## Healthcare Policy

# FEDERAL TRADE COMMISSION v. DANIEL CHAPTER ONE

### A STORY OF GOVERNMENT SUPPRESSION OF ALTERNATIVE MEDICINE

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#### FEDERAL TRADE COMMISSION v. DANIEL CHAPTER ONE: A STORY OF GOVERNMENT SUPPRESSION OF ALTERNATIVE MEDICINE

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#### Daniel Chapter One

During 2010, our firm was privileged to represent Daniel Chapter One ("DCO"), a Christian ministry which offered for sale certain dietary supplements, including herbal products. Our work during 2010 focused on:

- (a) the final stages of the proceeding against DCO before the Federal Trade Commission ("FTC");
- (b) the Department of Justice's enforcement action against DCO in the **U.S.** District Court for the District of Columbia; and. finally
- (c) DCO's appeal in the U.S. Court of Appeals for the D.C. Circuit attempting to reverse a "cease and desist" order issued by the FTC to prohibit DCO from marketing its dietary supplements primarily to persons battling cancer.

We were successful in having the FTC grant a petition for reconsideration because the original FTC order violated its own rules, and we were successful in having the District Court reject the Department of Justice's efforts to sanction DCO based on our argument that the District Court had no jurisdiction while the case was pending in the U.S. Court of Appeals. However, our work was completely unsuccessful in getting the U.S. Court of Appeals for the District of Columbia to assert control over the Federal Trade Commission's unconstitutional actions against Daniel Chapter One.

After our representation ended, a DCO motion for rehearing *en banc* in the U.S. Court of Appeals was filed, and denied, and the next step is for a petition for certiorari to be filed in the U.S. Supreme Court by May 17, 2011. We intend to file an amicus brief in support of DCO's petition.

Although the final chapter on the DCO litigation has not yet been written, the story of the Federal Government's war against dietary supplements, herbal remedies, and alternative medicine generally needs to be understood by the American people who increasingly distrust establishment medicine, and want their freedom to choose alternatives preserved.

#### A Historical Perspective

The attack on alternative medicine by the establishment medical community is by no means a new development. Almost four hundred years ago, London herbalist William Trigg encountered similar resistance from the British College of Physicians, which held a royal monopoly on practicing medicine, and rigorously prosecuted outsiders who treated the sick. The College particularly disliked Trigg's habit of treating people for free, at a time when doctor's fees were exorbitant and doctors regularly refused to see poor patients. In addition, Trigg had embarrassed other physicians by remaining in London during the Plague to care for his patients, while registered doctors had fled the city.

Trigg was prosecuted on three separate occasions for aiding the sick without being a member of the College of Physicians. On the third trial, William Trigg was permitted to call his cured patients as witnesses in his defense, and it is reported that at least 100 of Trigg's patients remained outside the courtroom waiting to testify when his case was dismissed.

By way of contrast, testimony from the persons who DCO had helped was considered irrelevant to its violation of regulations in advertisements. The testimony of lay witnesses were excluded. Furthermore, Trigg's case was tried before a real judge — what today would be known as an "Article III" judge — not an administrative law judge — a legal functionary working for the Executive branch. DCO was tried before the head of the FTC's Office of Administrative Law Judges, a component of the same agency that brought the charges against him, and the same agency that heard his first appeal. See <a href="http://www.ftc.gov/ftc/alj.shtm">http://www.ftc.gov/ftc/alj.shtm</a>. It is a sad commentary that William Trigg was afforded greater rights to defend himself under the cruel monarch Charles I, than DCO was given under our Constitutional Republic.

#### The Federal Assault on Dietary Supplements and Alternative Medicine

In the early 20<sup>th</sup> century, Congress created the Federal Trade Commission ("FTC"), granting it authority to prohibit "deceptive practices" and "false advertisement" in the nation's commerce. 15 U.S.C. sections 45 and 52. One would think that such plain statutory language would require the FTC to prove, in fact, certain advertising to be "false," or specific practices to be "deceptive," to justify taking action to stop any particular ad or practice. However, courts routinely accept the FTC's view that it need not prove, in fact, that an advertisement is false or that a practice is deceptive. Instead, courts permit the FTC to prove its case by requiring the advertiser to demonstrate affirmatively that the advertiser had a "reasonable basis" for the claims it made in the contested advertisement or disputed practice.<sup>1</sup>

Furthermore, under the FTC's "reasonable basis" theory, the FTC is allowed to ignore the actual words of the advertisement and attack what the FTC determines to be the "overall net impression" of the ad, rather than what the ad actually says. And claiming that the FTC knows better than the consumer the ad's "overall net impression," the FTC need not call even one consumer witness to testify. Instead, relying on its supposed "expertise" in marketing, the FTC has convinced the courts that it knows better than the American consumer the impression created by the advertisement.

In cases such as the one brought against Daniel Chapter One, the FTC takes its "reasonable basis" theory two steps further. Not only must an advertiser of dietary supplements prove it had a "reasonable basis" for health claims about such products, the FTC insists that the advertisement is based on "competent and reliable scientific evidence." As is the case with "reasonable basis," the FTC does not define what is or is not competent and reliable, or even what is "scientific." And the courts have not required such a definition from the FTC. Indeed, the courts have allowed the FTC to set

Such deference to the FTC prompted a federal judge in the U.S. Court of Appeals for the Ninth Circuit to write that he could not understand why the FTC should ever choose to prove a case by needlessly shouldering the burden of proving the actual falsity or deceptiveness of a claim. Indeed, we read appellate opinion after appellate opinion in which Article III judges simply parroted the FTC's administrative findings and methodology without questioning whether the FTC's enforcement practices conformed to the limited statutory authority conferred on it by Congress.

the bar even higher for health claims respecting cancer, there requiring the support of "controlled clinical studies" of the kind required by the Federal Drug Administration for the approval of a toxic pharmaceutical drug.

Marketing of dietary supplement products is largely based upon historically-verified use and **individual testimony** of effectiveness. Just as when blood letting was believed to be the optimum treatment for many diseases, now cutting (surgery), poisoning (chemotherapy), and burning (radiation) are viewed as optimal cures for cancer by the scientific and medical establishment. However, the American people increasingly are voting with their dollars and pursuing gentler alternatives better track records. It becomes a financial imperative that those who profit from establishment medicine use their connections in government to squash alternative approaches.

Because Daniel Chapter One's claims related to cancer, the FTC insisted that those claims had to be supported by the FDA standards for new drugs. Yet, it was uncontested that it would be economically infeasible to conduct controlled clinical studies of such supplements and remedies because no one could ever recover the costs of the studies even if they proved the remedy to be safe and effective. Moreover, in the **Dietary Supplement Health and Education Act of 1994**, Congress approved scientific support for dietary supplement health claims that fell short of "controlled clinical studies," and on that basis chose not to require FDA testing of such supplements before permitting them to be marketed. This law, however, is viewed as limiting only the power of the FDA, which now hands its cases over to the FTC, and watches while those that market dietary supplements are crushed by the imposition of a test of falsehood and deception that cannot possibly be met.

The Article III courts do little, if anything, to stop these powerful unelected bureaucracies. As a consequence of this judicial deference, the FTC — like the FDA and other government agencies — has become a tool of Big Pharma and organized medical interests (the only type of expert witness who is believed is a physician) which are dedicated to preservation of a government-subsidized monopoly and the undermining and eventual destruction of alternative and complementary medicine. Even though there is increasing evidence of corruption and of fabrication of so-called controlled clinical studies in peer-reviewed medical journals, government agencies like the FTC are not deterred from imposing their view of "science" on the American people.

If a church were to seize such power, imposing its "religious" view of health and healing, the courts would scream "separation of church and state" and rule in favor of individual choice. But when a government agency invokes the name of "reasonable basis," the courts bow before the altar of so-called "science" — actually "scientism" — and permit the agency to run roughshod over healthcare practices and programs outside the "mainstream."

Why should the government have the right to impose its "scientific" opinions as to the effectiveness, and even the safety, of medical practices and procedures? With the enactment of Obamacare is not the government using money coerced from the American people to subsidize one way kind of medicine to the exclusion of alternatives. Thomas Jefferson once said that to compel a man to furnish contributions to the propagation of **opinions** — not just religious opinions, but opinions — which he abhors and with which he disagrees is sinful and tyrannical.

Our founders warned against concentrating all three powers in one government body. 370 years ago the English Parliament finally abolished the **King's Court of Star Chamber** which used all three powers to suppress competition in the nation's trades and business. For nearly 100 years the Federal Trade Commission has increasingly trampled on family free enterprises such as Daniel Chapter One. It is past time to defund the FTC and other administrative agencies like it and return economic liberty, and health freedom, to the people. If this seems like a radical solution, one need only examine the story of how unconstrained power was used against a small Christian ministry which has helped many and hurt none — Daniel Chapter One.

#### The Story of Daniel Chapter One

Daniel Chapter One is a Christian house church which operates a healthcare ministry based on the spiritual gifts, education, training, and experience of its founders, James and Patricia Feijo. Structured as a nonprofit religious corporation sole under the laws of the State of Washington, and headquartered in Portsmouth, Rhode Island, DCO has presented the Gospel of Jesus Christ, taught Biblical principles of healthcare and healing from the Word of God, and offered a number of herbal and nutritional products for sale to the public for many years. DCO used the Internet, publications, speaking engagements around the country, and a daily radio show to share the Good News of Jesus Christ and the healing qualities of DCO products.

The products offered by DCO have included conventional herbal remedies, as well as a number of products that it developed according to Scriptural principles, its study of the combined legacy of 6,000 years of the use of herbs and nutrition, and its observation of many persons who had personal experience in using those products. DCO's products have been remarkably effective in promoting the health of Christians and non-Christians alike across the country. These products help the body rid itself of toxins and pathogens, and provide it with the nutritional components which the body requires to fight off disease. All of those products help the body strengthen its immune system to do what it was designed to do by God—to heal itself. http://www.danielchapterone.com

In the fall of 2008, however, DCO came under attack by the federal government for offering to the public these Scripturally-based and historically-proved dietary supplements as an alternative to "conventional" medicine — such as chemotherapy and radiation oncology. This attack was launched by the FTC, in conjunction with the FDA, to do the bidding of the wealthy and powerful Pharmaceutical industry and the establishment medical community, to impede the increasing use of alternative medicine by Americans. The FTC usurpation of the setting of the nation's health policy to limit patient choice was called "Operation False Cures." <a href="http://www.ftc.gov/opa/2008/09/boguscures.shtm">http://www.ftc.gov/opa/2008/09/boguscures.shtm</a>. Of course, the FTC never even had to prove the cures were false.

The FTC developed a theory that DCO was misleading the public solely because DCO had not tested any of its dietary supplements by controlled clinical studies of the kind conducted by the FDA before permitting the marketing of a toxic pharmaceutical drug. But there is no reason to test a nutritional supplement as one would a toxic pharmaceutical drug, and since most food supplements cannot be patented, it is financially impossible to meet the test established by the FTC.

DCO made no claim that its products were backed by FDA-style tests. Rather DCO promoted its products primarily on the basis of testimonies of persons who had benefitted from using those products in their fight against cancer. The FTC was unable to find even one person who testified that he had been led to think that DCO's product claims were based on FDA-style clinical studies. And, despite the devotion of enormous government resources in the effort to silence DCO's educational efforts about its products, the FTC was unable to find even one person who was harmed by them.

On the other hand, DCO brought many lay witnesses to testify under oath as to the safety and efficacy of DCO products. The FTC's Chief Administrative Law Judge ("ALJ") upheld the position of the FTC Complaint Counsel, shut his ears to these lay witnesses — keeping them from testifying about their personal experiences of healing with DCO products. The ALJ did allow DCO to present four expert witnesses, including a renowned herbalist, to testify, but immediately discounted all of their testimony for the sole reason that they were not Medical Doctors. Instead, the FTC relied exclusively on the testimony of one Medical Doctor who no longer practices medicine, but works as a professional expert witness and designs drug studies for the pharmaceutical industry being criticized by DCO. This same so-called expert witness could not even answer the ALJ's question as to whether an herb was a plant.

Wielding legislative, executive and judicial power, the five-person commission of the FTC simply rubber-stamped the findings of its ALJ. Hoping to obtain an independent review by an Article III court, DCO petitioned the United States Court of Appeals for the District of Columbia for a review of the FTC action against it. In its Petition for Review, DCO waged a vigorous challenge to the FTC's claim that it had the authority to require DCO to conform its dietary supplement ads to the FDA's "scientific" standards governing pharmaceutical drugs. Additionally, DCO challenged the FTC's authority to impose its view of "scientific truth" upon DCO, a religious nonprofit ministry. DCO's petition, however, was summarily denied.

Before DCO fought the FTC charges against it, DCO was warned by many that one cannot fight the FTC and win — that the deck is stacked by a system designed to achieve efficiency, not justice. Yet DCO was accountable to a Higher Power, and felt obligated to fight, in spite of the odds. It appears that none of the other nutritional supplement companies targeted by the FTC believed they could win, and no other federal court cases are now pending.

Because federal law limits the FDA's powers to regulate dietary supplements, the FTC has stepped in to impose upon herbal medicines and dietary supplements the FDA rules designed exclusively to govern toxic pharmaceutical drugs. The public health is being seriously jeopardized by the FTC, and Congress now needs to rein in its abusive campaigns against alternative medicine.

While DCO is still standing against the juggernaut of establishment medicine and for those Americans who have rejected the FDA and FTC-approved toxic and expensive medicine, the future of freedom of choice in medicine and healthcare is hanging by a thread. DCO's petition to the U.S. Supreme Court may be the only hope left before the FTC strikes again and puts alternative medicine out of business.

#### Conclusion

As seen from the story of William Trigg, the struggle between conventional and alternative medicine is anything but new. As with most areas of assault on individual rights, it is a battle that each generation appears required to fight for itself. The dangers and lack of success of conventional cancer therapies is widely documented, but robustly denied. The successes of alternative cancer therapies have been demonstrated by thousands of cancer survivors, but the government acts as though it is more interested in constraining healthcare options than achieving good results.

The battle (detailed in Attachment A, below) is not just between Daniel Chapter One and the FTC. It is between the millions of Americans who have seen through the tactics of manipulation by fear widely used by medical oncologists and radiation oncologists, and embraced the notion that the best medicine encourages the human body to heal itself, just as God designed it. The story of this battle for health freedom has been oft told, and a selected bibliography is provided (Attachment B, below) so that those of us who question or reject conventional approaches to cancer and other diseases can know that we may be swimming against the tide of the world system, but we are in good company.

#### Attachment A Litigation Proceedings

The details of the FTC's abusive campaign against DCO are detailed below.

1. <u>In the Matter of Daniel Chapter One and James Feijo</u>, FTC Docket No. 9329 – September 18, 2008 to January 25, 2010.

On September 18, 2008, the Federal Trade Commission ("FTC") filed a complaint charging Daniel Chapter One and James Feijo with having engaged in deceptive acts and practices respecting the marketing of four named dietary supplements in violation of 15 U.S.C. sections 45(a) and 52. The Complaint sought an order commanding DCO, *inter alia*, to cease and desist making any advertisement in connection with any of DCO's dietary supplements "unless the representation is true, nonmisleading, and at the time that it is made, [DCO] possess and rely on competent and reliable scientific evidence that substantiates the representation." Complaint, FTC Docket No. 9329, pp. 7-8.

After an administrative adjudicatory hearing, an FTC Administrative Law Judge ("ALJ") issued his initial decision rejecting all of DCO's legal and constitutional claims and defenses and granting the requested order. In that order, DCO was ordered to send a letter to those persons who had purchased its products which repudiated its health teachings, and embraced conventional medicine — something that DCO could never do. On appeal, the Commission affirmed and, on January 25, 2010, issued its Modified Final Order ("Order").

2. <u>DCO's Application to the FTC for a Stay of the FTC Order Pending Judicial</u> Review – March 23, 2010.

On February 25, 2010, pursuant to 15 U.S.C. section 45(g)(2)(A) and 16 C.F.R. section 3.56(b), DCO applied to the FTC for a stay of the Order.

http://www.wjopc.com/site/health/DCO Appl Stay.pdf

http://www.wjopc.com/site/health/DCO Memo Support Appl Stay.pdf

http://www.wjopc.com/site/health/DCO Appl Stay PropOrder.pdf

The application was supported by six declarations:

Declaration of James Feijo

http://www.wjopc.com/site/health/DCOdeclarations/Jim Feijo.pdf

Declaration of Patricia Feijo

http://www.wjopc.com/site/health/DCOdeclarations/Tricia Feijo.pdf

Declaration of Deane Mink, D.C. (http://www.minkchiro.com/)

http://www.wjopc.com/site/health/DCOdeclarations/Mink.pdf

Declaration of Karen Orr, D.C.

http://www.wjopc.com/site/health/DCOdeclarations/Orr.pdf

Declaration of Charles Sizemore, D.D.S. (http://www.drcharlessizemore.com/)

http://www.wjopc.com/site/health/DCOdeclarations/Sizemore.pdf

Declaration of Jerry Hughes (http://www.accentradionetwork.com/st.htm)

http://www.wjopc.com/site/health/DCOdeclarations/Hughes.pdf

On March 23, 2010, the application was denied.

#### 3. <u>DCO Emergency Motion for Stay is Denied</u> – April 1, 2010.

On March 26, 2010, DCO filed an emergency motion with the U.S. Court of Appeals for the District of Columbia Circuit ("DC Cir."), pursuant to 15 U.S.C. section 45(g)(2)(B), Federal Rule of Appellate Procedure 18, and D.C. Circuit Rule 18, for a stay pending review of the Order.

http://www.wjopc.com/site/health/DCO UDCA Motion Stay.pdf

http://www.wjopc.com/site/health/DCO UDCA Motion Stay Exhibits.pdf

On April 1, 2010, that motion was denied.

#### 4. The FTC Order Becomes Effective – April 2, 2010.

On April 2, 2010, pursuant to 15 U.S.C. section 45(g), the Order became "effective." See 16 C.F.R. section 3.56(a).

5. <u>DCO Comes Into Substantial Compliance with the Order, Claiming Partial Exemption under the Religious Freedom Restoration Act (RFRA)</u> – April 2, 2010.

When the FTC Order became effective, DCO worked hard to comply with the order, pending review of its case by a federal court. DCO's compliance was detailed in a letter to the FTC dated May 28, 2010, that since April 2, 2010 (the effective date of the Order), to comply with those portions of the Order that required DCO either to take certain action or to cease certain activities (i.e., Parts II, III and V of the Order), that: (I) DCO has not made any representations that any DCO program, service, or product "prevents, treats, or cures, or assists in the prevention, treatment, or cure of any type of tumor or cancer," as proscribed in Part II of the Order, and has withdrawn from its website, its e-Mail and its radio program all ads making the proscribed claims; (ii) DCO, by the same actions, has not made any representation "about the efficacy, performance, or health-related benefits" of any DCO program, service, or product, as proscribed in Part III of the Order; (iii) DCO transmitted to the FTC during April 13-May 3, 2010, by sworn declaration, a list of purchasers of the so-called four Challenged Products for the period from April 1, 2009, through and including April 9, 2010, as required by Part V.A of the Order; and (iv) compliance with Part V.B. of the Order — signing and sending an FTC-mandated and FTCwritten letter — would deprive DCO of its claims that the Order was unconstitutional and in violation of DCO's rights under RFRA.

#### 6. <u>DCO's Motion for RFRA Evidentiary Hearing</u> – April 22, 2010.

On April 22, 2010, in connection with their Petition for Review pending in D.C. Circuit, DCO filed a motion for an evidentiary hearing, in support of their claim that forced compliance with Part V.B of the Order would substantially burden DCO's free exercise of religion in violation of 42 U.S.C. section 2000bb-1(a), the Religious Freedom Restoration Act ("RFRA").

http://www.wjopc.com/site/health/DCO Order deny RFRAhearing.pdf

That motion was denied by the D.C. Circuit by Order dated July 6, 2010.

#### 7. <u>DCO's Petition for Review.</u>

On March 17, 2010, pursuant to 15 U.S.C. section 45(c), DCO filed a timely Petition for Review of the Order, contesting the legality and constitutionality of the Order, with the United States Court of Appeals for the District of Columbia Circuit. <u>Daniel Chapter One</u>, et al. v. FTC, Docket No. 10-1064 (D.C. Cir.).

DCO filed its opening brief on August 18, 2010, the FTC filed its brief in response on September 17, 2010.

http://www.wjopc.com/site/health/DCO Brief.pdf

DCO filed its reply brief on October 1, 2010.

http://www.wjopc.com/site/health/DCO Reply Brief.pdf

Oral argument was held before a three-judge panel (Ginsburg, Henderson, Kavanaugh) of the court on November 12, 2010.

8. <u>FTC Separate Enforcement Action in U.S. District Court</u> – August 13, 2010.

On August 13, 2010, United States Government filed a complaint in the U.S. District Court for the District of Columbia, seeking injunctive relief enforcing two parts of the Order, requiring DCO to sign and send a "corrective notice ... to past purchasers" of four dietary supplements, as mandated by Part V.B of the Order and to cease and desist from certain activities allegedly in violation of Part II of the Order. <u>U.S.A.</u> v. <u>Daniel Chapter One</u>, et al., Civil No. 10-1362 (EGS) (D.D.C.).

On September 1, 2010, DCO moved to dismiss, and also opposed the government's motion for a preliminary injunction.

http://www.wjopc.com/site/health/DCO Motion Dismiss.pdf http://www.wjopc.com/site/health/DCO MemoPA Opp PI.pdf

After briefing and a hearing, by Order dated September 14, 2010, the district court denied the FTC motion, and ordered that the case be stayed pending the decision by the D.C. Circuit in DCO's Petition for Review proceeding.

The FTC appealed that Order (<u>USA</u> v. <u>Daniel Chapter One, et al.</u>, No. 10-5370 (D.C. Cir.), and eventually filed an uncontested motion to dismiss that appeal, which motion was granted on January 7, 2011.

#### 9. <u>FTC Motion for Enforcement in U.S. Circuit Court</u> – October 8, 2010.

On October 8, 2010, the FTC moved for an order enforcing the FTC Order, arguing, as it had in the district court (in Civil NO. 10-1362) that DCO was flouting the FTC Order, in both refusing to send the FTC-mandated letters and in conducting certain activities that the FTC maintained were violative of the cease-and-desist mandates of the Order. After briefing, the D.C. Circuit entered an Order, dated November 22, 2010, enjoining DCO "to obey forthwith" the Order.

#### 10. <u>D.C. Circuit Decision Dismissing DCO's Petition for Review.</u>

On December 10, 2010, the D.C. Circuit panel issued its "Judgment" — an unpublished opinion — denying DCO's petition for review of the Order. (The clerk was directed to withhold issuance of the mandate until seven days after resolution of any timely petition for rehearing or petition for rehearing en banc. *See* Fed. R. App. P. 41(b); D.C. Cir. Rule 41).

#### 11. FTC Motion to Reconsider Publication of Opinion.

On December 21, 2010, the FTC, claiming the importance and precedential effect of this case, moved the court of appeals to reconsider its decision not to publish its opinion in this matter. DCO's new counsel, Sanger & Synsen of Santa Barbara, California filed a response supporting the FTC motion pointing out the disparity between the FTC's assertions in its motion that this case presents questions of exceptional importance and its claim on brief that this case is merely a "straightforward case of deceptive advertising." The DCO filing stated that DCO "cannot oppose the request to publish but do intend to petition for rehearing en banc (or review by the Supreme Court) given the conceded significance of the Court's Opinion."

#### 12. <u>FTC Motion for Expedited Issuance of the Mandate</u>.

On January 6, 2011, the FTC filed a Motion for Expedited Issuance of the Mandate so that it could "resume enforcement efforts and recover civil penalties" against DCO in district court.

#### Attachment B Selected Bibliography

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