiogenic. *LaMont Dep. Tr.* at 101, l. 3-7.

381. LaMont stated that there are no studies on Bio*Shark that are controlled clinical trials demonstrating its effectiveness. *LaMont Dep. Tr.* at 101, l. 17-22.
382. LaMont does not know of any good or reliable data on the amount of antiangiogenic activity per gram of shark cartilage. *LaMont Dep. Tr.* at 112, l. 6-11.
383. LaMont agreed that it would be ideal to study variables such as the bioavailability, the absorption, and the distribution of Bio*Shark in order to assess its effectiveness with respect to cancer. *LaMont Dep. Tr.* at 101, l. 23-25 - 102, l. 1-12.
384. LaMont probably would not use Bio*Shark or a product like it in her practice because she thinks that there are other ways to inhibit angiogenesis that are more certain. *LaMont Dep. Tr.* at 151, l. 6-11.

7 Herb Formula

James Duke, Ph.D.

385. Duke has no idea how much Burdock root in vitro would be necessary to eliminate cancer. *Duke Dep. Tr.* at 72, l. 1-8.
386. Duke understands that four of the herbs in 7 Herb Formula are the “Essiac formula [that] have had both positive and negative trials published in PubMed.” *Duke Dep. Tr.* at 73, l. 3-8.
387. Duke does not know how much of the elements that are in 7 Herb Formula are actually in the product sold by DCO. *Duke Dep. Tr.* at 78, l. 22-24.
388. Duke acknowledged that although two of the lignans in Burdock have shown antilymphomic properties, they probably were in vitro. *Duke Dep. Tr.* at 125, l. 5-9.
389. There are no clinical trials regarding Burdock’s efficacy as to cancer in Duke’s IE. *Duke Dep. Tr.* at 148, l. 13-19.
390. There is no indication in Duke’s IE that watercress has been evaluated in clinical trials for its efficacy in treating cancer. *Duke Dep. Tr.* at 154, l. 16-20.
391. There is no indication in Duke’s IE that turkey rhubarb has been evaluated in clinical trials to treat cancer. *Duke Dep. Tr.* at 155, l. 14-17.
392. There is no indication in Duke’s IE that sheep sorrell has been evaluated in clinical trials to measure its efficacy in treating cancer. *Duke Dep. Tr.* at 153, l. 18-23.

393. There is no indication in Duke's IE that slippery elm has been evaluated in clinical trials for its efficacy in treating cancer. *Duke Dep. Tr.* at 157, l. 6-17.
394. There is no indication in Duke's IE that Cat's Claw has been evaluated in clinical trials for its efficacy in treating cancer. *Duke Dep. Tr.* at 157, l. 18-25 - 158, l. 1-10.
395. Duke "do[es]n't think much of the Essiac formula." *Duke Dep. Tr.* at 129, l. 4-10.
396. Duke acknowledged that sheep sorrel is "touted" for cancer in the Essiac formula. *Duke Dep. Tr.* at 129, l. 12-14.
397. Duke would recommend Slippery Elm "more for stomach problems, mucous problems. It's famous for that." *Duke Dep. Tr.* at 130, l. 11-15.
398. Slippery Elm "is not one of the first things in [Duke's] cancer category." *Duke Dep. Tr.* at 130, l. 17-18.

James K. Dews

399. Dews "never heard of the 7 Herb Formula until this [lawsuit]." *J. Dews Dep. Tr.* at 59, l. 12-13.
400. According to Dews, 7 Herb Formula is a neutraceutical. *J. Dews Dep. Tr.* at 62, l. 19-20.
401. Dews is not prepared to talk about how the herbs in 7 Herb Formula may or may not benefit somebody with cancer. *J. Dews Dep. Tr.* at 39, l. 8-11.
402. Dews has never seen any controlled studies regarding 7 Herb Formula and its effectiveness in treating cancer. *J. Dews Dep. Tr.* at 58, l. 20-23.
403. Dews has never seen any studies that would say that 7 Herb Formula is effective in curing cancer. *J. Dews Dep. Tr.* at 58, l. 24-25 - 59, l. 1.
404. Dews does not know of any studies on whether 7 Herb Formula prevents cancer. *J. Dews Dep. Tr.* at 59, l. 5-8.
405. Dews is not familiar with any studies that say there is anticancer activity in any of the components from the herbs contained in 7 Herb Formula. *J. Dews Dep. Tr.* at 16-24.
406. Dews is not aware of any studies showing that 7 Herb Formula inhibits tumor formation. *J. Dews Dep. Tr.* at 59, l. 9-12.
407. Other than "folk-wise" uses of the herbs contained in 7 Herb Formula as a folk remedy for cancer, there have not been any scientific studies done on the herbs found in 7 Herb Formula relating to their effectiveness as a remedy for cancer treatment. *J. Dews Tr.* at 45, l. 21-25 - 46, l. 1-9.

408. Dews does not recall seeing cancer mentioned specifically in any studies relating to burdock root. *J. Dews Dep. Tr.* at 44, l. 11-14.
409. Dews has never “seen it stated that [Siberian ginseng] helps with cancer.” *J. Dews Dep. Tr.* at 46, l. 19-20.
410. Dews has not ever seen any studies that have found that Siberian ginseng reduces tumors. *J. Dews Dep. Tr.* at 47, l. 13-15.
411. Dews has never seen any studies showing that slippery elm can help with, for example, stomach cancer. *J. Dews Dep. Tr.* at 49, l. 17-20.
412. Dews has never seen any actual scientific studies done that would show that slippery elm can cure any disease. *J. Dews Dep. Tr.* at 50, l. 1-3.
413. Dews has not seen any scientific studies on rhubarb root relating to treating cancer. *Jim Dews Dep. Tr.* at 51, l. 23-25 - 52, l. 1-9.

Jay Lehr

414. Lehr has never spoken to Respondent James Feijo about 7 Herb Formula. *J. Lehr Dep. Tr.* at 24, l. 25 - 25, l. 1-2.
415. Lehr has not done any scientific literature searches on 7 Herb Formula. *J. Lehr Dep. Tr.* at 26, l. 2-4.
416. Lehr is not aware whether Jim Feijo has ever done any testing on 7 Herb Formula. *J. Lehr Dep. Tr.* at 28, l. 16-17.
417. Lehr is not aware of any double-blind studies done in connection with 7 Herb Formula. *J. Lehr Dep. Tr.* at 47, l. 25 - 48, l. 1.

Sally B. LaMont, N.D.

418. LaMont does not know whether 7 Herb Formula is effective in the treatment or cure of cancer. *LaMont Dep. Tr.* at 105, l. 20-25.
419. LaMont “do[es]n’t think that 7 Herb Formula is going to cure cancer.” *LaMont Dep. Tr.* at 205, l. 2-3.
420. LaMont acknowledged that there are no clinical studies on this particular [7 Herb] formula. *LaMont Dep. Tr.* at 106, l. 2-4.

421. LaMont does not know about the doses in 7 Herb Formula. *LaMont Dep. Tr.* at 104, l. 5-7.
422. LaMont does not know whether essiac has ever been evaluated in clinical trials to determine if it has any anticancer activity. *LaMont Dep. Tr.* at 106, l. 24-25 - 107, l. 1-2.
423. LaMont testified that “[i]t would be a stretch to suggest that this [7 Herb Formula] is on its own going to be effective in treating cancer.” *LaMont Dep. Tr.* at 117, l. 6-19.
424. LaMont “would be concerned about patients taking [7 Herb Formula] on its own and expecting their cancer to go away.” *LaMont Dep. Tr.* at 118, l. 23-25.
425. LaMont stated that “[i]t would be a stretch for [her] that [7 Herb Formula] is a solution to cancer.” *LaMont Dep. Tr.* at 120, l. 15-21.
426. Lamont “would be surprised if [7 Herb Formula] itself is the solution to cancer.” *LaMont Dep. Tr.* at 120, l. 23-24.
427. LaMont would have a concern if 7 Herb Formula was advertised as a cancer solution. *LaMont Dep. Tr.* at 120, l. 25 - 121, l. 1-7; 123, l. 12-15.
428. LaMont does not know whether the amount of cat’s claw in 7 Herb Formula is going to be effective. *LaMont Dep. Tr.* at 129, l. 18-22.
429. LaMont acknowledged that we do not know whether 7 Herb Formula as an independent agent would have any beneficial effects in respect to ovarian cancer. *LaMont Dep. Tr.* at 137, l. 14-19.
430. LaMont personally has never used any of the essiac tea formulas in her practice. *LaMont Dep. Tr.* at 150, l. 23-25.
431. LaMont does not think it is a good idea to take 7 Herb or GDU instead of having a polyp in the colon cut out. *LaMont Dep. Tr.* at 182, l. 23-25 - 183, l. 1-4.

GDU

James Duke, Ph.D.

432. Duke does not know how much of the elements that are in GDU are actually in the product sold by DCO. *Duke Dep. Tr.* at 78, l. 18-21.
433. Duke testified that he saw two or three studies on turmeric, “but they were not conclusive.” *Duke Dep. Tr.* at 120, l. 13-17.

434. Duke is not sure whether turmeric is more effective in fighting cancer than curcumin in an isolated form. *Duke Dep. Tr.* at 137, l. 16-25.
435. Duke does not remember any clinical studies on Bromelain. *Duke Dep. Tr.* at 124, l. 11-16.
436. Duke testified that Feverfew is “not the first thing I think about when I’m thinking cancer.” *Duke Dep. Tr.* at 129, l. 22-25 - 130, l. 1.
437. There are no clinical trials regarding pineapple Bromelain’s efficacy as to cancer in Duke’s IE. *Duke Dep. Tr.* at 148, l. 6-12.
438. Based on his review, there are no clinical trials regarding turmeric’s efficacy as to cancer in Duke’s IE. *Duke Dep. Tr.* at 153, l. 8-14.
439. There are no indications in Duke’s IE that Feverfew has been evaluated in clinical trials for its efficacy in treating cancer. *Duke Dep. Tr.* at 157, l. 1-5.

James K. Dews

440. Dews is not familiar with the product GDU. In fact, he does not have a clue what GDU is. *J. Dews Dep. Tr.* at 55, l. 3-4.
441. The active chemical in turmeric is curcumin, and curcumin is “very good at reducing inflammation.” *J. Dews Dep. Tr.* at 65, l. 17-24.
442. One cannot say that reducing inflammation is a cure for any particular disease. *J. Dews Dep. Tr.* at 66, l. 4-5.

Jay Lehr

443. Lehr has not spoken to Respondent James Feijo about GDU and what its components are. *J. Lehr Dep. Tr.* at 25, l. 18-20.
444. Lehr has not done any scientific literature searches on GDU. *J. Lehr Dep. Tr.* at 26, l. 7-8.
445. Lehr is not aware whether Respondent James Feijo has ever done any testing on GDU. *J. Lehr Dep. Tr.* at 28, l. 19-20.

Sally B. LaMont, N.D.

446. LaMont does not know whether the product GDU eliminates tumors. *LaMont Dep. Tr.* at 92, l. 11-19.

447. LaMont does not know whether GDU is effective in curing cancer. *LaMont Dep. Tr.* at 43, l. 2-11.
448. LaMont does not know whether GDU is effective in the treatment of cancer. *LaMont Dep. Tr.* at 92, l. 20-23.
449. LaMont is not aware of any clinical studies of GDU. *LaMont Dep. Tr.* at 42, l. 24-25 - 43, l. 1.
450. LaMont agrees that it would be fair to stay that it's impossible today to state the degree to which GDU is effective in the treatment or cure of cancer. *LaMont Dep. Tr.* at 45, l. 21-25 - 46, l. 1-8.
451. LaMont does not know whether GDU on its own at its dose would eliminate tumors. *LaMont Dep. Tr.* at 74, l. 19-25 - 75, l. 1-3.
452. LaMont recommends curcumin to inhibit inflammation. *LaMont Dep. Tr.* at 27, l. 3-10.
453. LaMont recommends that her patients use turmeric in their diet and have them supplement it in a dose of around 300 milligrams a day. *LaMont Dep. Tr.* at 27, l. 11-25.
454. LaMont's understanding is that 300 milligrams of turmeric per day has been commonly found to be effective at reducing inflammation. *LaMont Dep. Tr.* at 28, l. 1-5.
455. LaMont thinks that taking turmeric in high doses can inhibit clot formation. *LaMont Dep. Tr.* at 30, l. 23-25 - 31, l. 1-4.
456. One clinical study that LaMont can mention came out last month and involved the use of turmeric or curcumin in patients with pancreatic cancer. *LaMont Dep. Tr.* at 38, l. 7-25 - 39, l. 1-11.
457. According to LaMont, the 2008 study involving patients with pancreatic cancer used eight grams of a curcuminoid a day. *LaMont Dep. Tr.* at 38, l. 21-25 - 39, l. 1-3.
458. LaMont believes that GDU contains 300 milligrams of turmeric. *LaMont Dep. Tr.* at 40, l. 16-21.
459. LaMont does not know whether 300 milligrams of turmeric were also studied in the context of the 2008 study. *LaMont Dep. Tr.* at 41, l. 1-3.
460. LaMont is not familiar with any clinical studies of curcumin at 300 milligrams per day. *LaMont Dep. Tr.* at 41, l. 15-23; 42, l. 16-18.
461. LaMont has "no way of knowing how many milligrams [of quercetin] would produce a certain therapeutic response." *LaMont Dep. Tr.* at 64, l. 13-22.

462. LaMont agreed that the dosage found in GDU is on the lower end of the therapeutic spectrum. *LaMont Dep. Tr.* at 67, l. 8-16.
463. LaMont agrees that there is a big difference between seeing bromelain work in the capacity of a swollen ankle and having it work in the context of cancer. *LaMont Dep. Tr.* at 71, l. 23-25 - 72, l. 1-2.
464. LaMont does not know what dosage of feverfew was contained or used in the study from Molecular Cancer Therapies in April 2005. *LaMont Dep. Tr.* at 80, l. 21-23.
465. LaMont does not know what dosage of feverfew was used in the study from the British Journal of Pharmacology in 2002. *LaMont Dep. Tr.* at 81, l. 12-14.

BioMixx

James Duke, Ph.D.

466. Duke does not know how much of the elements that are in BioMixx are actually in the product sold by DCO. *Duke Dep. Tr.* at 78, l. 22-24.

Jay Lehr

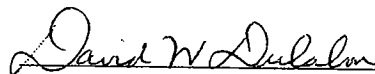
467. Lehr has never heard of the product BioMixx. *J. Lehr Dep. Tr.* at 22, l. 8-9.
468. Lehr has never spoken to Respondent James Feijo about BioMixx. *J. Lehr Dep. Tr.* at 25, l. 3-4.
469. Lehr has not done any scientific literature searches on BioMixx. *J. Lehr Dep. Tr.* at 26, l. 5-6.
470. Respondent James Feijo has not shared with Lehr the results of any testing done on BioMixx. *J. Lehr Dep. Tr.* at 28, l. 7-9.
471. Lehr is not aware whether Respondent James Feijo has ever done any testing on BioMixx. *J. Lehr Dep. Tr.* at 28, l. 10-12.
472. Lehr is not aware of any double-blind studies done in connection with BioMixx. *J. Lehr Dep. Tr.* at 47, l. 23-24.

Sally B. LaMont, N.D.

473. LaMont recognizes that BioMixx “certainly has not gone through those kind of clinical trials that would prove that it’s going to cure cancer.” *LaMont Dep. Tr.* at 172, l. 14-20.

474. LaMont “do[es]n’t think as a stand-alone [product] BioMixx is going to cure their cancer or probably even effectively treat it.” *LaMont Dep. Tr.* at 176, l. 16-22.
475. LaMont did not write that BioMixx is effective in the treatment of cancer in her report. *LaMont Dep. Tr.* at 210, l. 13-15.
476. LaMont is not concluding that BioMixx is effective in the treatment of cancer. *LaMont Dep. Tr.* at 211, l. 6-9.
477. LaMont is not concluding that BioMixx completely heals the destructive effects of radiation and chemotherapy. *LaMont Dep. Tr.* at 211, l. 10-20.

Respectfully submitted,



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

Dated: February 24, 2009

Exhibit

2

In the Matter of:

Daniel Chapter One, et al.

February 11, 2009

James K. Dews

Condensed Transcript with Word Index



For The Record, Inc.

(301) 870-8025 - www.ftrinc.net - (800) 921-5555

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FEDERAL TRADE COMMISSION
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25

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4

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

1 In the Matter of:)
2 DANIEL CHAPTER ONE, a corporation,)
3 and) Docket No. 9329
4 JAMES FEIJO, individually and as)
5 an officer of Daniel Chapter One)
6 -----)
7
8 Wednesday, February 11, 2009
9
10 Room 318
11 Federal Trade Commission
12 One Bowling Green
13 New York, New York 10004
14
15
16

17 The above-entitled matter came on for
18 deposition, pursuant to notice, at 10:34 a.m.
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25

PROCEEDINGS

1
2 - - - - -
3 Whereupon --
4 JAMES K. DEWS
5 a witness, called for examination, having been first
6 duly sworn, was examined and testified as follows:
7 EXAMINATION
8 BY MS. PAYNTER:
9 **Q. Good morning, Mr. Dews.**
10 A. Good morning.
11 **Q. My name is Carole Paynter, and I'm an attorney**
12 **with the Federal Trade Commission.**
13 **Along here with me are my co-counsel, Ted Zang**
14 **and David Dulabon.**
15 **And we all represent the commission in this**
16 **case.**
17 A. Okay.
18 **Q. And you're here this morning to give your**
19 **deposition for all purposes.**
20 A. Okay.
21 MS. PAYNTER: Okay. And first, before we move
22 forward into your testimony, just I would like to put on
23 the record, Mr. Turner, what actually is the respondent
24 alleging Mr. Dews is an expert on.
25 MR. TURNER: Herbal formulations, specifically

5

1 7 Herb Formula.

2 MS. PAYNTER: Okay. Because I believe that the

3 submission you gave previously said preclaim

4 substantiation of respondents' challenged claims, so it

5 was very broad, so are you limiting that now?

6 MR. TURNER: Yes. Well, that's -- what I just

7 said is what it should be and that's what it should have

8 said, so I didn't catch that when it went in.

9 MS. PAYNTER: Okay. Just to 7 Herb Formula.

10 MR. TURNER: Correct.

11 MS. PAYNTER: Okay. Thank you.

12 THE WITNESS: I'm not aware of what charges the

13 FTC has made and I don't want to be.

14 BY MS. PAYNTER:

15 **Q. Okay. Well, we'll see as we go forward what we**

16 **can get from you today. Okay?**

17 **As I mentioned, we are here to take your**

18 **testimony regarding matters in this case, the**

19 **Federal Trade Commission's action against**

20 **Daniel Chapter One and Mr. James Feijo, who is an**

21 **officer and owner of the company.**

22 A. Uh-huh.

23 **Q. First, have you ever been deposed before?**

24 A. Oh, yes.

25 **Q. Okay. And how many times have you been**

6

1 **deposed?**

2 A. I've lost count. Five or six times.

3 **Q. And in what kind of action have you been**

4 **deposed?**

5 A. This was mostly competitors, ex-employees,

6 things of that sort.

7 **Q. Have you ever appeared as an expert witness in a**

8 **case?**

9 A. I did in the State of New York -- New Jersey

10 versus Alan Shair in which the state had charged him

11 with selling a not dangerous substance, and my testimony

12 won him an acquittal and they changed the laws as a

13 result.

14 **Q. So can you give me more information about that?**

15 **What was he selling?**

16 A. Yeah. I had a customer who was a psychologist,

17 not a psychiatrist, so he was not an M.D., he was a

18 Ph.D., and he was very much interested in products that

19 could be used for -- in his practice, and he had asked

20 me to produce a substance known as hydroxymethylbutyrate

21 or HMB.

22 Now, that is what is commonly sometimes referred

23 to as the date rape drug. Now, it is a drug. It is

24 used. And in the right amounts it's helpful in that it

25 helps to relax the patient. In large amounts you can

7

1 overrelax and actually knock the people out to where

2 they don't know what's going on, and that's how this

3 came about.

4 And I told him I could not supply that because

5 it was questionable, that he wouldn't know what to do

6 with it or how to properly use it. He was not a

7 physician, so therefore -- he was not a medical doctor;

8 therefore, he could not use it.

9 Then he said, Well, I've got to have it. And I

10 said the closest thing I can get to it is

11 beta-hydroxybutyrate, which is the common amino acid

12 L-threonine, T-H-R-E-O-N-I-N-E, which has a similar

13 action.

14 And I said now -- he said he wanted to use it

15 for research and so he wanted a kilo. Everything we do

16 is metric, so that's I think metrically.

17 And so we supplied it, and I labeled it

18 properly. Well, he got it and he was telling his

19 patients it was HMB. He got a knock on his door at

20 two o'clock one morning, and they tore the door down and

21 put him in prison, and so they were charging him with

22 selling an unapproved substance.

23 In the meantime, they analyzed it and found

24 that it was L-threonine. They checked our records, and

25 it was indeed L-threonine. But they had to go on

8

1 through with the trial. It ended up that they thanked

2 me.

3 And as a result, you have to be careful with

4 chemical names. Just a slight difference can make a

5 major difference in the way they work.

6 **Q. Okay. Well, do you remember what year that was,**

7 **the case was?**

8 A. It's been about five or ten years ago.

9 **Q. Actually before we go on further, you mentioned**

10 **drugs. I should ask you today, are you taking any**

11 **medication that might affect your testimony today?**

12 A. No.

13 **Q. Okay. Thank you.**

14 **And just -- I know you've been deposed before,**

15 **so I know you've heard some of these instructions**

16 **already, but you know, when you do answer, we need you**

17 **to give a verbal response to the questions --**

18 A. Yes, ma'am.

19 **Q. -- so the court reporter can take it down.**

20 **If you don't understand something I've asked,**

21 **please ask me to clarify it and, you know, let me know,**

22 **and I'll rephrase it if I can.**

23 **If there is -- if you need to take a break, just**

24 **let me know, and at an appropriate time we can take a**

25 **break.**

9

1 **And then also, if there's anything that, as I**
 2 **said, that you need me to correct, I'll go back and**
 3 **correct it, and we can correct it on the record here**
 4 **today.**
 5 **Do you understand those instructions?**
 6 A. Yes, ma'am.
 7 I might mention, for her benefit, I'm stone deaf
 8 in that ear and I wear a hearing aid in this one, so I'm
 9 trying to speak clearly (indicating).
 10 **Q. Am I speaking --**
 11 A. And I'll try to hear -- yes. You're doing
 12 fine.
 13 **Q. Okay. Very good. Thank you.**
 14 **So sometimes I do speak fast. If I'm speaking**
 15 **too fast, please let me know and --**
 16 A. Okay. Yeah. But this bad ear is on her side,
 17 so...
 18 **Q. Okay.**
 19 **So court reporter, you've been warned. You have**
 20 **to shout.**
 21 A. You'll notice I'll turn my head.
 22 **Q. Okay. Well, do you want to sit on this side or**
 23 **are you --**
 24 A. No. It's fine. It's fine. I do pretty well.
 25 This is a pretty good hearing aid.

10

1 **Q. Okay. Good.**
 2 **So you mentioned that you were involved in an**
 3 **action with the State of New Jersey as an expert, but**
 4 **have you ever been involved in any action with yourself**
 5 **or your company where the federal government has sued**
 6 **you?**
 7 A. Right. Well, we do have two companies, but
 8 we've never been involved. We are regulated, certainly
 9 used to be inspected on a regular basis by the FDA. Now
 10 it's changed with the current situation. Usually it's
 11 the TDH, and sometimes the FDA follows up.
 12 **Q. And what's the TDH?**
 13 A. Texas Department of Health. They do the primary
 14 inspecting now.
 15 **Q. Have you ever been sued by the Texas**
 16 **Department of Health?**
 17 A. No.
 18 **Q. Or any other -- or any action by them?**
 19 A. No. I get along with them just fine.
 20 (Discussion off the record initiated by the
 21 court reporter.)
 22 BY MS. PAYNTER:
 23 **Q. Mr. Dews, can you tell me what your educational**
 24 **background is.**
 25 A. Yes. After high school -- I graduated from

11

1 schools in Fort Worth. I was raised in Fort Worth. And
 2 then I went to the University of Texas at Arlington --
 3 and of course the University of Texas has different
 4 schools around the state, and Arlington is between
 5 Dallas and Fort Worth -- and I majored in science.
 6 Then my father was an accountant, and I was
 7 helping him with his practice some, and so I also went
 8 to Texas Wesleyan, which is now a university, in
 9 Fort Worth, and I majored in business administration and
 10 accounting.
 11 **Q. And did you obtain a degree in any of the --**
 12 A. Didn't finish it.
 13 **Q. How many years did you attend college?**
 14 A. About two or three at UTA and about two at
 15 Texas Wesleyan.
 16 **Q. Since attending college, have you obtained any**
 17 **licenses or other certifications?**
 18 A. Well, I belong to quite a few of the different
 19 organizations involved, such as the tie, the
 20 AOAC (indicating). That's -- it used to be the
 21 American Organization of Analytical Chemists. Now
 22 they -- it's international, so they just changed the
 23 name to AOAC. But that is the agency that sets the
 24 methods of analyzing chemical compounds and determining
 25 the correct or the official method of analysis, which is

12

1 one of the things I do in my profession.
 2 **Q. Okay. And how long have you been a member of**
 3 **that group?**
 4 A. I think you have to be there I think it's eight
 5 or ten years before they give you a tie.
 6 **Q. And do they give you a certification?**
 7 A. Yes.
 8 **Q. And is it something that you have to update**
 9 **annually?**
 10 A. You have to be invited to join. You don't
 11 just -- they invite you.
 12 **Q. Okay.**
 13 A. And usually they require a degree. I gave them
 14 my background and they said, Hey, you're in.
 15 **Q. Okay.**
 16 A. Of course I also belong to the ACS,
 17 American Chemical Society; International Society of
 18 Pharmaceutical Engineers; International Food
 19 Technologists; Cosmetic, Toiletries and Fragrances
 20 Association -- we also make cosmetics -- you know,
 21 District Export Council.
 22 **Q. What kind of associations are those, the ones**
 23 **you mentioned, the cosmetic association and --**
 24 A. Well, if you're going to make cosmetics or
 25 perfumes or anything of that sort, then that's certainly

13	15
<p>1 an organization you would belong to.</p> <p>2 And of course we kind of specialize -- we make</p> <p>3 all kinds of products. We don't determine that. Our</p> <p>4 customers ask us what they want. But we do a lot of</p> <p>5 nutraceuticals, which we were the first company to make</p> <p>6 them, mostly because physicians were asking for those</p> <p>7 kinds of products.</p> <p>8 Q. Well, just going back, the associations, though,</p> <p>9 those are trade associations? Do you get --</p> <p>10 A. Trade associations. Some of them are quasi.</p> <p>11 Just like Food Chemical Codex, that's made up of</p> <p>12 government and industry where they set the monographs</p> <p>13 for each ingredient and what it's used for and whether</p> <p>14 it's safe to use or what the -- what conditions it might</p> <p>15 not be safe.</p> <p>16 Q. Okay. And going back to the case of the</p> <p>17 State of New Jersey versus Mr. Shair -- was it Shair,</p> <p>18 was his name?</p> <p>19 A. Yeah.</p> <p>20 Q. In terms of your testimony, were you testifying</p> <p>21 just about what you had done for him?</p> <p>22 A. What I had done which was confirmed by the tests</p> <p>23 that they ran.</p> <p>24 Q. Okay. So were you testifying just about the</p> <p>25 effects of the drug or more of the factual --</p>	<p>1 don't remember them all and I didn't save the</p> <p>2 transcripts.</p> <p>3 Q. Okay. Well, just that in terms of, you know,</p> <p>4 your purpose here is to be as an expert --</p> <p>5 A. Yeah. I'm called quite often. Like insurance</p> <p>6 companies will call me and ask me if some nutraceutical,</p> <p>7 would that -- they're trying -- someone is trying to get</p> <p>8 it covered by insurance and would that just be</p> <p>9 justified, and I said, well, theoretically it may not</p> <p>10 because it's not intended to cure or help to cure a</p> <p>11 disease.</p> <p>12 Nutraceuticals cannot be claimed to cure or help</p> <p>13 to cure a disease. That's the definition, the legal</p> <p>14 definition.</p> <p>15 Q. Okay. In regards to -- well, let's go into what</p> <p>16 your company -- you said -- you mentioned you have two</p> <p>17 companies; is that correct?</p> <p>18 A. Yeah. Dews Research Laboratory only makes</p> <p>19 products for other companies to sell, period. We don't</p> <p>20 get involved in the marketing. We've got enough to do</p> <p>21 just making the products.</p> <p>22 Q. And your other company, what's the other</p> <p>23 company?</p> <p>24 A. Now, unfortunately, it's kind of the analogy</p> <p>25 would be like the farmer. The farmer doesn't get much</p>
<p>1 A. It's not a drug. Threonine is an amino acid.</p> <p>2 It's a food.</p> <p>3 Q. I apologize. Yeah.</p> <p>4 A. Okay. And that can get pretty tough because,</p> <p>5 you know, who would know which is which. Sometimes</p> <p>6 there's a thin line.</p> <p>7 But mainly that what I supplied was L-threonine.</p> <p>8 I did label it correctly. What he relabeled it as was</p> <p>9 out of my control. The only thing that I could -- if</p> <p>10 you ask my opinion, the only thing I could say he was</p> <p>11 guilty of is poor judgment.</p> <p>12 Q. So then your testimony wasn't really about the</p> <p>13 effects of the amino acid, for example --</p> <p>14 A. No.</p> <p>15 Q. -- or efficacy; it was about the facts of the</p> <p>16 actual --</p> <p>17 A. The similarities in chemical construction.</p> <p>18 Q. Okay. And were you actually qualified as an</p> <p>19 expert or you were just called as a witness?</p> <p>20 A. I was called as a witness in the -- in his</p> <p>21 trial.</p> <p>22 Q. Okay. Well, in terms of giving testimony based</p> <p>23 on your expertise in the pharmaceutical/nutraceutical</p> <p>24 area, have you ever given testimony in that regard?</p> <p>25 A. Probably over the years, yes, but you know, I</p>	<p>1 for his crop, but the company marketing the food does</p> <p>2 because they have the advertising behind them.</p> <p>3 The same thing with us. My customers make a</p> <p>4 tremendous profit. I don't make that much. I have to</p> <p>5 compete with companies that aren't as careful about the</p> <p>6 quality, so price is definitely a driving factor.</p> <p>7 Now, the profit is in the marketing. And there</p> <p>8 are a lot of products which I became familiar with and a</p> <p>9 lot of physicians saying, Yeah, I want you to make this</p> <p>10 product, and I'll say, Well, this is the minimum order,</p> <p>11 and then I can't afford that. But I hear that enough</p> <p>12 and I say, Hmm, there's enough demand for that product,</p> <p>13 why not --</p> <p>14 Q. Okay.</p> <p>15 A. -- put it in a company, so we formed a separate</p> <p>16 company, and that's all they do is market -- it's one of</p> <p>17 my customers.</p> <p>18 Q. What is the separate company? What's it</p> <p>19 called?</p> <p>20 A. It's Dews Twenty First Century Products.</p> <p>21 Q. And that company actually sells products.</p> <p>22 A. Yeah. My wife and daughters run that company.</p> <p>23 I don't -- certainly I -- the gentlemen would probably</p> <p>24 agree with me if they've been married. You don't tell</p> <p>25 your wife how to run her company; you advise her.</p>

17

1 **Q. And can you just give me an example of what kind**
 2 **of products you sell?**
 3 A. A lot of nutraceuticals, a lot of cosmeceuticals
 4 in this country because they're much easier to make and
 5 they're much easier to sell. The profit margins are
 6 reasonable.
 7 It's a good business to be in if your point is
 8 to be in business. And I have to be. I have to
 9 generate the cash flow.
 10 **Q. Well, are you involved in creating the products,**
 11 **or is it just your wife and your daughters?**
 12 A. They market. I do most of the creation and --
 13 because I get the calls and then -- where they're not
 14 willing to put up enough money to make a minimum batch,
 15 so when I get enough calls, I say, Barbara, you know,
 16 there's a lot of demand for this.
 17 And a lot of times they're old drugs that are no
 18 longer drugs.
 19 **Q. And Barbara is your wife?**
 20 A. My wife.
 21 **Q. Okay. Well, can you tell me -- you've used the**
 22 **word "nutraceuticals" before. Can you just define what**
 23 **those are?**
 24 A. Yeah. Basically they -- if you were to merge
 25 food supplements and pharmaceuticals together, you would

18

1 get nutraceuticals.
 2 If you merged cosmetics and pharmaceuticals
 3 together, you would get cosmeceuticals. That's what I
 4 was going to a while ago.
 5 The difference? Well, of course,
 6 nutraceuticals, you ingest it, and cosmeceuticals, you
 7 put it on the outside. That's the nuts and bolts of the
 8 actual manufacturing of nutraceuticals, cosmeceuticals,
 9 pharmaceuticals, OTC or prescription. It's the same.
 10 The ingredients are different, but the technology is the
 11 same.
 12 **Q. Okay. So can you give me an example of a**
 13 **nutraceutical?**
 14 A. Yeah. Right now, a very popular thing is to
 15 extract out certain chemical compounds that are in many
 16 foods, and this is interesting because, well, is it an
 17 herb or is it a food. Well, the only difference is in
 18 what you call it.
 19 **Q. Okay.**
 20 A. Now, does the herb do anything or does the food
 21 do anything? Well, in a roundabout way, it's not the
 22 herb or the food that's doing anything; it's the
 23 chemicals that exist within that. And that's why we
 24 have to be able to analyze these things, to measure, to
 25 see if that chemical is there, and that's pharmacology.

19

1 That's what I do.
 2 I received my basic scientific training. I
 3 took the courses in chemistry, physics, biology, all of
 4 this, pretty much in premed, but I went this direction.
 5 Then you take that and you -- it's the chemical
 6 that you want. You have to be able to analyze it.
 7 Now, a lot of times we'll take that food or that
 8 herb and we'll start separating it. We take it apart.
 9 That's the science of pharmacology.
 10 Now, I received my basic education and then I
 11 worked within companies, and I do work with a lot of
 12 universities with their research center and their
 13 scientists, and so I was trained after that by
 14 pharmacologists, mostly European, how to do this
 15 profession.
 16 **Q. Okay. Well, can you tell me what kind of**
 17 **nutraceutical your company might produce?**
 18 A. Sure. Well, popular when I started in that --
 19 and this kind of gets -- and I apologize for that. It's
 20 not an easy question.
 21 **Q. No. But just --**
 22 A. Hey, we've got five minutes. Tell me how to do
 23 a brain surgery. No. It doesn't work that way.
 24 But anyway, I was talking about one in
 25 particular, and that's the anthocyanins. These are

20

1 things which have an antioxidant property. And they
 2 exist in a lot of foods, particularly fruits, but they
 3 also exist in other foods. And the chemical compounds
 4 are very much identifiable. You can measure them.
 5 Now, we take that whole food, and what's the
 6 most largest percentage in there? Water. Is that a
 7 chemical? Is that the chemical we want? No. So we get
 8 rid of the water.
 9 The second thing, well, fiber. Does fiber? No.
 10 We're looking for this chemical. By removing
 11 things we increase the level of the chemical. This is
 12 traditional pharmacology. This is just standard -- it's
 13 Pharmacology 101.
 14 **Q. Okay.**
 15 A. Okay?
 16 Then we increase that level so that that could
 17 be put into a tablet or a capsule or in a cosmetic or
 18 whatever, and it has a benefit.
 19 Does it rise to the level of a drug claim?
 20 Probably not.
 21 Would it be beneficial? Probably would.
 22 Would it hurt anybody? That's the first rule.
 23 No.
 24 Then why not do it. I guess I'm just a stupid
 25 Texan, but it makes sense to me and evidently it makes

21

1 sense to a lot of people. This is a multibillion-dollar
 2 industry now.
 3 **Q. Okay. Well, I know you have a lot to share, so**
 4 **I'm going to try to keep --**
 5 A. Okay. You asked me and I think --
 6 (Discussion off the record initiated by the
 7 court reporter.)
 8 BY MS. PAYNTER:
 9 **Q. You were mentioning you need -- when you're**
 10 **preparing nutraceuticals or pharmaceuticals, you need to**
 11 **make sure that it's safe?**
 12 A. Uh-huh.
 13 **Q. And how do you go about doing that?**
 14 A. Well, the first thing we look at is the herb
 15 itself. And there is data published, easily found,
 16 that tells you exactly what's in it. Beyond that, it
 17 tells you what it should do, what properties that
 18 chemical would have if used externally or internally.
 19 That's published. It's usually backed up by clinical
 20 data.
 21 Does that clinical data rise to the level that
 22 the Federal Trade Commission would say it substantiates
 23 the claim? Maybe not. But there certainly is data,
 24 and it tells exactly what this should do and at what
 25 level.

22

1 **Q. So when someone calls you to develop or -- do**
 2 **you develop the product or you just --**
 3 A. I put it together. Yeah. I make it.
 4 I'm sorry.
 5 (Discussion off the record initiated by the
 6 court reporter.)
 7 BY MS. PAYNTER:
 8 **Q. When someone calls you or contacts you to make**
 9 **them a product, what are the steps that you go into to**
 10 **say whether you could make it or not?**
 11 A. First I go to the references which are
 12 published. There are quite a few of them.
 13 As far as chemical and structure and how to
 14 analyze them, that's in the Merck Index. It's an
 15 international compilation of almost any chemical that
 16 you could think of for any use, and it tells you what
 17 it is, what the history of it is, what studies have
 18 been done on it, how you can identify it in your
 19 laboratory, everything there is that you'd want to know
 20 about it.
 21 Then you go into the different -- there's the
 22 Physicians' Desk Reference. And there is one for
 23 prescription pharmaceuticals. There's also one for
 24 over-the-counter drugs. There's also one for herbal
 25 products. And as a matter of fact, there's one for

23

1 veterinary products.
 2 So right there, you would go to the PDR, which
 3 is privately published but semiofficial in that this is
 4 the reference physicians use in the United States about
 5 that particular herb or that particular ingredient. And
 6 right there it will tell you what it is, what the active
 7 chemicals are.
 8 I've already determined what the active
 9 chemicals are. Now I'm going to look to see are those
 10 dangerous and, if they are dangerous, at what level,
 11 because a lot of things can be harmless at a lower level
 12 and very dangerous at too much.
 13 So -- and then other times the active chemical
 14 that we find in an herb and the customer wants to use
 15 another herb, are they compatible. One could negate the
 16 properties of the other, so we have to determine that.
 17 And there also the data tells us what level it's
 18 normally used.
 19 So -- so -- and it will tell you the whole herb
 20 or the extracted herb or the concentrated herb.
 21 And so all that data is published. It's
 22 published in the PDR. It's published in the German
 23 monographs, the Chinese monographs, the
 24 British Pharmacopoeia.
 25 A lot more herbs are used by the rest of the

24

1 world than are used in this country.
 2 **Q. Okay. So when someone asks --**
 3 A. Officially.
 4 Excuse me.
 5 **Q. When someone asks you to make a product and you**
 6 **do that analysis, do they tell you why they would like**
 7 **to create this particular --**
 8 A. What we run into a lot is they're looking at it
 9 strictly from marketing and people are asking for these
 10 herbs and a lot of times you say, Well, why do you want
 11 to use that combination? Well, someone told me that's
 12 good stuff. Good stuff in what way, you know. That --
 13 so a lot of times we find what's driving the request is
 14 more hype, and that does occur, so we want to make sure
 15 to get rid of the hype.
 16 **Q. And how do you do that?**
 17 A. By looking at any incompatibilities, any
 18 possible harm, and then we have to say, well, do not
 19 exceed this amount, you know, you better put that on
 20 your label. And by doing our due diligence, that's what
 21 we do. We're not involved in their marketing, but I do
 22 have to have a rough idea of what they're trying to
 23 achieve and why they're trying to achieve it.
 24 **Q. Do you have anyone ever contact you to make a**
 25 **product to treat cancer, for example?**

25

1 A. I've -- off the record, I always tell them, you
 2 know, don't even mention that word to me. You know,
 3 you're not doing yourself any favor. You're not only
 4 shooting yourself in the foot; you're slitting your own
 5 throat. This is the surest way in the world to make
 6 sure that product idea never sees the light of day.
 7 Keep it simple.

8 **Q. And why do you -- well, can you just elaborate**
 9 **why you say that they'd be shooting themselves in the**
 10 **foot?**

11 A. Because I know how our government views this
 12 sort of thing.

13 **Q. How do we -- can you just tell me how we view**
 14 **that sort of thing?**

15 A. Well, you have to be -- a study was done by
 16 Tufts University for the FDA, what is the average cost
 17 of a new drug approval, how long does it take average
 18 and how much does it cost. I can remember when it cost
 19 a thousand bucks, but I'm an old man. Today the study
 20 found out five years and \$1.4 billion.

21 How much do you have to sell that product for
 22 if you're going to gamble? You may not get approved.
 23 You may go through phase one, phase two, phase three,
 24 phase four, any number. How much oversight is enough?
 25 So the worst thing you could do is get this

26

1 approved as a drug, if that's the product you're trying
 2 to do, do you have that kind of money to gamble.

3 **Q. But if someone -- but you said if someone calls**
 4 **you and they might say something about cancer and your**
 5 **advice would be to them --**

6 A. Don't ever mention that word to me again or I'm
 7 going to drop you so fast, it will make your head swim.

8 **Q. And why is that?**

9 A. Because I know it's a very negative thing. And
 10 I can see both sides of the argument. But if it helps
 11 them, well, yeah, I understand how you feel about this.

12 The problem is that the public's and the
 13 government's interpretation of the word "cure" is
 14 totally different. To the public, if it makes me feel
 15 better psychologically or actually, it's a cure. To the
 16 government, that's not so.

17 **Q. Okay. And --**

18 A. You might as well be speaking two different
 19 languages.

20 **Q. So in your experience, the government's idea of**
 21 **a cure is at a higher level than the average person?**

22 A. It's at a level that they set. The
 23 government -- governments set and bureaucracies set
 24 whatever rules they set. They're doing this as
 25 Congress dictates them to do or as they understand what

27

1 Congress dictates them to do. And that's it. That's
 2 the rules.

3 I don't agree that wearing a seat belt is
 4 necessarily going to save my life, but I'll guarantee
 5 you I don't want to pay the \$200 fine.

6 **Q. Okay. So with respect to cancer then, your**
 7 **view is the government doesn't want -- doesn't allow**
 8 **people to say that they have products that cure cancer?**

9 A. They have certain rules and they are the police,
 10 and you obey the rules.

11 **Q. Okay. Well, in your -- is it a laboratory? Is**
 12 **that what you have?**

13 A. Yes, that's exactly what it is.

14 **Q. In the laboratory do you also -- do you test**
 15 **drugs at all?**

16 A. We do test a lot of things.

17 And keep in mind, what's a drug in this country
 18 is usually not a drug in any other country. The
 19 United States is totally at odds with the rest of the
 20 world because I manufacture -- over half of my business
 21 goes overseas, and every country is different.

22 **Q. Well, in this country, what is -- what would --**
 23 **in your experience, what is considered a drug?**

24 A. Well, it's something -- a drug or a
 25 pharmaceutical, I mean, that's what the proper name

28

1 should be. You also use the word "drug" for illegal
 2 street drugs --

3 **Q. Right.**

4 A. -- so you have to make that -- but the claim is
 5 that it cures or helps to cure a disease, and that we
 6 just don't do, will not be involved in that. And if we
 7 see that one of our customers is doing it, we will
 8 advise them that I would stop doing this if I were you.

9 **Q. Well, then in terms of a drug or pharmaceutical**
 10 **and the testing of those, do you test those? Do you**
 11 **test drugs in your lab?**

12 A. We test to see if that chemical compound that is
 13 in that herb or that food is actually there and what the
 14 level is.

15 If you're going to say it in your documents,
 16 which they prepare their own labels from that, then they
 17 need to have that information.

18 **Q. And so you would provide them with a written**
 19 **statement --**

20 A. It has so much of this chemical compound in it,
 21 and we have certified that, usually done with a
 22 certificate of analysis, and we prepare the certificate
 23 of analysis.

24 Now, keep in mind all these -- no other country
 25 has nutraceuticals, only the USA, so in foreign

29

1 countries we have to submit the documents for a new drug
2 approval in their country according to their
3 regulations. They're not interested in ours.

4 As a matter of fact, you insult them to say that
5 they don't know what they're doing.

6 **Q. Well, have you ever conducted any controlled
7 studies at your --**

8 A. Not in a clinical -- I'm not a clinician. I
9 don't practice medicine. I don't practice any part of
10 healthcare itself. I'm interested in making the product
11 and trying to make sure that it's probably safe for its
12 intended use.

13 **Q. Okay. Are you involved in the labeling of the
14 products?**

15 A. Very seldom. And we prefer not to. I try to do
16 that as best I can for my wife's company, and sometimes
17 we will help to find a printer who can print the labels
18 and we try to go through the -- I'm very familiar with
19 Title 21 of the congressional Federal Register and I
20 have to know that and I generally know it better than
21 most of the people inspecting me because I've been at it
22 longer.

23 **Q. And you mentioned before you provide a
24 certification for the products you --**

25 A. The certificate of analysis, depending on what

30

1 each country requires.

2 **Q. Do you maintain those records?**

3 A. Yeah.

4 **Q. And how long do you maintain records for?**

5 A. You keep records forever.

6 **Q. Okay.**

7 A. You keep samples of every batch of every product
8 and every ingredient that you produce yourself because
9 we do that, we make some of the ingredients themselves,
10 and extraction is a perfect example. But those samples
11 are kept for six years because most of the dating we put
12 is five years.

13 Now, I know that dating is not required on a
14 nutraceutical in the United States, but it is in the
15 rest of the world, and nothing is sold only in the
16 United States anymore.

17 **Q. So dating, what does that refer to?**

18 A. You put a date, best before, and usually we use
19 five years. And then the Title 21 says whatever date
20 you put plus a year, and that's six years.

21 **Q. And so that's what you put on the certification
22 that you send to the -- to the --**

23 A. That it has been, we've done an analysis, the
24 active ingredient that we're suggesting you could put on
25 the label has been analyzed in our laboratory, and we

31

1 can certify that it's there and we can certify as to all
2 the other physical characteristics.

3 **Q. Okay. Well, as I mentioned before, this is a
4 case against a company called Daniel Chapter One --**

5 A. Uh-huh.

6 **Q. -- correct?**

7 **Are you familiar with that company?**

8 A. No. Not until this came up.

9 **Q. Are you familiar with the owner of the company,
10 James Feijo?**

11 A. Never heard of him.

12 **Q. Or Patricia Feijo?**

13 A. No. I think they talked to me on the telephone
14 since this has come up.

15 **Q. Okay.**

16 A. That was my first time I ever heard of them.

17 **Q. Was there a reason specifically why you were
18 retained as an expert in this case?**

19 A. Not a lot of companies do this. And you wonder,
20 well, why do you do this, why don't you -- it's -- the
21 industry in this country has moved to the point some
22 years ago that the pharmaceutical industry and the
23 healthcare industry is pretty well dominated by the big
24 international conglomerates. The little guy is really
25 just not a player anymore.

32

1 Well, if you're going to be a little guy, what
2 can you do. Well, when physicians began to ask for me
3 for -- they said, You know, we want vitamin C tablets.
4 I said, Why don't you send them to the health food
5 store, or even the pharmacy has a department that has
6 that. And the answer was: We want pharmaceutical
7 quality control in these types of products. We want to
8 know that it goes through a more rigorous manufacturing
9 and quality control and quality assurance.

10 Well, we were already making pharmaceuticals, so
11 we never really changed anything.

12 Now, this did not make us very competitive in
13 the nutraceutical field because we're competing against
14 companies that don't do that.

15 Interesting enough, since the FDA put in their
16 new GMPs, our business has shot up a thousand percent.

17 **Q. And what's a GMP?**

18 A. Good manufacturing practices.

19 **Q. Oh.**

20 A. These are the steps that are required to assure
21 the quality and that the product is made the way it
22 should be. And actually they call it now CGMPs,
23 current good manufacturing practices, because they do
24 change.

25 And I know we have to do certificates of free

1 sale for most of the countries, foreign countries, and
2 that we have to have the agency that oversees our
3 operation directly to certify that this product is
4 freely sold throughout the United States and is approved
5 to be sold and that the company has been inspected
6 within the last year and found to be in compliance with
7 all of the regulations, and we are.

8 And we have the TDH there, and every once in a
9 while we see the FDA that kind of follows up, usually
10 not on the whole inspection, just one or two questions
11 the TDH was not experienced enough to know the answer
12 to, and that happens quite often.

13 But we get those certificates. We've never been
14 turned down on them. And they generally state that we
15 are in significant compliance, which means we go beyond
16 what most companies do.

17 **Q. And is that why you were retained as an expert
18 in this case?**

19 A. I think so.

20 **Q. Okay.**

21 A. Because I do have knowledge of herbs. I do have
22 knowledges of where you can find the references. I know
23 they are widely published and very easily obtained.

24 **Q. Well, has your company ever created products for
25 Daniel Chapter One?**

1 A. No. Not that I was aware of.

2 **Q. And what products of Daniel Chapter One are you
3 familiar with?**

4 A. Well, since this has happened, I understand they
5 have a product called the 7 Herb Formula, which I
6 recognized because it's based on an old pharma known as
7 essiac, which is four herbs that were used, the story
8 is -- and I don't know whether it's true or not. Maybe
9 this is an urban, you know, story.

10 But the story is a nurse in Canada -- I believe
11 she was from Quebec, judging by the spelling of her
12 name -- created these four herbs that she knew that the
13 Indians living in that area or at least she said had
14 used these herbs and that she recommended it for cancer.
15 I was aware of that.

16 Now, does that mean I can't touch it because
17 someone else misused it? No. It just means don't
18 mention it for cancer. That's all.

19 And I was asked by a gentleman out of Dallas if
20 I could make that product. He didn't know where to get
21 the herbs or what proportions to use, though it's
22 published. You just need to know where to look. And
23 then he said okay. And I told him, I said, Well, here's
24 where to get these herbs. I can even sell you little
25 bags of it, you know, if that's what you want, and I can

1 put it together in the right proportions.

2 And then he said, Well, there's some other herbs
3 could we add, and then we kind of -- he had suggestions
4 of other herbs, and I suggested a few things that you
5 might want to put with it, not saying what it could be
6 used for but would that be synergistic, would that be a
7 good combination if someone would strictly want it for
8 the herbal purposes, and that's how they came up with
9 the 7 Herb.

10 I never heard any more from him after that. And
11 I've learned since then that his customer was Daniel,
12 but I didn't know that until this came up.

13 **Q. So did you -- did he actually have an official
14 account with you to create that --**

15 A. We had made a few products for him in the past,
16 and he said, I'm going to ask you to do something a
17 little different, can you tell me where to find these
18 herbs and can you give me some direction on how much to
19 use and if they're safe to use.

20 **Q. And I'm sorry. His name was?**

21 A. Bill Maclean.

22 **Q. And do you know -- was he a doctor?**

23 A. I don't think so. I think he called himself
24 that, but as I started this whole thing, that's more
25 respect than it is official title.

1 **Q. Okay.**

2 A. And you can call yourself a doctor.

3 **Q. Okay. Do you -- did he work for any specific
4 company that you're aware of?**

5 A. He had his own company.

6 None of my customers work for me.

7 **Q. And you mentioned that you talked to the Feijos
8 since you've been --**

9 A. One telephone call, and that's the first time
10 I'd heard their name.

11 **Q. And had you discussed 7 Herb Formula?**

12 A. Not with them. You know, I put this together
13 for Bill Maclean. I didn't know what he did with it.
14 And we didn't -- after we did that once or twice, we
15 never heard from him again on the subject.

16 **Q. So -- well, I guess the best thing we can do --
17 in preparation for today, for example, did you look at
18 any documents before you came in here today?**

19 A. Not much. As I told Mr. Turner from the start,
20 I will not testify as to any of their marketing because
21 I don't know anything about it and I'm -- that's not
22 what I do. I make products. That's all.

23 **Q. You will not testify -- well, will you
24 testify --**

25 A. As to the claims or counterclaims or -- I'm

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1 just -- that's not what I do. I'm not -- I don't know
 2 about that and I don't want to know about that.
 3 **Q. So are you willing today to give an opinion**
 4 **about the claims that were made by the company?**
 5 A. No. I don't even want to see the claims.
 6 **Q. So -- excuse me. Off the record.**
 7 **(Discussion off the record.)**
 8 **(Recess)**
 9 BY MS. PAYNTER:
 10 **Q. Before we went off the record, I was asking you**
 11 **whether you had ever seen Daniel Chapter One's**
 12 **advertising; correct?**
 13 A. I saw it after this, after I was asked to
 14 testify. I saw their Internet site, and the only thing
 15 I looked at, what is the 7 Herb Formula. I need to know
 16 what herbs they're talking about.
 17 **Q. And are you aware that the 7 Herb Formula is**
 18 **recommended to be used with people --**
 19 A. I'm not aware of that.
 20 **Q. Can you hold on? Hold on.**
 21 A. I'm sorry.
 22 **Q. When you looked on the Web site, did you see**
 23 **there were statements about 7 Herb Formula being --**
 24 A. I made a --
 25 **Q. -- being used --**

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1 **(Discussion off the record initiated by the**
 2 **court reporter.)**
 3 BY MS. PAYNTER:
 4 **Q. -- in connection with cancer treatment?**
 5 A. Because of my role in this whole process, I was
 6 very careful to make sure I need to know the names of
 7 the seven herbs, period. I will not look or make any
 8 determination of anything else. That's not what I'm
 9 hired to do.
 10 **Q. Well, with respect to your knowledge about**
 11 **herbs, are you familiar with the way herbs have been**
 12 **studied by scientifically or otherwise for the effects**
 13 **of the herbs, the chemicals in the herbs?**
 14 A. That's the question? Okay.
 15 Yes, I am familiar with what has been published
 16 on the effects of these herbs.
 17 **Q. Okay. So we'll talk about in that respect. Is**
 18 **that okay?**
 19 A. That's it.
 20 **Q. Okay. When -- you mentioned also that you had**
 21 **spoken to the Feijos after being --**
 22 A. They got on the --
 23 **Q. -- after being retained in this case.**
 24 A. Yeah. They -- one of the times that Mr. Turner
 25 or another attorney from his office was asking me

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1 questions about this and I was responding, they got on
 2 the line and introduced themselves. That's the first
 3 time I had ever heard of them.
 4 **Q. Well, did they mention to you that they were**
 5 **being prosecuted for making claims about cancer?**
 6 A. They didn't have to. Mr. Turner had already
 7 told me that.
 8 **Q. Okay. So are you prepared to talk about how**
 9 **these herbs may or may not benefit somebody who has**
 10 **cancer?**
 11 A. No. I'm willing to talk about what these herbs
 12 have been used for and what studies have been done,
 13 period.
 14 **Q. Okay. I'm going to have the court reporter mark**
 15 **the Federal Trade Commission's complaint against**
 16 **Daniel Chapter One, which I'm going to ask you some**
 17 **questions about 7 Herb Formula. Okay?**
 18 **So she's going to mark this for us.**
 19 **(Dews Deposition Exhibit Number 1, complaint,**
 20 **was marked for identification.)**
 21 THE WITNESS: Okay. I need to ask a question
 22 here. Are you asking me to study this form that you
 23 just got through --
 24 BY MS. PAYNTER:
 25 **Q. No. I'm not going to ask you to study it.**

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1 A. Okay.
 2 **Q. Okay?**
 3 **But we'll use it as a reference as we go, asking**
 4 **some questions about the herbs themselves.**
 5 A. Okay.
 6 **Q. Okay?**
 7 A. As I've said and I told Mr. Turner from the
 8 start, I will not testify as to the charges that the FTC
 9 has made nor as what your defenses, so that's your job.
 10 I'm only -- can testify as to what the herbs are and how
 11 they're used.
 12 **Q. Okay.**
 13 A. So therefore, I give this back to you. I refuse
 14 to read it because I think it has the charges that you
 15 made. If I wouldn't do it for him, I'm not going to do
 16 it for you either.
 17 **Q. Okay. But would you be willing just to look**
 18 **at -- you looked at the Web site already; right?**
 19 A. No. Only as to the herbs that are in the
 20 7 Herb Formula.
 21 **Q. So I'm going to show you a page that was taken**
 22 **from the Web site. You don't have to read the charges.**
 23 **You don't have to read the charges, but it does have the**
 24 **list of the herbs that are in here, and I wanted to go**
 25 **over some of the statements about the herbs because you**

1 are a specialist in the herbs and what they do.
 2 **Correct?**
 3 A. I know what the herbs are and I have them
 4 memorized, so ask me the herb, and I'll tell you what's
 5 been published on it. I don't have to read that.
 6 **Q. Well, I would just like you to take a look at it**
 7 **with -- and it's not -- you know, it's not making you**
 8 **liable for anything, but you have been put forward as an**
 9 **expert on the herbs, and it is appropriate for me to**
 10 **show you a reference that we can use here in this**
 11 **deposition.**
 12 A. I in my opinion --
 13 **Q. So if you want to talk to Mr. Turner about**
 14 **whether you want to continue here today, that's**
 15 **between -- we're happy to step out and allow you to**
 16 **discuss that.**
 17 A. Okay. I'm going to tell you I've been around
 18 this long enough, I know what -- how these things go.
 19 I know what the herbs are. I know what they've
 20 been recommended before officially. I do not know what
 21 they have -- what you allege they said.
 22 For me to read that would be sheer speculation
 23 on my part. I'm not an expert in marketing, nor am I an
 24 expert on how the rules are promulgated by the
 25 Federal Trade Commission, and so therefore, I'm not

1 interested. I'm not going to read what you have said
 2 you charged them with.
 3 **Q. All right. Well, let's see if we can do it**
 4 **without the exhibit. Okay?**
 5 A. Right.
 6 **Q. We'll make our best effort.**
 7 **Well, first of all, you said you are aware of**
 8 **what's in 7 Herb Formula.**
 9 **Can you tell me what's in it?**
 10 A. Yeah. I think -- and I may not get these in the
 11 correct order, if there is an order -- there is one
 12 called sorrel. And this is a -- it's a member of the
 13 Rumex family. We refer to it as dock or yellow dock.
 14 Herbs have a lot of different names, even
 15 different plant genus names from one country to
 16 another.
 17 And it's generally used for inflammation. It
 18 does help to reduce inflammation. It does have a very
 19 mild laxative action if you take enough of it. If you
 20 don't take enough of it, it doesn't have any such
 21 action. And mainly that's what it's used for.
 22 Now, this -- do you want me to take them one at
 23 a time?
 24 **Q. Well, first I'm asking you to tell me what's in**
 25 **7 Herb.**

1 A. Right.
 2 **Q. Okay?**
 3 **So can you just please tell me what are the**
 4 **seven herbs in 7 Herb Formula.**
 5 A. Yeah. Let's just go with the names first.
 6 **Q. Yes, please.**
 7 A. Sorrel is one. Sheep sorrel I think is the
 8 common name.
 9 Slippery elm.
 10 Burdock root.
 11 That's three.
 12 Rhubarb root.
 13 That's four and that's the essiac. To that
 14 they have added Siberian ginseng, watercress, and
 15 cat's claw.
 16 See, I do have them.
 17 **Q. Yes. You got them right.**
 18 **So why don't we talk about first burdock root.**
 19 **What is burdock root?**
 20 A. Burdock root used in sufficient quantities can
 21 give a laxative action, although used in less it would
 22 not. It's used for inflammation.
 23 As I recall, I think the German monograph makes
 24 the statement "used for purifying the blood." Well, I
 25 suppose that would be true in Germany but not in this

1 country, although I think it's in the PDR also, the
 2 herbal PDR.
 3 So those are the general uses for it, to reduce
 4 inflammation and that sort of thing.
 5 **Q. Do you know whether burdock root has ever been**
 6 **used in the treatment of cancer?**
 7 A. I'm sure it has and I'm sure it was used
 8 informally. It could have been used by a medical
 9 practitioner, but I don't know that they would be too
 10 verbal about the fact.
 11 **Q. Are you aware of any studies that have ever been**
 12 **done on burdock root and its treatment of cancer?**
 13 A. I don't recall seeing cancer mentioned
 14 specifically, only the general properties.
 15 **Q. And sheep sorrel you mentioned.**
 16 A. Uh-huh.
 17 **Q. Can you tell me again what sheep sorrel is?**
 18 A. It's in the Rumex family. It's also referred to
 19 as dock. It's also antiinflammatory. It helps as a
 20 diuretic to get rid of excess moisture content.
 21 You could probably make the stretch to say,
 22 well, with cancer don't you have excess fluids. I
 23 suppose, but I've never seen it specifically stated that
 24 way.
 25 **Q. Well, have you ever seen any studies done on**

45	<p>1 sheep sorrel --</p> <p>2 A. That it reduces inflammation.</p> <p>3 I'm sorry.</p> <p>4 Q. -- studies of sheep sorrel in connection with</p> <p>5 the treatment of cancer?</p> <p>6 A. It -- only that it reduces inflammation.</p> <p>7 Q. And so can you say what kind of studies have you</p> <p>8 seen in connection with sheep sorrel?</p> <p>9 A. Yes. It's in the PDR for herbal drugs. It's in</p> <p>10 the German monographs. It's in quite a few books that</p> <p>11 are published for physicians' references.</p> <p>12 Physicians are very interested in this sort of</p> <p>13 subject because it's become very popular, so their</p> <p>14 patients are asking for this.</p> <p>15 It's in the -- I believe it's in the</p> <p>16 Chinese Medica which is the official, and so -- and in</p> <p>17 the British Pharmacopoeia it's listed.</p> <p>18 Q. Are you familiar with whether sheep sorrel has</p> <p>19 ever been used in folk -- let's say, as a folk remedy</p> <p>20 for cancer?</p> <p>21 A. Yeah. Now, there, any of these seven herbs</p> <p>22 could have been used folk-wise for that, but not</p> <p>23 officially, not bluntly.</p> <p>24 Q. Well, when you say "not officially," you mean in</p> <p>25 terms of the scientific studies done?</p>	47	<p>1 Siberian ginseng produces saponins or --</p> <p>2 A. Yeah. The saponins are plant hormones,</p> <p>3 phytohormones, and almost any food has these things in</p> <p>4 it, and they have effects upon the body depending upon</p> <p>5 which one you're using.</p> <p>6 Q. Would they have effects on tumors?</p> <p>7 A. Might. Certainly a tumor would require that a</p> <p>8 lot of moisture go into that area and maybe more than</p> <p>9 the surrounding tissue. Therefore, if you were to</p> <p>10 reduce the moisture content, it might, it could be</p> <p>11 helpful, but I've never seen it stated exactly that</p> <p>12 way.</p> <p>13 Q. Have you ever seen any studies that have found</p> <p>14 that Siberian ginseng reduces tumors?</p> <p>15 A. No. Just that it reduces in -- or it gives a</p> <p>16 person more energy and which I think is mainly what it's</p> <p>17 used for.</p> <p>18 Most of these herbs have a lot of different uses</p> <p>19 that have been used. Some of them were, you know, like</p> <p>20 you say, native or traditional and some were studies,</p> <p>21 and they tend to get kind of mixed up.</p> <p>22 Q. Okay. Another component is cat's claw, as you</p> <p>23 mentioned.</p> <p>24 A. Uh-huh.</p> <p>25 Q. And what is cat's claw?</p>
46	<p>1 A. Right. Generally they speak in terms -- anyone</p> <p>2 who's a health practitioner, whether they're a physician</p> <p>3 or even a naturopath, they're well aware that certainly</p> <p>4 in many conditions which might be considered to be</p> <p>5 diseases there are symptoms that -- such as excess fluid</p> <p>6 retention in soft tissue, that some of these things will</p> <p>7 reduce the inflammation in soft tissue, but they're not</p> <p>8 going to say it helps with cancer, other than folk</p> <p>9 medicine.</p> <p>10 Q. Okay.</p> <p>11 Okay. The other -- the other component --</p> <p>12 another component is Siberian ginseng or ginseng.</p> <p>13 A. Uh-huh.</p> <p>14 Q. Can you describe what that is?</p> <p>15 A. Sure. Sure. It's -- I'm trying to remember</p> <p>16 the plant genus name, but anyway, it's --</p> <p>17 Eleutherococcus. It is used mainly to -- for energy.</p> <p>18 It's an energizing -- it contains chemicals that tend</p> <p>19 to energize. But I've never seen it stated that it</p> <p>20 helps with cancer, just that it energizes.</p> <p>21 Certainly if you're on chemotherapy or</p> <p>22 something of that, your energy levels are pretty low,</p> <p>23 so it might be beneficial. It certainly won't hurt.</p> <p>24 It might help.</p> <p>25 Q. Are you familiar with the statement that</p>	48	<p>1 A. Cat's claw's plant genus name is -- oh, what is</p> <p>2 that? Tomentosa is the second name. I can't think of</p> <p>3 the first name now. I didn't get enough coffee this</p> <p>4 morning.</p> <p>5 Q. Okay.</p> <p>6 A. But anyway, it's used in South America. It's</p> <p>7 supposed to support the immune system.</p> <p>8 Q. Have you seen studies that have found cat's --</p> <p>9 A. The PDR says so and also give the bibliography</p> <p>10 of the studies.</p> <p>11 Q. Have you ever seen any of those studies?</p> <p>12 A. Yes.</p> <p>13 Q. And do you know what kind of studies those were?</p> <p>14 Were they double-blind studies?</p> <p>15 A. Most of them were more single-blind, although</p> <p>16 some were double-blind, and I'd have to go back and look</p> <p>17 at it to see exactly which ones were and which ones</p> <p>18 weren't.</p> <p>19 But yes, it does seem to have an effect upon</p> <p>20 supporting the immune system.</p> <p>21 Could it be used by itself? No. Of course not.</p> <p>22 Would it be helpful? It might would.</p> <p>23 Q. Well, when you say "could it be used by itself,"</p> <p>24 you mean to treat cancer?</p> <p>25 A. For any particular condition, and I'm not</p>

1 singling out cancer.
 2 **Q. Why do you say it couldn't be used by itself?**
 3 A. If the only thing it's doing is supporting the
 4 immune system, the word "support" itself means it has to
 5 work with something else, so that right there would
 6 negate such a claim.
 7 **Q. Another component is slippery elm.**
 8 A. Slippery elm again helps -- it's emollient; that
 9 is, it helps tissue. It helps to get the moisture,
 10 excess moisture, down. It's very soothing to the lower
 11 tract.
 12 It's very high in sugars, and sugars are very
 13 good. And there's quite a few sugars; there's not just
 14 one. And that's -- it's used a lot in cough syrups
 15 because it helps to get the excess fluids out, and so
 16 it -- that's its purpose.
 17 **Q. Have you ever seen any studies showing that it**
 18 **can help with, for example, stomach cancer?**
 19 A. No. I've never seen that specifically in those
 20 words.
 21 **Q. Well, in other words?**
 22 A. Well, if it reduces inflammation of the
 23 stomach, whatever the condition is, it might be
 24 helpful.
 25 **Q. But as far as you're aware, you've never seen**

1 **any actual scientific studies done that would show that**
 2 **it's helpful in any disease.**
 3 A. No. Helpful maybe, but curing, no.
 4 **Q. Okay. Thank you for that clarification.**
 5 **Another component is watercress, and what would**
 6 **that be used for?**
 7 A. Watercress is the flower nasturtium and so of
 8 the mustard family, and it's used mainly to reduce
 9 inflammation.
 10 **Q. Are there any studies, scientific studies**
 11 **conducted on --**
 12 A. There are studies on all of these but
 13 not usually pertaining to any particular disease but
 14 only to their overall effect upon the body.
 15 **Q. And in your business you have to be familiar**
 16 **with those studies?**
 17 A. Oh, yeah. The first thing I've got to do.
 18 It was real interesting when we started doing
 19 the Chinese herbs because they have a totally different
 20 way of looking at healthcare particularly, and it
 21 sounded so foreign when the first thing I had to
 22 understand is how does that relate to western medicine.
 23 And as I got into it, the only difference was the
 24 terminology or most of the differences was in the
 25 terminology. There's some things that are different,

1 you know.
 2 But they talk about the upper burner. Well,
 3 that's your sinuses and your lungs. The lower burner is
 4 your stomach, you know. But on first when you read the
 5 names, you know, that -- what are they talking about.
 6 Then as you dig into it, oh.
 7 And this is the sort of thing -- maybe this is
 8 why I ended up doing what I do. I love to study and
 9 learn things.
 10 **Q. Well, as we go on, the last component is turkey**
 11 **rhubarb root and --**
 12 A. Rhubarb used in sufficient quantities has a
 13 laxative action. And if it's low quantities, it
 14 wouldn't, enough, it would. It depends on the person.
 15 It depends on the person's psyche at the time that
 16 they -- or physiological makeup at the time that they
 17 use it, but it does -- and it is listed also as a blood
 18 purifier, and I guess if you get a mild laxative action,
 19 that could be said to be one way to do it.
 20 **Q. One way to do what?**
 21 A. If you remove excess feces from your intestinal
 22 tract, that probably would help to purify your system.
 23 **Q. Okay. Well, have you ever seen any studies of**
 24 **rhubarb root as it relates to treating cancer?**
 25 A. Only in a native, you know, and in traditional.

1 **Q. Traditional medicine?**
 2 A. Could you call it medicine?
 3 **Q. No.**
 4 **So when you say in the native folklore -- is**
 5 **that what you're saying?**
 6 A. Yeah.
 7 **Q. But in terms of the scientific studies, have you**
 8 **ever seen any on rhubarb root?**
 9 A. Not really.
 10 **Q. Okay.**
 11 A. The only thing it could mention is purifying,
 12 but it wouldn't specifically say for any disease.
 13 **Q. So what would be your opinion if a company were**
 14 **to make a claim that all of these herbs or in**
 15 **combination actually could help to treat cancer? Would**
 16 **you agree with that statement?**
 17 A. Well, certainly if someone were to ask me that,
 18 number one, I don't advise on that subject other than
 19 maybe my wife, but I would say, If I were you, I
 20 wouldn't go there.
 21 That's just like you can get into your car and
 22 you can drive from here to another city and drive a
 23 hundred miles an hour and not get caught and not get a
 24 ticket, but does that change the law. If I were you, I
 25 wouldn't do that. You're just asking for a problem.

1 Q. Well, is it your view that there's any -- is
2 there any truth in the statement that these herbs taken
3 together could treat cancer?

4 A. Well, remember, you're talking about officially
5 or in the opinion of the person --

6 Q. Just your opinion, not officially.

7 A. In my opinion, I don't know that it would rise
8 to that level, but I don't know that it would be
9 detrimental to use it.

10 Q. Okay. And just for the record, are you familiar
11 with the product Bio*Shark?

12 A. Never heard of it.

13 But it's the typical kind of name they usually
14 would use for chondroitin -- let's see if I can spell
15 it. C-H-O-N-D-R-O-I-T-I-N -- sulfate, just like the
16 mineral, S-U-L-F-A-T-E.

17 This is a -- it's a very complex carbohydrate
18 and it's actually a protein-carbohydrate complex. It
19 exists in many things, but it's particularly high in
20 shark cartilage. And it does help your body to produce
21 hyaluronic acid.

22 And studies have shown that it does help to
23 lubricate the joints, and certainly being 73 years old,
24 I have a need to lubricate my joints. I use it. It
25 works. It's not a drug. It's not approved as a cure

1 sermons.

2 Q. Well, let's see.

3 Well, are you familiar with the product GDU?

4 A. No. I don't have a clue what that is.

5 Q. Are you familiar with the product called
6 BioMixx?

7 A. No.

8 Q. When you went back to look at the Web site, did
9 you -- to look at the herbs in 7 Herb Formula, did you
10 get any information about the quantities of each
11 component within it?

12 A. I don't recall that being in there. And since I
13 had put the seven herbs together for Mr. Maclean, I knew
14 what the quantities are.

15 Q. Well, what are the quantities?

16 A. Oh, I'd have to go back and look now. I don't
17 have that in front of me, but I'm guessing that he
18 continued to use the same proportions as they did
19 before, which -- I also told him where to find the
20 references. Hey, look them up for yourself.

21 Q. So did you have -- do you have records regarding
22 the transaction with Dr. Maclean?

23 A. It's so far back, I'd have to dig to find them,
24 but I probably could. I don't know. I really -- having
25 been in business 35 years, I have a lot of records.

1 for anything, but then it's not curing, is it? It's not
2 getting at the cause of the arthritis; it's helping with
3 the results of it.

4 Q. Well, are you familiar with the use of shark
5 cartilage in the treatment of cancer?

6 A. No. I've heard that, but I've never really seen
7 any data.

8 Now, there may be some out there, but generally
9 when I see those, a mention of a disease, particularly
10 cancer or weight loss, I shy away with whatever it's
11 saying about it.

12 Q. And why is that?

13 A. Because I know it's just going to get you in
14 trouble.

15 Q. Okay. Well, what about in terms of the truth of
16 the ability to, you know, affect cancer?

17 A. I think at some point, whether you're doing what
18 I do in making the products or doing what they're doing
19 in marketing the products, what are you here for? Are
20 you here to preach a sermon of what you believe? Are
21 you here to help the public? Are you here to make a
22 living?

23 I think number one it would be to make a
24 living, number two and almost as close is helping the
25 public, but that doesn't leave any room for preaching

1 I've run out of -- I have to build buildings to store
2 them, and a lot of them I just throw away.

3 Q. Do you remember if Dr. Maclean told you what the
4 7 Herb was going to be used for?

5 A. No. And I don't want to know.

6 Q. Okay.

7 A. That's not what I do.

8 Q. Did he ever come back to you and say, Can you
9 just test the 7 Herb to make sure I have the components
10 correct?

11 A. As I said, he said -- after I told him where to
12 get the herbs and where to find the references on them
13 since he didn't want me to make the product, I made up a
14 few small but just the herbs in the right proportions in
15 little bags, and I said, if you'll take this and put it
16 in water and heat the water and brew a tea, then you can
17 make the product, but know, if I were you, I'd add a
18 preservative to it, you don't want this stuff mildewing
19 on you, and advised him.

20 But if he ever tried to tell me any disease
21 state, I would shut him up in a New York minute and say,
22 I don't want to hear it. I don't go there.

23 Q. Well, you advised him to make it as a tea; is
24 that right?

25 A. Oh, yeah.

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- 1 **Q. And why as a tea?**
 2 A. Because he said he wanted to make a liquid. A
 3 liquid is a tea. It depends on what you call it.
 4 **Q. So do you know, was he providing it as an actual**
 5 **like a powder substance or actual tea bags?**
 6 A. It's my understanding that he was brewing a
 7 liquid of some sort.
 8 I think he wanted to test the herbs in those
 9 combinations to see if it achieved the result that he
 10 was trying to get, and as I said, I don't want to know
 11 what results you're trying to get.
 12 **Q. Well, could you use the combination of herbs as**
 13 **just something to put into like a drink?**
 14 A. Uh-huh, you could.
 15 **Q. Does it have to be --**
 16 A. It's just a food. It doesn't have to be a
 17 drug.
 18 **Q. Does it have to be heated to get any effects?**
 19 A. Well, if you want to get the chemicals out of
 20 the herb -- remember, they're bound up there with the
 21 fiber and other naturally occurring compounds. If you
 22 want to -- you know, that's the first thing we have to
 23 do is, when we look at the herb, what's in there that
 24 we're trying to get out and what is it soluble in it.
 25 That's how you separate it.

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- 1 Fiber is not soluble in water, not even hot
 2 water.
 3 **Q. Okay.**
 4 A. That's pharmacology.
 5 **Q. Besides looking at the Web site to go over the**
 6 **seven herbs in here, did you read anything else in**
 7 **preparation for today?**
 8 A. I think you asked that and I've answered it. I
 9 made a point, I only want to see the herbs. I want to
 10 make sure it's the same herbs that I remember.
 11 **Q. Okay. But I think in your report did you go**
 12 **back -- you mentioned the German monographs and**
 13 **other --**
 14 A. I look at each herb, yeah, what's the herb,
 15 what are the different references that have been
 16 published on it, what do they use it for and what it's
 17 been indicated for officially and unofficially, at what
 18 levels. Again, all that information is readily
 19 available.
 20 **Q. So can I ask you, to your knowledge, are there**
 21 **any controlled studies regarding 7 Herb Formula and its**
 22 **effectiveness in treating cancer?**
 23 A. I've never seen any.
 24 **Q. Have you ever seen any studies that would say**
 25 **that 7 Herb Formula is effective in curing cancer?**

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- 1 A. I've never seen any, and if anyone tried to
 2 present them to me, I'd do the same thing I did here a
 3 while ago. I really don't think it's a good idea for me
 4 to look at that.
 5 **Q. And what about if there are any studies on**
 6 **whether it prevents cancer?**
 7 A. I guess a lot of things could, but I don't know
 8 of any studies.
 9 **Q. And are you aware of whether there are any**
 10 **studies showing that 7 Herb Formula inhibits tumor**
 11 **formation?**
 12 A. No. I had never heard of the 7 Herb Formula
 13 until this, this came up, so I really haven't had time
 14 to delve into it. And besides that, that's not what I
 15 do. I'm busy doing what I do.
 16 **Q. Well, with regard to the herbs in**
 17 **7 Herb Formula, are you familiar with whether there are**
 18 **any studies that say there's anticancer activity in any**
 19 **of those components?**
 20 A. No studies, no. And you know, there might be
 21 some mention it might. Some physicians might have
 22 indicated it. I'm not sure whether it was a
 23 double-blind study or what because I really didn't delve
 24 into it.
 25 **Q. And then are you familiar with the studies that**

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- 1 **are done to get drugs to market?**
 2 A. Oh, yeah. Yeah. I've done it.
 3 **Q. Can you just describe generally --**
 4 A. It varies from country to country, but generally
 5 you get a medical school at one of the universities, and
 6 I've participated in a lot of them.
 7 I did the only one done on DHEA as a matter of a
 8 fact. I did that for Southwestern Medical. And we did
 9 the study.
 10 And it has to be controlled. You have to set
 11 it up to where the physicians don't know which is
 12 which. You've got a placebo. Sometimes there's a
 13 triple blind where you might have three things. One of
 14 them will be the actual chemical itself. At that point
 15 it's not a drug because it hasn't gone through the
 16 studies. It's in the process yet. And then you make
 17 up a placebo which looks exactly like it. And the
 18 only -- and you have to label it for a study only and
 19 not to be sold.
 20 And the only distinction between the placebo and
 21 the real thing is a lot number. And the only person who
 22 can know which is which within the physicians' side or
 23 the university or the physicians is one secretary. We
 24 prefer not to have the physicians know because we don't
 25 want them to begin to see results that are not really

15 (Pages 57 to 60)

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1 there because they want to see the results and which is
2 the placebo.

3 In my company, I don't know. I have one
4 secretary that knows which is which that keeps up with
5 that.

6 And then you compile the data that you got from
7 the study, depending on how many respondents, how many
8 people were in the study, and you analyze that data and
9 then you say, well, this many under this lot number this
10 is the results we saw and under this lot number this is
11 the results you saw. Then we can say okay. Now, are
12 you through, there's no more data coming? No. That's
13 it. Okay. Now we can determine which is which and
14 compile the results.

15 **Q. And your company has participated in studies
16 like that?**

17 A. Oh, yeah. Yeah.

18 **Q. In what kind of studies?**

19 A. We made the active component. We made the
20 placebo. We were asked to do this. We did it. There's
21 not a lot of companies that do what I do.

22 **Q. Okay. And what kind of -- you mentioned DHEA
23 was --**

24 A. Dehydroepiandrosterone. It's one of those
25 phytohormones. It's -- it's a precursor to the anabolic

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1 hormones. It could be any one of them.

2 And that's -- they say, Well, boy, that's the
3 latest thing out. I said, That's old hat. Good Lord, I
4 did that study twenty-some-odd years ago.

5 You don't know what it's going to turn into. It
6 depends on how your body handles it.

7 Understand something, which is a misconception
8 everybody has, including the government, no vitamin, no
9 mineral, no drug, none of them do anything by
10 themselves. Your body uses that to perform certain
11 functions, mixes that or combines it with or metabolizes
12 it with something else, and that has an effect that
13 leads to a structure/function claim.

14 So getting the idea of, oh, well, yeah, this
15 drug and it does -- no, it doesn't. It helps your body
16 to do it. A drug does that and so does a nutraceutical.
17 The difference is, a drug you can make a disease-curing
18 claim, a nutraceutical you can't.

19 **Q. 7 Herb Formula, is that a nutraceutical?**

20 A. Oh, yeah. It would be classified as such, if
21 you kept all your labeling and all your advertising
22 within line.

23 **Q. And has your company ever done any studies --
24 you mentioned the double-blind studies -- with regard to
25 cancer drugs have you been involved?**

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1 A. No. We haven't been asked to do that. We
2 don't do anything unless we're asked. And usually it's
3 the university that's doing the study. We're just
4 supplying the necessary materials to do it with and the
5 control.

6 **Q. And in terms --**

7 A. And I have to fight with the physicians
8 sometimes. I'm not going to tell you which is which.

9 **Q. Well, when you reach -- before you reach the
10 stage of giving actual drugs, what -- are you familiar
11 with the stages that come before that, you know, the
12 phase one, phase two trials?**

13 A. It could run through as many as four phases and
14 which is why our healthcare is so high, and so you see
15 why people are turning to nutraceuticals, and a lot of
16 them are old pharmaceuticals that are no longer
17 pharmaceuticals.

18 **Q. And in terms of phase one/phase two animal
19 studies, are you -- is it your opinion that findings in
20 animal studies can be extrapolated to --**

21 A. In this country --

22 **Q. -- to humans?**

23 A. Oh, I'm sorry. I know the answer and I
24 apologize.

25 **Q. Okay.**

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1 A. In this country, animal studies are no longer

2 the end usable result. You tend to go to human studies.

3 You might start with animal studies. You want to see,
4 well, you know, looking at this chemical structure and a

5 potential for harm -- and that's the study of

6 pharmacology. And you see why I can't get involved with
7 too many things, because this is difficult enough in
8 itself.

9 **Q. Right.**

10 A. -- looking at that, I think there's a potential
11 here for harm.

12 Well, how much should I use? Well, we don't
13 know yet, do we?

14 So let's try it on animals first. We can begin
15 to get some feedback of if it's harmful and what levels
16 to use. If we kill the animal, we know that's too much.
17 If we get no results, that's too little.

18 So we begin to zero in on what is safe for an
19 animal. Now, with that data, we can take that and see
20 whether we want to go to phase two or phase three or
21 whatever phase, because you may have several animal
22 studies, and to see, well, now let's try it on humans.
23 You know, we have a pretty good idea of what's too much,
24 what's too little, and the fact that it's safe, it
25 appears to be safe up to this point, and now we can

1 begin -- so by the time the humans actually get it,
2 we've already done that safety.

3 **Q. Okay. And so that now it's not proper to take**
4 **results from animal studies to say that it works in**
5 **humans the --**

6 A. As a rule, that's not done -- in other countries
7 it's still done -- because a funny thing has occurred
8 here. People will spend whatever for their health.
9 They'll go in debt, they'll sell everything they've got
10 to stay alive a little bit longer.

11 At what point does the cost override the
12 benefit. And that's a tough call. I'm not saying that
13 anybody is right in this. It's a tough call. Other
14 countries say the main thing is for the health of the
15 public. In this country, well, I'm not saying it's
16 right or wrong. I'm saying that's the way it is.

17 **Q. Well, in terms of your knowledge of herbs, are**
18 **you familiar with the -- with turmeric?**

19 A. Yes.

20 **Q. Or which is -- what's the active component in**
21 **that?**

22 A. The active chemical is curcumin.

23 **Q. Yes.**

24 A. Curcumin is very good at reducing inflammation,
25 very, very good, and that's why the Indians put so much

1 of it in all their foods. It's also why it's a main
2 thing used in allopathic medicine. It does reduce
3 inflammation.

4 Now, can you say that reducing inflammation is a
5 cure for any particular disease? No. But could you say
6 that it might be helpful? Yeah, you could probably make
7 that statement.

8 **Q. And are there studies that have shown that**
9 **curcumin is helpful?**

10 A. Yeah. It is -- of all the -- and by the way, if
11 you think that all of pharmaceuticals -- and I'm talking
12 about prescription -- are not herbs, you're wrong. A
13 lot of them are, and boy, I mean there's a list a mile
14 long.

15 And you know, the point is, you're interested in
16 a certain chemical compound, and where you get it really
17 doesn't matter as long as you've got it. You can make
18 it synthetically. You can find it in plants. These
19 plants develop these compounds.

20 So yes, it has effect. Generally when we look
21 at that, we're not interested in curing cancer, we're
22 interested in reducing inflammation. There's a
23 distinction.

24 **Q. Well, with curcumin, have you seen actual**
25 **studies on humans using curcumin?**

1 A. Yes. There are quite a few studies. It does
2 reduce inflammation.

3 If someone were really doing a study or if I was
4 involved in a study and someone says, Well, we want to
5 do a study on curing cancer, I'll say, Well, then count
6 me out. Because I think you have to start with you're
7 trying to work upon the symptoms of the disease. We're
8 not trying to cure the disease by working on a symptom
9 of the disease. There's a big difference.

10 So if you want to do this study on curcumin to
11 see if it does indeed reduce inflammation and to what
12 degree and at what level can you get too much, if any,
13 and at what level is too low, well, I talked about this
14 a while ago, then count me in, but when you start trying
15 to cure a disease when you haven't even figured out how
16 to do anything about the symptom, I know I'm dealing
17 with a bunch of amateurs.

18 MS. PAYNTER: Okay. Again, I'm just going to
19 step out one second. I'll be right back. We're almost
20 finished I think.

21 (Recess)

22 MS. PAYNTER: So I'm going to withdraw Exhibit
23 Number 1 --

24 THE WITNESS: Okay.

25 MS. PAYNTER: -- and I would like to make

1 Exhibit Number 1 Mr. Dews' expert report.
2 (Dews Deposition Exhibit Number 1, Report of
3 Expert Witness Jim Dews, was marked for
4 identification.)

5 BY MS. PAYNTER:

6 **Q. So, Mr. Dews, I'm handing you Exhibit Number 1,**
7 **which is a copy of your expert report.**

8 A. Let me get my glasses.

9 Here we go. Let's see what it is.

10 Yeah, this is -- this is -- was answering
11 questions which they asked me over the telephone.

12 **Q. Okay.**

13 A. Yeah.

14 **Q. If you can go to page 7, please.**

15 A. Okay.

16 Okay.

17 **Q. And I just wanted to ask you questions just**
18 **regarding some things that are on here.**

19 It says you're being compensated \$35.00 per
20 hour?

21 A. Yes. Uh-huh.

22 **Q. Or 280 per day plus expenses; correct?**

23 A. Right.

24 **Q. And in section III it says "Materials**
25 **Considered."**

1 **Do you see that?**
 2 A. Okay. Section --
 3 **Q. On page 7?**
 4 A. On page 7?
 5 **Q. Yes.**
 6 A. I don't see that.
 7 **Q. Do you see at the bottom?**
 8 A. Oh, this. I'm looking at the wrong number.
 9 **Q. Page 7, please.**
 10 A. Sorry.
 11 **Q. That's okay.**
 12 MR. TURNER: It's I think here (indicating).
 13 THE WITNESS: Now we got it. I'll keep those in
 14 order. Yeah. Okay.
 15 BY MS. PAYNTER:
 16 **Q. And it says "Materials Considered."**
 17 **Do you see that?**
 18 A. Yes. Uh-huh.
 19 **Q. And it says that you reviewed the German**
 20 **monographs on herbs --**
 21 A. Right.
 22 **Q. -- in the 7 Herb Formula.**
 23 A. Yeah.
 24 **Q. And what is the German monographs on herbs?**
 25 A. Okay. The German government -- herbal medicine

1 monographs are published in that book. And the reason
 2 why someone had to do that is because in Germany they
 3 speak and read German.
 4 **Q. Okay.**
 5 A. In the United -- it is published -- it was
 6 published in German and then republished in English so
 7 the rest of the world could read what they're saying.
 8 **Q. Okay. The next item is British Pharmacopoeia,**
 9 **and you have a notation here, "Burdock root is**
 10 **recognized as a drug if you're in England."**
 11 A. Right. And there are quite a few of the herbs
 12 in the seven herbs that are.
 13 And the official listing of the
 14 British Pharmacopoeia is the Martindale. It's not the
 15 same Martindale you attorneys use. And that is the
 16 British Pharmacopoeia, and it's published by a
 17 publishing company but in connection with the British
 18 government. And it lists -- there's a lot of herbs
 19 listed in there and indications and uses and
 20 contraindications and how a physician would use it.
 21 **Q. And again, it would be in connection with saying**
 22 **treats inflammation or supports immune system?**
 23 A. Right. As a rule, that's what you do. You --
 24 and a physician -- you're not going to go to that
 25 physician and he's going to pull out one pill and here,

1 is -- remained official there even when it stopped being
 2 here. And it's, according to the German government or
 3 their variation of the FDA, what can be used by a
 4 practitioner and what claims can be made for it. And
 5 that's -- those are the official laws in that country
 6 for using these types of products. The indications are
 7 spelled out.
 8 **Q. In reviewing the herbs in 7 Herb Formula as**
 9 **identified in the German monographs, were there any**
 10 **indications for use in cancer treatment?**
 11 A. I don't -- I don't -- generally speaking, in
 12 most countries that use herbal medicine, you just don't
 13 see that kind of claim. You see it reduces
 14 inflammation. It helps to purify the blood, you see
 15 that. You'll see -- but they don't mention a disease as
 16 a rule.
 17 **Q. Would it --**
 18 A. More the symptoms.
 19 **Q. So for example, they might say that one of those**
 20 **components helps reduce tumors?**
 21 A. It helps reduce inflammation.
 22 **Q. Okay. The next item says "Herbal Drugs and**
 23 **Phytopharmaceuticals."**
 24 **Do you see that one?**
 25 A. Yeah. And that really is the same. The German

1 take this pill and it will cure your disease. He has to
 2 use all of the tools at his disposal.
 3 How am I going to go about alleviating your
 4 symptoms? Well, reducing the inflammation is certainly
 5 one of the things that you would do, but it doesn't cure
 6 the disease by itself.
 7 **Q. Okay. Well, in the British Pharmacopoeia, do**
 8 **you recall all of the herbs are listed in there?**
 9 A. Most of them are listed. There are a few that
 10 are maybe not as popular in some countries, and so they
 11 tend to get -- not make it.
 12 **Q. Okay.**
 13 A. The next -- oh, excuse me. Go ahead.
 14 **Q. The next one then, the USP or the**
 15 **United States Pharmacopoeia.**
 16 A. Right. That's everything that's officially a
 17 drug. And of course to be officially a drug you have to
 18 treat a disease, and certainly since we don't do that in
 19 this country with herbs, they're not listed as a drug,
 20 as a cure for any specific disease.
 21 **Q. So the components in 7 Herb are not listed in**
 22 **number 4; is that what you're saying?**
 23 A. Right. It's just I need to look at that to make
 24 sure they're not listed.
 25 **Q. I see.**

