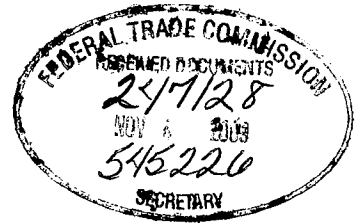


IN THE UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION



Commissioners: Jon Leibowitz, Chairman
Pamela Jones Harbour
William E. Kovacic
J. Thomas Rosch

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

DOCKET NO. 9329

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

PUBLIC DOCUMENT

RESPONDENTS' REPLY BRIEF

Respondents Daniel Chapter One, a corporation, and James Feijo, individually and as an officer of Daniel Chapter One, hereby submit the following Reply Brief in the above-captioned action.

Dated: November 4, 2009

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INTRODUCTION

“What are they allowed to say?” At the close of oral argument the Administrative Law Judge asked the FTC Complaint Counsel this question. The question puts the fundamental issue in this case succinctly before the Commission. What can individuals in Respondents’ position say? The Respondents in this case are Daniel Chapter One, a ministry organized as a Corporation Sole under the laws of Washington State, and James Feijo, its overseer and only member.

James Feijo leads Daniel Chapter One as its overseer, a position established by the Corporation Sole statute of Washington State. A Corporation Sole is, according to The Guide to Representing Religious Organizations, published by the American Bar Association in 2009, “a common ‘religious’ corporate form that still exists in most, if not all, states...and is controlled by one person....” Daniel Chapter One maintains a home church, conducting bible studies, christenings, and other church activities in the home of the overseer and his family.

In addition to services in the home in which they live, owned by the ministry, the Feijos conduct services in other homes across the country and abroad. As part of the work of the ministry, the Feijos have taken Bibles to people behind the Iron Curtain who, during the Cold War, conducted church services secretly in their homes. These home church activities abroad included taking Bibles to Poland, East Germany and China (during the *Tiananmen Square* demonstrations). The ministry also maintains relationships with missionaries from their ministry in The Netherlands and Israel.

The Daniel Chapter One ministry believes, based on contents from the Christian Bible and from herbal science, that the human body has the innate capacity to heal itself and that herbs

exist that assist this natural process. In accordance with this belief, Daniel Chapter One formulates and provides herbs in various combinations, based on biblical guidance and herbal science, to individuals who believe, as the Feijos do, that herbs help strengthen the human body's immune system and other innate self healing capacities. Information about the Daniel Chapter One herbs appears on its web site, in its radio broadcasts and in various ministry publications such as newsletters and handbooks.

FTC Complaint Counsel complains about and seeks to prohibit certain statements made in these information sources. Complaint counsel says "They told consumers **"How to fight cancer is your choice!"** (emphasis by Complaint Counsel). Respondents stand by their right to tell people truthful information that can help them strengthen their natural capacities for well being. Complaint Counsel argues that any deviation from statements supported by placebo controlled double blind clinical studies or their equivalent constitutes misrepresentation under the FTC Act. Complaint Counsel argues that any statement about the role of herbs in assisting the body that is not supported by double blind studies constitutes an illegal claim that the herb can treat, cure, or prevent cancer, inhibit tumors, or ameliorate the adverse effects of radiation and chemotherapy,. Such a claim, Complaint Counsel says, makes the herb for which it is made a drug requiring double blind clinical trials that prove the truth of the statement

Respondents Daniel Chapter One and Mr. Feijo do not claim that the herbs they identify do anything other than assist the natural functions of the body. They provided five expert witnesses to attest to their approach to the natural healing capacities of the body. One expert was a world renowned herbal researcher who worked for nearly thirty years for the United States Department of Agriculture, for part of that time in a joint project with the National Cancer Institute as an herbal expert. He testified that herbal science data supported Respondents' statements about their herbal formulations.

Another expert, a naturopathic physician trained in herbal effects who reviewed the literature relied upon by Respondents to ensure that their statements about herbs were accurate, also testified that herbal literature relied upon by Respondents supported the statements they made about their formulations.

Respondents' third scientific expert, a member of the National Academy of Engineering, associated with the US National Academy of Sciences, and of the Swedish, Russian, and Japanese Academies of Science, with sixty years of scientific experience and a national reputation as a leader in understanding Complementary and Alternative Medicine modalities, testified to the growing scientific doubts about relying on placebo controlled double blind studies to separate truthful from untruthful information.

Respondents' fourth expert, with over thirty years of scientific study design, who uses one of Respondents' herbal formulations (not at issue in this case) testified, based on dozens of hours of detailed scientific conversation with Mr. Feijo, to the level of scientific competence Mr. Feijo brought to his development of herbal formulations. The fifth expert, with more than four decades of herbal formulation experience, described how he created one of the formulations at issue using sound herbal science based on the directions given to him.

Speaking of one ingredient in one of Respondents' formulations, the Administrative Law Judge pointed out to Complaint Counsel that "Your own expert said there was some promising research." It was in this context that the Administrative Law Judge asked Complaint Counsel "What can [people in Respondents' position] say?" That is the question this Commission needs to answer.

Complaint Counsel have stated repeatedly, as they did again in Complaint Counsel's Answering Brief ("CC Br."), that any claim about supporting and improving the structure and function of the body's natural systems for self defense or better wellness, that also mentioned cancer, requires double blind placebo controlled studies proving that it is effective against cancer. Complaint Counsel persisted in this mistaken argument even after their own expert witness testified that testing one single chemical entity to this level would cost 100 million dollars. Respondents' experts testified that one herbal ingredient in one of Respondents' formulations contained a minimum of 500 and possibly as many as 5000 single chemical entities.

Equally challenging to the government's case, Respondents engaged in the activities Complaint Counsel complains of for over twenty two years without a single consumer complaint. Only when the agency conducted an Internet surf seeking web sites that used both the word "cancer" and the words "dietary supplements" did Daniel Chapter One appear as a target. The agency found 130 originations that fit its criteria. It issued a press statement condemning all of them as law violators. The agency made no effort to distinguish those that, like Respondents, had sound herbal science substantiating their statements about supporting the natural systems of the body from those that were making unsubstantiated health claims. Indeed, it appears that no one with the competence to understand structure and function claims was ever consulted by the FTC.

Respondents offered over eighty witnesses with affidavits to testify to how important Respondent's herbal formulations were to their personal well being. Complaint Counsel and the Administrative Law Judge rejected this offer out of hand, claiming that what the user of the formulations believed was irrelevant. Complaint Counsel and the Administrative Law Judge claimed that they were in a position to tell from the face of the Respondents' statements about

their herbal formulation that Respondents misled people who used the formulations. Complaint Counsel argued, again Respondents believe erroneously, that the law requires no extrinsic evidence of deception to make their case.

Complaint Counsel's Answering Brief inaccurately states that the ALJ made 425 detailed independent Findings of Fact in his Initial Decision ("Decision"). In fact, the ALJ did not make independent Findings of Fact, but rather adopted Complaint Counsel's proposed Findings of Fact almost verbatim. This act alone warrants the utmost scrutiny by the Commission, as a matter of fundamental administrative law.

Among the positions that the Commission must take in order to affirm the Initial Decision are:

- It must find, for the first time, that the FTC Act, which confers jurisdiction on for profit entities and not-for-profit trade associations made up of for profit entities, includes jurisdiction over a not-for-profit religious ministry;
- It will have to conclude that in the legislation requiring substantiation of claims Congress intended that only double blind placebo controlled studies qualify as substantiation for statements such as those made by Respondents;
- It will have to conclude that demonstrating the absence of double blind studies is all that is required of the government to find a party liable for illegal statements;
- It will have to conclude that the Commission and only the Commission can decide exactly how an implied statement will be viewed by members of the public, and that extrinsic evidence of the effect of statements is no longer

