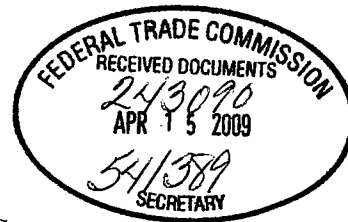


ORIGINAL



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

In the Matter of
DANIEL CHAPTER ONE,
a corporation, and

JAMES FEIJO,
Individually, and as an officer of
Daniel Chapter One.

DOCKET NO. 9329

PUBLIC DOCUMENT

Hearing: April 23, 2009
10:00 a.m.

RESPONDENTS' PRE-HEARING BRIEF

I. INTRODUCTION

The evidence at trial will demonstrate that Respondent Daniel Chapter One ("DCO") is a non profit religious ministry organized as a corporation sole under the laws of the State of Washington with Respondent James Feijo as its overseer. The evidence will establish that DCO engages in the proselytizing of body mind spirit health based on the Christian Bible in accordance with its purposes as reflected in its recognition as a Corporation Sole, that it urges its followers to conduct healthy lives in accordance with God's creations, including healthy eating, and that it makes available certain herbal products and nutritional supplements to further well being through the innate healing intelligence of the body as a creation of God.

The evidence will show that DCO claims that the four DCO herbal products in question, Bio* Shark, 7 Herb Formula, GDU, and BioMixx (collectively, in this case the "DCO Products"), can strengthen the immune system, reduce inflammation and

congestion and create certain other structure and function effects that help engage the innate intelligence of the body and strengthen it whatever its condition. It will also show that the scientific record on the herbs contained in the four products at issue substantiates that they can strengthen the immune system, reduce inflammation and congestion and create certain other balancing structure and function effects, that DCO carefully presented this, drawing accurately on information contained in the herbal scientific record. The record will show that DCO presented this information as educational knowledge that its followers had a right to receive. The evidence will show that DCO made no health claims. Rather they confined their statements about the herbs they used to structure and function claims, purposely refraining from making health claims. The evidence will also show that at the time they made these claims, Respondents had in their possession sound scientific evidence providing them a reasonable basis for their representations in compliance with the FTC Act.

The evidence will also show that the community embracing the DCO approach consisted primarily if not exclusively of individuals who recognize DCO as a healing ministry and seek its spiritual guidance as part of their personal healing quests and that they have a right to receive this information. The evidence will show that there have been no consumer complaints about the products at issue and that to the contrary there has been an outpouring of spontaneous, unsolicited testimonials to the benefit of the DCO healing mission including the herbs that accompany it. Respondents will also present evidence that their statements on behalf of the herbs and nutritional supplements at issue are constitutionally protected speech either as religious speech or as commercial speech incidental to religious speech.

At trial, Respondents will present credible and persuasive evidence that they made no health claims and that the non health claims they made were supported by sound scientific evidence as well as being an integrated part of their missionary message.

II. STATEMENT OF FACTS

A. The Feijos Started DCO By Faith, As A Ministry, To Help Support Home Churches Around The World. And Expanded It To Help People Closer To Home As Well

Jim and Patricia (Tricia) Feijo will testify to the following facts as set out in their depositions and their responses to interrogatories and requests for admissions and production of documents. The individuals proffered as witnesses by Respondents in this case will support these facts as indicated in the summaries of their testimony.

Jim and Tricia Feijo met in 1981 and married in 1983. Tricia had worked as a bench technician on cancer drug animal studies at a Worcester, Massachusetts research facility and was disillusioned by the negative outcomes she observed. Jim had been a high school teacher and sports coach, all levels, and noted that nutritional intervention that helped high performance athletes also helped critically ill individuals. Jim and Tricia were drawn together by their shared desire to be Christian missionaries. They prayed for a ministry with which to serve God and their fellowman.

Jim and Tricia spent considerable time with retired missionaries Fred Bopp, and Mr. and Mrs. John Buffum. Mr. Bopp laid hands on Jim and Tricia, blessing them to the Lord's service, even before they were married. Tricia spent time with Mrs. Buffum, learning natural cooking and natural healing from her, and also visiting shut-ins and delivering food. In 1983, the year of their marriage, Jim read in the book of Daniel, in Chapter One, that Daniel and his men sought to obey the dietary laws God gave His

people and thus refused to eat the king's meat and drink his wine (as was expected of them as slaves in his service). Jim and Tricia tested the diet of "pulse" and water for 10 days, and felt good and strong doing so. They came to call it the Daniel Chapter One diet.

In 1985 Jim and Tricia traveled to Europe with EuRail passes and backpacks, met Christians and fellowshipped, and shared the gospel with non-Christians. On their return, after visiting in home churches in Europe, they prayed for revelation and guidance. Fred Bopp and the Buffums prayed for and with them, and were in agreement that Daniel Chapter One health ministry was what they were to do. They began by bringing nutritional supplements to people in need in nursing homes. Also, the Feijos felt led to start a health food store because Tricia had learned much about whole foods and whole foods cooking, and Jim had studied herbology and nutrition. A health ministry based on food offered a way to minister to others, by teaching about healthy diet and by providing healthy foods and supplements in alignment with biblical teachings. The tiny store not only had a bible name, but a banner inside that proclaimed "Jesus is God."

B. The Feijos Developed The DCO Ministry With Managerial Help From Family And Friends

1. The Feijos Developed The Ministry Across The World.

In the summer of 1986, Jim and Tricia returned to Europe with Jim's 11 year old daughter Jill. Besides plane tickets and EuRail passes, once again they went with very little but backpacks, and camped (sleeping on trains, on train station floors, in parks. and eating mostly bread and cheese from the market). Tricia's parents watched the store. While in Europe, they once again met many Christians by God's hand, and grew spiritually. God gave them spiritual gifts as spoken of in the book of I Corinthians, 12:7-10.

Through the house church in Holland, they made relationships with people of the house church in Poland and Israel, as well as those they already knew and helped with money gifts in Newfoundland. (Biblical authority for house church is “The churches in the province of Asia send you greetings. Aquila and Priscilla greet you warmly in the Lord, and so does the church that meets at their house.” I Corinthians 16: 19) The relationships with the fellowships they helped on this trip continue today with various members offering to testify at this hearing on behalf of the Feijos and their missionary work.

During 1987-88 a few families joined Jim and Tricia in the ministry, and moved into the 2 room flat (11 people!). That Spring God called the Feijos, divinely, to Israel. They went with one-way plane tickets, meeting/camping with other disciples in the desert, seeking the Lord Y’shua – Jesus the Christ—through fasting and prayer. They met with Christians and non-Christians in Jerusalem and Bethlehem. God brought them back, though they were prepared to stay in Israel to live and work, and had entrusted Daniel Chapter One to the believers at home in Rhode Island.

There were weddings and baptisms and daily breaking of bread at Daniel Chapter One in Rhode Island. All were welcome, and the ministry saw a steady flow of people. Patrons and neighbors became friends and family, and the fellowship met the needs of each person who the Lord brought through the doors. “Suppose a brother or sister is without clothes and daily food. If one of you says to him, ‘Go, I wish you well; keep warm and well fed,’ but does nothing about his physical needs, what good is it? In the same way, faith by itself, if not accompanied by actions, is dead.” James 2: 15-17.

In 1989 Jim and Tricia were called to China again, and went by faith with just

plane tickets. A young Christian man, Mark Daniels, who lived and worked at Daniel Chapter One watched the store while they were gone. (He came to live there when he needed a place to stay.) Once in China, God provided a place for Jim and Tricia to stay in Hong Kong (“Pilgrims Home” for missionaries), and business visas to travel into the mainland through Revival Church. They went to Revival Church to volunteer their services, and were given the task of currying bibles into mainland China. A brother in Christ they met gave them Chinese money. Jim handed his wallet over to the Overseer of the house church in Guangau.

They were asked to return to China to live/work – possibly to help run an orphanage – by the missionary for World Missions Far Corners, Bobby Watts. On this trip they also met the doctor who invited them back to conduct research in Beijing two years later, when she brought a woman to Jim and Tricia to baptize. It was May 1989, the summer of Tiananmen Square, and Jim and Tricia marched with the students there. They baptized 2 women in China, and later Jim baptized 3 men in Hong Kong, at Pilgrims Home.

In 1990 Jim and Tricia once again felt the Lord was calling them to leave their homeland, brothers, sisters, parents and children, now to serve Him overseas. They left the Daniel Chapter One Ministry to others. Through prayer, a new Overseer was appointed. Jim and Tricia tried to return to China through Poland (to visit the house church there.) They were denied visas, so they lived and ministered in the house church in Poland that year.

They ministered spiritually, and researched the availability of herbs and health foods, to try to help some of the Believers in ministry there. Once again there were house

weddings and other spiritual ministry. They were called suddenly back to America the following year, by God's revelation through the Holy Spirit.

2. The Feijos Rebuilt And Expanded The Ministry At Home.

When they returned and during 1990-91: The store was in shambles, run severely into the red by mismanagement of the Overseer left in charge. Out of necessity, Jim had to take the role of headship back, to try to salvage Daniel Chapter One. Jim and Tricia were invited to China by the Chinese government, to lead research at the Beijing Research Institute of Sports Science. They went and had a very successful trip, met with the approval of the scientists, but also with much opportunity to minister in the house church and to share the Gospel of Jesus Christ with non-believers.

David Bertrand watched the store with the help of Jim's son. One other Daniel Chapter One location that had opened before the Feijos went to China was given away – not sold – to 2 young men in need. Later in the year Jim and Tricia returned again from China.

In 1994 Jim and Tricia opened another storefront in Massachusetts, with a focus on nutritional supplements. They were approached and asked to host a one hour local radio program, which they began and called "Daniel Chapter One HealthWatch," referring to God's watchmen. They were repeatedly warned that the name was not good radio 'business', that it would estrange people and limit their audience. Jim was also warned that he should not say, "God bless you!" at the end of the show, or "May the Truth of Jesus set you free!". He resolved that to honor God was more important than public opinion or trying to build an audience.

In 1996 the Feijos took their radio program to Talk America, a national radio

network. They paid to air a one hour a week national radio show, in addition to their local program, at the suggestion of a man helping in the ministry. Soon after, they started a daily national program, including nights and weekends. The reason was to reach more people, to touch more lives, to further the Kingdom of Heaven on earth. To accommodate the busy schedule, they set up a radio broadcast room in the house.

Their house was open, and one year an elderly missionary from World Missions Far Corners, Theodore Stapp, came to live with them. His heart was failing, and he asked God to finish his life with Jim and Tricia. Instead of dying, Theodore regained his health after he stopped his heart drugs and took instead Daniel Chapter One nutritional supplements. He later went back to Vietnam to live and work. (Jim and Tricia also supported the house church in Vietnam.) Theodore died just last year, 2007-2008, in a car accident. For the last 10 years since his healing, his heart was strong!

At about this time, 1996, they expanded the herbal and nutritional products available to their followers including adding the first of the four products that are the subject of this hearing—7 Herb Formula. Over the next five years they added the other three products to their offerings. 7 Herb Formula is based on an herbal preparation available for over 100 years to which Jim Feijo proposed adding three additional herbs. He sought and obtained the services of two professional herbal formulators to evaluate his proposal and ensure that the new preparation met all requirements of sound herbal preparation. See deposition of Jim Dews. Each of the other three products are produced to required industrial standards by Universal Nutrition, a certified supplement manufacturer which supplies DCO with the vast majority of its products produced to proper industry and government standards. See depositions of Claudia Kinney from

Universal Nutrition and Jim Feijo.

In 2000 DCO created the Accent Radio Network built with the help and under the supervision of Jedediah Harrison. He was a producer for DCO HealthWatch, on a network which suddenly folded. Jim wanted to provide work for the young man, and also sought a way to have more freedom on the radio (networks would sometimes attempt to censor their religious speech, or run advertisements that the Feijos did not want associated with their program and message.)

Jim and Tricia were asked to, and did, make public appearances, conduct remote radio broadcasts, and speak in churches and doctors offices and health stores. They never charge. Their talks are not about products or disease. They lecture about spiritual warfare (Jezebel, an evil spirit who wants people sick), the Bible diet and healthy dictates, basic naturopathy for acute illness for children – use of hydrotherapy, etc. People who listen to them on radio enjoy meeting them, as you would friends or family. But the groups are relatively poor and small, and it is never a monetarily profitable venture.

In 2002 Daniel Chapter One became a Corporation Sole.¹

3. DCO Advances Its Health Ministry With The Use Of Traditional Herbs Supported By Generally Accepted Scientific Information.

In 2004 Jim and Tricia were brought down to Florida by a Daniel Chapter One Tennis Open, conducted by Scott Williams, a Christian coach with a tennis ministry in

¹ Complaint Counsel has sought to put into evidence documents from the State of Rhode Island which purport to recognize Daniel Chapter One as a “Domestic For Profit Corporation.” They did not seek to put into evidence the documents from the same online file where they found the “corporation” documents that show that DCO had whatever status was supposedly granted by the state almost immediately revoked and apparently never qualified as a corporation—it had no board, had no officers, and kept no financial records. Jim Feijo says he was unaware of the filing when it was made, did not believe it was accurate when he found out about it, decided to let whatever it was lapse and promptly forgot about it. DCO, from its inception until its recognition by Washington State as a Corporation Sole, was at all times organized and operated as a non profit unincorporated religious organization.

Florida. Seeing opportunity for ministry in Florida, they purchased a house for ministry purposes. One bedroom was immediately converted to a radio broadcast room, and one doubles as an office and bedroom.

They now spend time working in both locations, and have let others use both houses. Jim and Tricia serve in ministry from both Rhode Island and Florida. Doing live radio, visiting the sick and elderly, meeting people and sharing the gospel. Tricia also edited a medical homeopathy textbook during 2004.

One example of the Feijos using the house in Florida for ministry occurred in 2005. DCO allowed five people – total strangers – the opportunity to live in the Florida house when they needed a place to stay. They stayed for two to three months. It was after a major hurricane hit the area. Two of the men were pastors (plus one couple, and another man), and one shared later with Jim and Tricia that they were all amazed that someone would just give them the key to a house and say, “use it as long as you need to.” He said it made him search his own heart, to see if he could do the same. In 2006 Tricia was invited into a Fellowship Program in Advanced Case Management at Pioneer University, and received the title FsHom (Fellowship in Homeopathy), in 2007.

Jim and Tricia have an open-door policy with the ministry buildings that are houses. They have never taken rent from anyone, or money for food or other living expenses from those who live with them. For example in 2007 a young woman who wanted to be a missionary and was on a waiting list with Voice of the Martyrs, came up from Florida to stay at Daniel Chapter One in Rhode Island, to learn natural healing and spiritual ministry. Another, older woman came and stayed from Massachusetts during the week, to help out with art and to expand her computer skills.

In 2000 the 7 Herb Formula website was designed by Ruth Duffy, now deceased, then the wife of Richard Duffy, and donated to DCO. Mrs. Duffy suffered and died after being treated with conventional cancer treatment and the Duffys' desire and intent was to share information with the public that could help others. Richard Duffy, who lives in Israel, is on Respondents' witness list. He intends to testify to the fact that Daniel Chapter One is a ministry and supports the house church in Israel.

As part of its health missionary work, which includes a two hour radio show five days a week for the past eight years, DCO includes making herbs and nutritional supplements available in various formulations to enhance the immune system, and diminish inflammation and provide nutrients for optimizing metabolic function. The herbs they use in their products are well known for these purposes. These effects on the body improve the balance between body, mind and spirit, assisting the well being of individuals whatever their mental, physical or spiritual condition. The statements made about these products by DCO were also well known and supported by the scientific evidence. See Expert Reports and Depositions of Drs. James Duke and Sally LaMont. Also see section IV below for details of the relationship between the products and the statements made about them.

In the past 23 years of Daniel Chapter One, Jim and Tricia Feijo have given away untold, unrecorded amounts of money; many thousands of dollars, to missions, missionaries, individuals in need, and athletes and teams. (For example: they funded the Israeli National Jr. Men's Fastpitch Softball Team to go to Sydney, Australia for the World Championships.) Daniel Chapter One has also given away untold amounts of nutritional products, donating as much as an entire store to a church.

They do not keep records of such donations because God in His Word says not to, not to even let your right hand know what your left is doing, to do your giving in secret. God says to be doers of the Word, not just hearers. “Do not merely listen to the Word, and so deceive yourselves. Do what it says . . .the man who looks intently into the perfect law that gives freedom, and continues to do this, not forgetting what he has heard, but doing it – he will be blessed in what he does.” (James 1:22, 25)

Jim and Tricia Feijo claim Jesus Christ as their example, and He fed the hungry and healed the sick, and commands us to do the same. (Matthew 10:8) That is what the early church did, and supported the poor among them as well as the poor in the world. They gave according to their ability, not out of guilt, duty, or compulsion. The New Testament church was a community; they shared life, and cared for each other as a family.

In the book of Acts, chapter 4:14-20, the rulers, elders, and teachers of the law gathered and brought the disciples Peter and John before them because they were teaching and healing. “But since they could see the man who had been healed standing there with them, there was nothing they could say. So they ordered them to withdraw from the Sanhedrin and then conferred together” “What are we going to do with these men?” they asked. “Everybody living in Jerusalem knows they have done an outstanding miracle, and we cannot deny it. But to stop this thing from spreading any further among the people, we must warn these men to speak no longer to anyone in this name.”

Then they called them in again and commanded them not to speak or teach at all in the name of Jesus. But Peter and John replied, “**Judge for yourselves whether it is right in God’s sight to obey you rather than God. For we cannot help speaking**

about what we have seen and heard.”

III. ARGUMENT

A. Complaint Counsel Has No Evidence That Daniel Chapter One Has Violated 15 USC §§ 45 And 52.

Complaint Counsel must prove the violations of 15 USC §§45 and 52 by clear, cogent and convincing evidence. See Respondents’ Motion for Summary Decision. Regardless, by any measure, Complaint Counsel’s evidence falls short.

For instance, Complaint Counsel contends within the introduction of its Trial Brief that Respondents have “preyed upon desperate, sick consumers” when Complaint Counsel has expressly admitted that they have conducted no investigation into – and will produce no evidence concerning – the type of people reached by Daniel Chapter One’s ministry. To the contrary, evidence will show that Daniel Chapter One’s ministry reaches a devoted following of people across a broad spectrum of health conditions, many of whom are very health conscious. In fact, the common characteristic of those to whom Daniel Chapter One’s ministry is directed is that they are people who practice Biblically substantiated natural healing methods, using Daniel Chapter One products that include far more than the challenged products at issue here.

This is only one example of the extent to which Complaint Counsel misrepresents both facts and law. The full breadth of these misrepresentations have been addressed in Respondents’ Motion for Summary Decision. These misrepresentations are addressed again in this Trial Brief. And they will be again presented at the hearing itself.

At the same time, there are two aspects of this case on which Respondents and Complaint Counsel do agree. These aspects deserve emphasis:

- The parties agree that this case concerns the overall net impression allegedly crafted by Daniel Chapter One. This case does not concern any express claims that Daniel Chapter One has made.
- The parties agree that the *overall mosaic* must be explored in order for the overall net impression of Daniel Chapter One's statements to be evaluated properly.

1. Respondents' Offer Of Proof.

1. Daniel Chapter One is formed as a Corporation Sole in Washington State under the Revised Code of Washington § 24.12. Daniel Chapter One's purpose is to spread the message of health and healing through natural means, as substantiated by the Bible. As such, Daniel Chapter One's statements are directed to a specific, unique religious constituency.
2. Daniel Chapter One states on its website the following:

Welcome to Daniel Chapter One Online!

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

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

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

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

3. Daniel Chapter One states on every page of its website the following:

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.

4. Daniel Chapter One states on its product labels the following in regard to each of the Challenged Products:

*These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent disease.

5. Daniel Chapter One expressly stated only the following about the Challenged Product Bioshark:

"Bioshark is pure skeletal tissue of sharks which provides a protein that inhibits angiogenesis -- the formation of new blood vessels. This can stop tumor growth and halt the progression of eye diseases . . ."

6. Daniel Chapter One expressly stated only the following about the Challenged Product 7 Herb Formula:

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

7. Daniel Chapter One expressly stated only the following about the Challenged Product 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. . ."

8. Daniel Chapter One expressly stated only the following about the Challenged Product 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."

9. Daniel Chapter One experts will testify that the Daniel Chapter One express statements described in ¶¶ 5-8 above are accurate.

10. Daniel Chapter One did not expressly state or imply any of the following about the Challenged Product Bioshark:

"Bioshark inhibits tumor growth"

"Bioshark is effective in the treatment of cancer"

11. Daniel Chapter One did not expressly state or imply any of the following about the Challenged Product 7 Herb Formula:

"7 Herb Formula is effective in treating and curing cancer"

"7 Herb Formula inhibits tumor formation"

12. Daniel Chapter One did not expressly state any of the following about the Challenged Product GDU:

"GDU eliminates tumors"

13. Daniel Chapter One did not expressly state any of the following about the Challenged Product BioMixx:

"BioMixx is effective in the treatment of cancer"

"BioMixx heals the destructive effects of radiation and chemotherapy"

14. These Challenged Products represent but a fraction of Daniel Chapter One's complement of healing products offered to its devotees.

15. The Commission has no factual extrinsic evidence that Daniel Chapter One alleged practices caused substantial injury to consumers.

16. The Commission has no factual extrinsic evidence that Daniel Chapter One alleged practices are likely to cause substantial injury to consumers.

17. The Commission has no factual extrinsic evidence that Daniel Chapter One alleged practices cannot be reasonably avoided by consumers.

18. The Commission has no factual extrinsic evidence that Daniel Chapter One alleged practices are not outweighed by countervailing benefits to consumers.
19. The Commission has no factual extrinsic evidence that Daniel Chapter One alleged practices are not outweighed by countervailing benefits to competition.
20. The Commission has no factual evidence of consumer perceptions about Daniel Chapter One, its products or its claims, either express or implied.
21. The Commission has no factual evidence of consumer expectations about Daniel Chapter One, its products or its claims, either express or implied.
22. The Commission has no factual evidence about the cost of developing substantiation for Daniel Chapter One express claims.
23. The Commission has no factual evidence about the amount of substantiation experts in the field of dietary supplements believe is reasonable for structure/function claims about those supplements.
24. The Commission has no factual evidence concerning whether the express statements made by Daniel Chapter One as described in ¶¶ 5-8 above are false, misleading, unfair, or deceptive.
25. Daniel Chapter One has substantiation for the express claims it made about the Challenged Products, as described in ¶¶ 5-8 above.
26. The Commission's expert did not testify about the Daniel Chapter One express statements described in ¶¶ 5-8 above.

2. The Required Elements Of Proof On Which Complaint Counsel's Evidence Must Be Evaluated.

Daniel Chapter One and Complaint Counsel strongly disagree about the elements of proof that must be met in this case. Daniel Chapter One contends that Complaint Counsel must prove its case with extrinsic evidence. Complaint Counsel contends that the FTC is entitled to rely exclusively on "its own viewing of the ad" to determine the overall net impression of Daniel Chapter One's religious ministry. In so stating, Complaint Counsel relies on *Kraft v. FTC*, 970 F. 2d 311, 318 (7th Cir. 1992), and on *FTC v. Colgate-Palmolive*, 380 U.S. 374, 385 (1965). However, not only do *Kraft* and

Colgate-Palmolive not support Complaint Counsel’s position, but the recent body of FTC law at large confirms the need for Complaint Counsel to produce extrinsic evidence.

This is especially true for statements made about dietary supplements, and most especially when those statements are made by a religious ministry to further its message about Biblically-substantiated healing methods.

1. *Kraft* does not justify Complaint Counsel’s lack of evidence.

The *Kraft* case concerned the respondent’s express false representation about the number of ounces of milk contained in its cheese product. Unlike the present case, *Kraft* involved an express claim. Also, although the Commission’s findings in *Kraft* were based on its own impression of the express advertisements, the Commission there also “noted that the available extrinsic evidence was consistent with its findings.” *Id.* at 316. In other words, extrinsic evidence was involved in the Commission’s determination. *Kraft* does not allow the Commission to rely exclusively on its own exclusive determination of the overall net impression.

2. *Colgate-Palmolive* does not justify Complaint Counsel’s lack of evidence.

Colgate-Palmolive does not justify Complaint Counsel’s lack of extrinsic evidence either. The Court there expressed at p. 385 of its opinion the long-standing principle that appellate courts give deference to agency interpretation of facts and evidence. But nowhere within that opinion does the Court say that the agency may use its expertise as a replacement for the evidence itself. Furthermore, like *Kraft*, the case concerned not an overall net impression, but rather an outright fabrication of fact, i.e., a falsified test.

The present situation is much different, for here the Court is faced with the

following: (a) the determination of an overall net impression case; (b) of natural dietary supplements; (c) about which Daniel Chapter One makes accurate and allowable structure/function claims; (d) to a specific constituency of religious believers who place their faith in Biblically-based natural healing methods.

3. The Law Requires Complaint Counsel To Produce Extrinsic Evidence.

Complaint Counsel must address several factors in order to prove violations of §§45 and 52. For instance, where the charges against a respondent are based on the “overall net impression” rather than on express claims, those charges must be proved by substantial evidence of consumer expectations in order for Complaint Counsel to prevail. *Thompson*², 791 F. 2d at 197. Accord, *Thompson* Policy Statement at p. 2.

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

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

See *Thompson* Policy Statement at p. 2.

The *Thompson* Policy Statement states clearly that these factors apply to charges of false/misleading advertising, deception and unfairness. “The Commission’s determination of what constitutes a reasonable basis depends, as it does in an unfairness analysis, on a number of factors relevant to the benefits and costs of substantiating a particular claim. These factors include [the 6-point list described above.]”

These factors are identical to the statutory requirements of 15 USC 6§45(n)

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

applicable to claims of unfairness. In other words, Complaint Counsel must effectively meet the same standards of proof for false advertising and deception, as §45(n) requires for unfairness. Agency presumptions and policy guidance alone will not suffice.

The Commission must also examine the allegedly deceptive practice from the perspective of a reasonable consumer. If the representation is directed *primarily* to a particular group, the FTC is required to examine reasonableness from the perspective of that group.³ See FTC Policy Statement appended to *Cliffdale Associates*⁴ (hereinafter *Cliffdale* Statement). That is, the FTC must determine the effect of the challenged claims on a reasonable member of the target group. In this case, that group consists of the constituents of Daniel Chapter One's religious ministry devoted to natural health.⁵

When such a specific group of recipients is involved, extrinsic evidence about that group's reasonable perceptions is necessary. *Id.* See e.g., *Thompson*, 791 F. 2d at 197, where the Circuit Court made special note that "The issue of [consumer perception of the claims] was extensively addressed by expert testimony."

4. Qualified Expert Evidence Is Required To Challenge Substantiation.

Qualified expert testimony or other extrinsic evidence is required not just to satisfy the FTC's burden on the issue of consumer perception. Qualified expert testimony is also required to address the question of substantiation. This is especially true for cases involving natural dietary supplements.

The FTC's Official Guidance to the Dietary Supplement Industry says that the amount and type of substantiation required for dietary supplements is determined by what

³ Note that the representation need not be directed *exclusively* to a particular group.

⁴ See FTC Statement on Deception, appended to *Cliffdale Associates*, 103 FTC 110, 174 (1984), hereinafter *Cliffdale* Statement.

⁵ See *Cliffdale* Statement at footnotes 13 and 29.

experts *in the relevant field* would consider to be adequate.⁶ This is consistent with the qualifications required of an expert under the relevancy prong of the *Daubert* standard.⁷

In other words, without testimony from experts who are specifically qualified about dietary supplements (e.g., naturopaths and phyto-nutritionists), Complaint Counsel does not meet its burden of proof about the alleged lack of substantiation for Daniel Chapter One's claims as a matter of law.

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

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

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

[A] statement for a dietary supplement may be made if:

(A) the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, **describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans**, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient,

(B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and

(C) the statement contains, prominently displayed and in boldface

⁶ *Dietary Supplements: An Advertising Guide for the Industry*, produced by Complaint Counsel as evidence of policy in this case. A copy is provided at Appendix 2, Bates no. FTC-DCO 1041 to 1070. See p. 1052, specifically.

⁷ *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

type, the following: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”.

A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.

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

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

5. Daniel Chapter One’s Substantiation Is More Than Adequate To Meet The Required Legal Standards.

Daniel Chapter One has substantiated its structure/function claims. And it has done so more than adequately. Daniel Chapter One supplied considerable substantiating

