No. 10-1064

In The
United States Court of Appeals
for the District of Columbia Circuit

DANIEL CHAPTER ONE,
a corporation sole, and

JAMES FEIJO,
individually, and as an officer of
Daniel Chapter One,
Petitioners,

v.

FEDERAL TRADE COMMISSION,
Respondent.

On Petition for Review from the Federal Trade Commission

REPLY BRIEF OF PETITIONERS

*Herbert W. Titus
William J. Olson
John S. Miles
Jeremiah L. Morgan
William J. Olson, P.C.
370 Maple Ave. W., Ste. 4
Vienna, Virginia 22180-5615
(703) 356-5070
wjo@mindspring.com
Attorneys for Petitioners

* Counsel of Record
October 1, 2010

TABLE OF CONTENTS

TABLE OF AUTHORITIES

* Authorities upon which we chiefly rely are marked with asterisks.

GLOSSARY OF ABBREVIATIONS

ALJ	Administrative Law Judge
ALJ Dec.	Initial Decision of the Administrative Law Judge
Commission	Federal Trade Commission
Comm. Op.	Opinion of the Commission
DCO	Daniel Chapter One and James Feijo, its Overseer
DSHEA	Dietary Supplement Health and Education Act of 1994
FDA	Food and Drug Administration
FTC	Federal Trade Commission
FTC Br.	Brief of Respondent Federal Trade Commission
FoF	Findings of Fact
Miller Report	Expert Report of Denis R. Miller, M.D.
Order	Modified Final Order
Pet. Br.	Brief of Petitioners
RFRA	Religious Freedom Restoration Act

SUMMARY OF ARGUMENT

The FTC brief erroneously argues that the FTC has jurisdiction over Daniel Chapter One ("DCO") — a nonprofit ministry/house church — because DCO made "profit" from its sales of dietary supplement products. However, 15 U.S.C. section 44 requires the FTC to prove that DCO sold such products **for the purpose** of enhancing its members' profits. Unable to make that showing, the FTC brief resorts to a string of *ad hominem* charges against Mr. Feijo and his wife, unsupported by the administrative record.

The FTC brief asserts that the Commission found that the "net overall impression" of DCO's health benefit claims represented that its products could prevent, treat, or cure cancer, and, thus, that DCO implied that there was a "reasonable basis" for DCO's "cancer cure claims." Since there was no demonstration that any DCO product representation was, **in fact**, false or deceptive — with not one person claiming to be deceived or injured by DCO — the FTC's entire case rested upon the FTC's non-statutory "reasonable basis" theory. Under the "reasonable basis" theory, DCO was required to substantiate its claim by "competent and reliable scientific evidence" — which, in turn, the FTC decided required "controlled clinical trials."

The FTC Brief argues that "controlled clinical trials"" were required on the ground that a reasonable consumer would have expected that cancer treatment

claims for dietary supplements, like pharmaceutical drugs, would be based on such controlled clinical studies. But there is nothing in the record to support this rationale. Rather, the record shows that the "controlled clinical studies" standard was imposed solely because of the FTC's expert oncologist's personal opinion that such studies were necessary to protect the public health — an area of public policy not entrusted to the FTC — wholly unauthorized by 15 U.S.C. sections 45 and 52, which confine the FTC's powers to protect the public only from deceptive and false advertising.

The FTC Brief also argues that the FTC has the power to do what the FDA was barred from doing in Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999). For the reasons stated in Pearson, the First Amendment commercial speech doctrine applies here, and the FTC has failed to justify its action under the Supreme Court's three-part test.

Lastly, the FTC Brief fails to rebut DCO's showing that the FTC Order requiring DCO (i) to "rely" only on evidence unilaterally determined by the FTC to be true according to empirical science, violated DCO's rights under the First Amendment, and (ii) to send an FTC-composed letter, violated the First Amendment and the Religious Freedom Restoration Act ("RFRA").

ARGUMENT

I. IN AN ERRONEOUS EFFORT TO ASSERT JURISDICTION OVER A MINISTRY, THE FTC BRIEF HAS UNJUSTIFIEDLY DISPARAGED DANIEL CHAPTER ONE AND THE FEIJOS' RELATIONSHIP TO IT.

A. The FTC Brief Urges an Erroneous Legal Test for Asserting Jurisdiction over DCO.

In an effort to justify expansion of its jurisdiction to cover DCO, a nonprofit ministry/house church, the FTC brief has placed principal reliance upon a trade association case, California Dental Ass'n. v. FTC, 526 U.S. 756 (1999). The FTC brief has repeated the same mistake made by the Administrative Law Judge ("ALJ"),[1] maintaining that the "jurisdictional touchstone" of the FTC Act is "profit." *See* FTC Br., p. 23. The California Dental Court actually said something more specific and quite different: "[T]he **object of enhancing its members' 'profit**' [is] the FTC Act['s] jurisdictional touchstone." *Id.*, 526 U.S. at 767 (emphasis added).

There is a marked difference between: (i) a trade association like the California Dental Association designed to engage in activity with the obvious purpose of "enhancing" its commercial members' profits; and (ii) a religious

---

[1] *See* Initial Decision of the Administrative Law Judge ("ALJ Dec."), p. 70, A-236.

ministry, like DCO, that engages in net income-producing activity to fund its ministry. Under the FTC brief's misreading of California Dental, the two types of nonprofit organizations would be conflated because both engage in activities that generate a profit. But the plain language of 15 U.S.C. section 44 requires more than making a profit, restricting FTC's jurisdiction to those corporations that are "**organized** to carry on business **for** its own profit or that of its members." (Emphasis added.) And the burden to demonstrate that an entity is "organized" for the purpose of making a profit for that entity or its members falls squarely on the FTC. *See* Community Blood Bank v. FTC, 405 F.2d 1011, 1015-17, 1019-20 (8th Cir. 1969).

Thus, the FTC brief is seriously mistaken when it argues that "[w]here, as here, overwhelming evidence demonstrated that DCO **generated funds** from commercial activities, and the **use** of such funds was not confined to charitable purposes, jurisdiction is proper." *See* FTC Br., p. 24 (emphasis added). Under the California Dental test, the FTC must show that DCO "generated funds" from its product sales **for the purpose** of enhancing the profits of DCO or its member, James Feijo.

Not only has the FTC brief failed to meet its jurisdictional burden, it has devoted many pages to disparaging DCO, and James and Patricia Feijo, in an

apparent effort to establish jurisdiction under a flawed theory and an *ad hominem* attack unsupported by the record.

B. The FTC Brief's Claim that DCO Is Primarily a Multi-Million Dollar Business, and Only Incidentally a Religious Ministry, Is Not Supported by the Record.

The FTC falsely states that DCO, "[o]pened as a health food store **in 1986**, [and] was incorporated in 1990 as a **for-profit** corporation for the purpose of marketing dietary supplements." *See* FTC Br., p. 3 (emphasis added). In fact, however, the administrative record shows that "**[i]n 1983**, DCO began ... as a **house church,**"[2] and was "created for the purpose of healing based on the scripture of Daniel Chapter One and other biblical verses, including Genesis 1:29 where ... God said he created food for healing." ALJ Dec., Findings of Fact ("FoF") 16, A-173.

Thus, from the start, DCO has engaged in "ministry activities ... reaching out to interested persons to inform them about [DCO's] perspectives on the integration of spiritual and physical well-being." ALJ Dec., FoF 18, A-173. Not until three years later did DCO open a health food store and, even then, it did so as an adjunct to the ministry, not the other way round, as the FTC brief erroneously represents. *See* FTC Br., p. 5. Indeed, the ALJ stated that DCO developed its line

---

[2] ALJ Dec., FoF 11, A-173 (emphasis added).

of products out of a "combined spiritual and scientific approach that maintains the balance of bodily systems" and has promoted, and continues to promote, those products "in furtherance of the Feijos' spiritual and scientific beliefs." ALJ Dec., pp. 68-69, A-234-35.

Neither the ALJ nor the Commission found that DCO's activities during the 1990's, when it functioned as a for-profit corporation, divorced DCO's product development and sales from its religious mission. *See* ALJ Dec., p. 70, A-236; Opinion of the Commission ("Comm. Op."), p. 2, A-300. Nor did the Commission find that the revocation of DCO's for-profit corporate status prompted James Feijo to reorganize as a corporation sole, as the FTC brief has implied — stating vaguely that "**[a]t some point**, DCO's corporate status was revoked ... and in 2002, it reorganized itself as a 'corporation sole.'" *Compare* FTC Br., p. 4 (emphasis added) *with* Comm. Op., p. 4, A-302. Indeed, as the ALJ found, DCO's for-profit corporate status was terminated at least **five years before** DCO reorganized as a corporation sole. *See* ALJ Dec. FoF 26, 28, A-174.

In short, the FTC brief's undue emphasis upon DCO's corporate status in the 1990's appears to have been deliberately designed to create the false impression that DCO is **really** a for-profit corporation, and that its restructuring as a nonprofit corporation sole was a sham. But neither the ALJ nor the Commission

made any such finding. *See* ALJ Dec., pp. 67-76, A-233-42 and Comm. Op., pp. 4-8, A-302-06.

C. The FTC Brief's Claim that James Feijo "Treats DCO's Assets as His Own" Is Not Supported by the Record.

Twice the FTC brief states, as if it were a finding of fact, that James Feijo "treats DCO's funds [assets] as his own." FTC Br., pp. 2, 5. However, neither the ALJ nor the Commission made such a factual finding. Nor is the FTC's statement a reasonable characterization of any factual finding in the record.

Out of 425 findings of fact itemized in detail by the ALJ, the FTC brief has cited only one to support of its allegation that James Feijo treated DCO's assets as his own — that "Feijo does not have his own individual bank account." *See* FTC Br., p. 5 (citing IDF76, JA179). In doing so, the FTC brief appears to have embraced not a factual finding, but the ALJ's *non sequitur* that "**since** James Feijo had **no individual bank account**, he used DCO's assets at will, thereby treating those assets as his own." *See* ALJ Dec., p. 76, A-242 (emphasis added).

In addition to this flimsiest of record support, the FTC brief purports to rely upon a potpourri of fact determinations and legal analyses found on pages four through eight of the Commission Opinion (*see* FTC Br., p. 2, citing JA302-306), as if its present claim — that James Feijo treated DCO's assets as if they were his

own — were self-evident. But it is not. Even after the FTC brief narrows its citation to page 5 of the Commission opinion (*see* FTC Br., p. 5 (citing JA303)), one is still left in the dark.

In truth, the FTC brief's claim that James Feijo treated DCO's assets as his own appears to be more rhetorical flourish than hard fact or reasoned inference based upon the ALJ's or the Commission's findings. Neither the ALJ nor the Commission found that James Feijo breached his fiduciary duty to DCO. *See* ALJ Dec., pp. 73-74, A-239-40; Comm. Op., p. 8, A-306. And for good reason. While DCO funds were used to pay the Feijos' living expenses (*see* FTC Br., p. 5), such payments should be considered appropriate in light of the Feijos' full-time service in the multi-faceted DCO ministry.[3]

In sum, the ALJ and the Commission never found that DCO's ministry of spiritual and physical wellness — including its marketing of dietary supplements — was anything but genuine. *See* ALJ Dec., pp. 68-69, A-234-35; Comm. Op., pp. 4-6, A-302-04. Thus, unlike In re Ohio Christian College, 80 F.T.C. 815 (1972), upon which the FTC relies[4] — and in which the Commission found that

---

[3] *See, e.g.,* ALJ Dec., FoF 8-21, 37-41, 84-86, 91, 94, 97, 99-100, 103, 108-111, 114, 117, 122-23.

[4] *See* FTC Br., pp. 23, 32.

Ohio Christian College was "little more than a 'diploma mill,'" not a bona fide educational program (*id.* at 846) — the FTC cannot claim that James Feijo was the equivalent of the head of a phantom college.[5]

D. The FTC Brief's Claim that DCO's "Handsome" Profits Were Devoted "to Support a Lavish Lifestyle for [the] Feijo[s]" Is Not Supported by the Record.

The FTC brief represents to this Court that the Commission "found that ... DCO did **not devote its profits to any charitable purpose**, but used them instead to support a **lavish lifestyle** for Feijo." *See* FTC Br., p. 16 (emphasis added). But the Commission made no such finding. Nor did the Commission find that the Feijos were an "**eleemosynary front**" (FTC Br., p. 31 (emphasis added)), using DCO funds to "**bankroll**" a "**country-club lifestyle**" (FTC Br., p. 6) (emphasis added).

According to the FTC brief's version of the facts, "the Feijos use DCO's funds to ... pay for **their two homes**...." *See* FTC Br., pp. 5-6 (emphasis added). *See also* FTC Br., p. 31 ("Feijo uses DCO's funds ... to pay for **Feijo's two homes** (one in Rhode Island, and one on a Florida country club)..." (emphasis added)). The FTC brief also charges that James Feijo used DCO funds to purchase "**his** two

---

[5] Moreover, in the Ohio Christian College matter, the hearing examiner found the testimony of the school officials "inherently incredible." *Id.* at 839. The ALJ made no comparable finding here.

Cadillacs." FTC Br., p. 31 (emphasis added). Both claims are false. Neither the ALJ nor the Commission found that **either** house is owned by the Feijos (*see* ALJ Dec., FoF 55, A- 177; Comm. Op., p. 8, A-306), or that **either** car is owned by them. *See* ALJ Dec., FoF 56, A-177. Rather, each house is owned by two different corporate soles, of which James Feijo is trustee/overseer, and both cars are owned by DCO. While the ALJ and the Commission found that the houses and the cars were available for the Feijos' use, use is **not** ownership. Furthermore, neither the Commission nor the ALJ found that the Feijos used either house or car in any way inconsistent with the owners' ministry purposes.

Additionally, the FTC brief has launched a broadside charge that "[t]he Feijos financed their **country-club lifestyle with the roughly $2 million per year** generated by DCO's sales of 150 to 200 dietary supplement products." FTC Br., p. 6 (emphasis added). There is nothing in the record that lends even the slightest support to the FTC brief's prejudicial juxtaposition of DCO's $2 million a year income, on the one hand, and expenses relating to the Feijos' lifestyle, on the other. For example, in support of its statement that "the Feijos use DCO funds ... to bankroll discretionary entertainment expenses" (FTC Br., p. 6), the FTC brief was able to point to only $25,000 of such alleged expenses over a 40-month

period,[6] or $625 per month. The FTC brief claims that the Feijos were using DCO funds to support a "lavish" lifestyle. FTC Br., p. 16. To the contrary, the ALJ never found that the Feijos lived lavishly. *See* ALJ Dec., p. 75, A-241. Indeed, the ALJ acknowledged that the uncontested and uncontradicted testimony of the Feijos that neither "take salaries for their work and ... live modestly," but concluded that neither of these facts "affects jurisdiction in this case," it being "sufficient for the purpose of finding jurisdiction that the economic benefits conferred are more than '*de minimus*' or 'merely presumed.'" *Id*.

The FTC brief also maintains that "the evidence" before the ALJ and the Commission "established [that the] Feijo's [made a] **handsome profit** from [DCO's] activities." FTC Br., p. 28 (emphasis added). Without quantifying any alleged "profit," the FTC brief extrapolates from DCO's "roughly $2 million per year [in] sales" and "**acquisition costs** [of] less than a third the sales price," to reach the conclusion that the "revenues" from $2 million in sales "derive from a **substantial markup**." *See* FTC Br., pp. 6-7 (emphasis added). By this truncated method, the FTC brief seeks to mislead by creating an impression of a more sizable net profit than could reasonably be inferred from the record. *See, e.g.,* ALJ Dec., p. 70, A-236 and Comm. Op., p. 5, A-303. By any method of accounting,

---

[6] *See* FTC Br., p. 6.

the cost of goods sold would be more than the bare acquisition costs detailed by the FTC in the administrative record. The FTC is well aware of the various activities in which DCO is engaged to educate about spiritual and physical wellness and market its products, including, but not limited to, operating a website, conducting a daily radio talk show, producing and distributing product literature, and setting up and servicing a distribution system. *See* FTC Br., pp. 4-5, 7-8. Although the record reveals nothing of DCO's costs for such activities, that is no reason for the FTC brief to ignore them altogether in its quest to portray DCO to be a business subject to its jurisdiction.

II. THE FTC BRIEF'S CLAIM THAT DCO'S ADS CREATED THE OVERALL NET IMPRESSION THAT ITS PRODUCT CLAIMS WERE BASED UPON CONTROLLED CLINICAL STUDIES IS NOT SUPPORTED IN FACT OR BY LAW.

The original complaint did not charge, and the administrative hearing was not based on, any allegation that DCO's product representations were, **in fact**, false or deceptive. Rather, the FTC's entire case rested upon an application of the FTC's "reasonable basis" theory. *See* ALJ Dec., p. 99, A-265. Thus, the FTC brief urges this Court to affirm the FTC's action in this case on the ground that the Commission correctly applied that theory to the facts of this case.

A. The FTC Brief's Claim that DCO's Ads Created an Overall Net Impression in a Reasonable Consumer that its Products Had Been Tested by "Controlled Clinical Studies" Finds No Support in the Record.

In its review of the administrative record, the FTC brief asserts that "[a]n essential first step in any deceptive advertising case is determining what claims the advertising makes[,] consider[ing] both the express and implied claims" — "the **entire net impression**." FTC Br., p. 33 (emphasis added). Thus, in the administrative proceeding below, the FTC brief stated that "the **Commission** evaluated DCO's advertising ... and correctly found [i] that DCO **represented** that those products could prevent, treat, or cure cancer, **and** [ii] thus expressly or implicitly claimed that a **reasonable basis** existed for DCO's cancer-cure claims." *Id.* at pp. 33-34 (emphasis added). *See also id.*, pp. 35-36.

With respect to the second factor — the claimed existence of a "reasonable basis" — the FTC brief acknowledged that "the **Commission** had to determine what **level of substantiation DCO impliedly represented** that it possessed." *Id.*, p. 36 (emphasis added). According to the FTC brief, "the **Commission**" was bound to make this determination by "an **assessment of the actual advertisement**, considering the likely **impact on a consumer** of all its elements." *Id.* (emphasis added).

Since the Commission had found that the overall net impression of DCO's claims for its herbal products were "cancer-cure ... claims," the FTC brief argues that the Commission determined that "a reasonable consumer would normally assume [DCO's cancer-cure claims] are backed up by scientific evidence." *Id.,* p. 36. Thus, the FTC brief stated that "the **Commission**" determined that DCO's claims "must be substantiated by '**competent and reliable scientific evidence**.'" *Id.*, p. 37 (emphasis added).

Without any citation to the administrative record, however, the FTC brief interjects a brand new claim: that consumers of DCO's herbal products would "reasonably assume" that DCO's cancer-cure claims would be substantiated by the same kind of "**scientific testing**" that the Food and Drug Administration ("FDA") requires of a new pharmaceutical drug:

> Consumers are **well aware that drug products** that purport to treat disease are heavily regulated and **subject to substantial pre-market testing**. Thus, **consumers would reasonably assume** that, when **DCO touts its products** as a treatment for cancer, *i.e.,* as an **alternative** to products marketed by **drug** manufacturers, **DCO has first subjected those products to scientific testing**. [FTC Br., p. 38 (emphasis added).]

The FTC's novel "consumer expectation" rationale, however, has no support in the administrative record, and a new rationale for agency action may not be asserted for the first time on appeal.

In the ALJ's effort to set the standard governing the amount of substantiation necessary to show that DCO's cancer-cure claims are "reasonable" — that is, based on "competent and reliable scientific evidence" — he demonstrated no interest in assessing what reasonable consumer expectations, if any, were generated by DCO's actual advertisements. Rather, in a section of his Initial Decision entitled, "[t]he amount of substantiation **experts** in the field **believe** is **reasonable**,"[7] the ALJ relied solely on the testimony of Dr. Denis Miller, the FTC's "expert in cancer research and cancer treatment,"[8] to set the scientific standard by which the reasonableness of DCO's product claims would be measured:

> **His opinions**, which were thorough and well-reasoned, were that competent and reliable scientific evidence is required to demonstrate that a cancer treatment is effective; and that competent and scientific evidence means **controlled clinical studies**[9].... [DCO] contend[s] that the relevant field is dietary supplements.... Where, as here, a dietary supplement is claimed to have medical effects, however, it is appropriate **to rely on the opinion of an expert in the medical field**. [ALJ Dec., pp. 103-04, A-269-70 (footnote and emphasis added).]

---

[7] ALJ Dec., p. 103, A-269 (emphasis added).

[8] ALJ Dec., p. 103, A-269.

[9] By "controlled clinical studies," the FTC expert meant such studies as are employed by the FDA to approve a new pharmaceutical drug, including Phase I, Phase II, and Phase III studies which are part of a "complicated, lengthy, and expensive process." Expert Report of Denis R. Miller, M.D. ("Miller Report"), pp. 7-10, A-76-79.

Likewise, relying exclusively on Dr. Miller's testimony, the Commission adopted the FDA's "controlled clinical studies" standard as the only "reasonable basis" upon which DCO could substantiate its product's cancer claims:

> Dr. Miller explained that in order to constitute competent and reliable scientific evidence that a product treats, cures, or prevents cancer, the products' efficacy and safety must be demonstrated through **controlled clinical studies** (tests on humans).... He further testified that studies performed in test tubes or in animals, testimonials and other anecdotal reports are not substitutes.... He testified that harm potentially may occur from remedies that are alternatives to those that have undergone **clinical studies** on humans.... And, he testified **that for these reasons,** the need to substantiate a claim by clinical studies (*i.e.*, on humans) was the same **whether the purported agent was a herbal medicine or a more conventional pharmaceutical agent.** [Comm. Op., p. 18, A-316 (emphasis added).]

In short, neither the ALJ nor the Commission determined that "consumer expectations" had anything to do with the decision to apply the "controlled clinical studies" standard in this case. The FTC brief's representations[10] to the contrary are inaccurate.

Even if the ALJ and Commission had examined the "reasonable basis" issue from the perspective of the reasonable consumer — instead of solely from the perspective of an oncologist committed to the FDA-review process — they would have had no foundation upon which to assert that a reasonable consumer would

---

[10] *See, e.g.,* FTC Br., pp. 20-21, 46.

have expected that DCO had implied that its cancer treatment claims for its dietary supplements were based upon the same kinds of scientific evidence as such claims made on behalf of pharmaceutical drugs. The FTC brief acknowledges, as did the ALJ below, that "DCO's advertising is replete with **testimonials** that tout the products' success in treating cancer." *See* FTC Br., pp. 11-12 (emphasis added). *See also* ALJ Dec., FoF 179-253, pp. 24-40, A-190-206. Neither the ALJ nor the Commission found that such testimonials impliedly created an overall net impression that DCO had subjected their products to pre-market clinical testing such as that undergone by new pharmaceutical drugs. *See* ALJ Dec., pp. 83-95, A-249-61. To the contrary, the ALJ found testimonials were different from, and fall far short of, such scientific tests:

- "**Testimonials** do **not substitute** for a well-designed **clinical trial**." [ALJ Dec., FoF 351, A-222 (emphasis added).]
- "**Anecdotal reports** are the **weakest form of evidence** to support the anti-cancer activity of a new agent." [ALJ Dec., FoF 352, A-222 (emphasis added).]
- "**Testimonials** have very **little scientific** validity." [ALJ Dec., FoF 353, A-222 (emphasis added).]

In light of the fact that DCO's ads were "replete with testimonials,"[11] why would "consumers ... reasonably assume" — as the FTC now contends — "that,

---

[11] *See* FTC Br., p. 11.

when DCO touts its products as a treatment for cancer ... DCO has first subjected those products to scientific testing"? *See* FTC Br., p. 38. And why would such a consumer reasonably assume — as the FTC also now contends — that DCO's dietary supplement products, like pharmaceutical drugs, are "heavily regulated and subject to substantial pre-market testing"?[12] Notably, in 1994, Congress enacted the Dietary Supplements Health and Education Act ("DSHEA"), 108 Stat. 4325, wherein Congress found: "dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare." DSHEA, sec. 2(14), Pet. Br., Addendum, p. (xii). The FDA advises the public there are no clinical trials required for dietary supplements. *See* FDA, "Food: Overview of Dietary Supplements,"[13] p. 2 ("Unlike drug products that must be proven safe and effective for their intended use before marketing, there are no provisions in the law for FDA to 'approve' dietary supplements for safety or effectiveness before they reach the consumer.") *See also* Pet. Br., p. 36. Is it the position of the FTC that the fictional "reasonable consumer" that the FTC brief has created for this

---

[12] *See* FTC Br., p. 38.

[13] http://www.fda.gov/Food/DietarySupplements/ConsumerInformation/ucm110417.htm

case is ignorant and uninformed? Such paternalistic assumptions are wholly unwarranted. *See* Pearson v. Shalala, 164 F.3d 650, 655 (D.C. Cir. 1999)

B. The FTC Brief's Claim that the "Controlled Clinical Studies" Standard Was Correctly Applied to DCO's Ads Finds No Support in In re Thompson Medical Co.

The FTC brief denies DCO's argument that the ALJ and the Commission raised the bar, "by requiring that it possess competent and reliable scientific evidence consisting of clinical tests supporting its claims." FTC Br., p. 38. Instead, the FTC brief claims that it was merely setting the bar at the "level of substantiation consumers would reasonably expect," just as the FTC did in *"In re Thompson Medical Co*., 104 F.T.C. at 821-22." FTC Br., pp. 38-39.

Thompson Medical Co, is inapposite. First, Thompson Medical Company was a pharmaceutical company. In re Thompson Medical Co., 104 F.T.C. 648, 786 (1984), *aff'd.*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987). Second, the product at issue was Aspercreme, a nonprescriptive drug. *Id.* Third, the Commission had engaged in a careful analysis of what reasonable consumers might understand about the qualities and effectiveness of Aspercreme based upon representations made in the ads. *See, e.g., id.*, 104 F.T.C. at 808-10. Fourth, on appeal, the court stressed that Thompson Medical's advertising "strongly suggested" a false fact — "that Aspercreme and aspirin were somehow

related." 791 F.2d at 191. Fifth, the Commission carefully applied a six-factor test, considering: (1) the product involved; (2) the type of claim; (3) the benefits of a truthful claim; (4) the ease of developing substantiation for the claim; (5) the consequences of a false claim; and (6) the amount of substantiation experts in the field would agree is reasonable. *Id.*, 104 F.T.C. at 821-22.

In contrast, this case involves a religious ministry with a Biblical name, marketing dietary supplements (not drugs), the representations as to the effectiveness of which were not subjected to a careful assessment of reasonable consumer expectations or to a six-factor test, or any other like test. Instead, in setting the standard governing the substantiation of DCO's claims, the ALJ and the Commission relied solely on the expert opinion of one man,[14] without expertise in the field of botany or herbal medicine,[15] and in disregard of the opinion of a renowned expert in herbal medicine,[16] unilaterally to require that a herbal supplement meet the same pre-market testing standard as a pharmaceutical drug. The ALJ and Commission had the temerity to do so, notwithstanding the ALJ's finding that, as a practical matter, the "controlled clinical study" requirement

---

[14] *See* FTC Br., pp. 39-40.

[15] *See* Tr., p. 163, l.17-169, l.3, A-112-15. *See also* FTC Br., p. 41, n.14 ("Dr. Miller was not qualified as an expert botanist....").

[16] *See* ALJ Dec., FoF 330, 387, A-219, A-227.

could never be met in assessing the efficacy and safety of a dietary supplement. *See* ALJ Dec., FoF 350, A-222. It is difficult to ignore the hostility to alternative medicine implicit in the FTC's action in this case. *See, e.g.,* Alternative Medicine: Expanding Medical Horizons (A Report to the National Institutes of Health on Alternative Medical Systems and Practices in the United States), pp. xlii-xlvi (Sept. 1992).

C. The FTC Brief's Misapplication of its "Reasonable Basis" Theory in this Case Is Beyond its Statutory Authority.

In a remarkable footnote, the FTC brief claims that, notwithstanding the fact that "courts and the Commission have sometimes referred to the falsity and reasonable basis claims as separate categories[,] there is **no meaningful distinction** between the two categories." FTC Br., p. 44, n.17 (emphasis added). If true, one wonders why the original FTC complaint did not track the statutory language and charge that DCO's cancer-cure claims were, in fact, false. *Compare* 15 U.S.C. § 52 *with* Complaint ¶¶ 15, 16. And — if the two theories are the same — why did the ALJ explicitly disclaim that his analysis of DCO did not rest upon the falsity theory, but rather "[t]he Complaint in this case makes allegations under the reasonable basis theory ... the analysis in this decision considers the **reasonable basis theory only**"? *See* ALJ Dec., p. 99, A-265 (emphasis added).

The answer is simple. The standardless "reasonable basis" theory (the legitimacy of which has been unchallenged or assumed in the federal courts) allows the FTC "flexibility" to set the standard of truth-telling wherever it pleases, for whatever reason it chooses. And that is what happened in this case.

When two of DCO's expert witnesses testified that there was a "reasonable basis" for DCO's cancer-cure claims, the ALJ dismissed that testimony as falling short of the "competent and reliable scientific evidence **necessary** to substantiate advertising claims that any of the Challenged Products prevent, treat, or cure cancer, [and] inhibit tumors...." *See* ALJ Dec., FoF 387 and 397, A-227-29 (emphasis added). Relying solely on the expert testimony of the FTC's oncologist witness, the DCO expert testimony that there was a "reasonable basis" for DCO's health claims was disqualified as not sufficiently "scientific":

> "Competent and reliable scientific evidence" is required to conclude that a cancer treatment is effective.... To constitute competent and reliable scientific evidence that a product treats, cures, or prevents cancer, the product's efficacy and safety **must** be demonstrated through **controlled clinical studies**.... Clinical studies are studies on humans.... **Only** data from well-designed, **controlled, clinical trials** will substantiate claim that a new therapy is safe and effective to treat, cure, or prevent cancer. [ALJ Dec., FoF 343-346, A-221 (emphasis added).]

In justifying the imposition of what the ALJ called "a higher level of substantiation in this case,"[17] the ALJ made no reference to consumer expectations, but only to the testimony of Dr. Miller that DCO's products had not been proven by controlled clinical studies to be either efficacious or safe. *See* ALJ Dec. 103, A-269. Thus, the ALJ's conclusion had nothing to do with whether DCO's ads would mislead or deceive a reasonable consumer. Instead, the higher level of substantiation was justified as "necessary" to protect the public from what the FTC decided was a threat to the public health.

According to the ALJ, "under the 'falsity' theory, in order to prevail, the government must carry the common-sense burden of proving the express or implied message conveyed by the ad is false." ALJ Dec., p. 99, n.4, A-265. Under the "reasonable basis" theory, however, the FTC need only find some rationale to raise the evidentiary standard to a level beyond an advertiser's proffered substantiation. That rationale, as in this case, need not be concerned with the falsity or deceptiveness of DCO's advertisements. Rather, utilizing its "reasonable basis" theory, the FTC may find an ad to be false or deceptive because the FTC believes the claim to threaten the public health. That is what the FTC did in this

---

[17] ALJ Dec., p. 103, A-269.

case, but an action for such purpose is wholly unauthorized under either 15 U.S.C. sections 45 or 52.[18]

III. THE FTC BRIEF IS MISTAKEN ABOUT DCO'S CONSTITUTIONAL AND RFRA CLAIMS.

A. DCO's Reliance on Pearson v. Shalala Is Not Misplaced.

The FTC brief argues that "DCO's heavy reliance upon this Court's decision in *Pearson v. Shalala*, 164 F.3d 650 ... is misplaced." FTC Br., p. 50. It is mistaken.

In essence, the Pearson Court found that the FDA had utilized its "significant scientific agreement" rule in such a way that any claim made in violation of that rule was "inherently misleading." Pearson v. Shalala, 164 F.3d 650, 655 (D.C. Cir. 1999). Such is the case here. Under the FTC's application of its "reasonable basis" doctrine, the FTC has found DCO's cancer claims inherently misleading solely because DCO failed to substantiate them by an FTC-adopted scientific standard of "controlled clinical studies." *Compare* Comm. Op., p. 20, A-318 *with* FTC Br., p. 49. According to Pearson, then, the First Amendment applies. And the FTC must meet its burden under the three-part test

---

[18] The FTC appears to believe it may "collaborate[]" with the FDA (FTC Br., p. 48, n.24), but it may not misuse powers Congress entrusted to the FTC to regulate advertising to set a national health policy in violation of DSHEA section 2(13) (Pet. Br., Addendum, p. (xii)).

set forth in Central Hudson Gas & Elec. Co. v. Pub. Serv. Comm'n, 447 U.S. 557 (1980). *See* Pet. Br., pp. 51-53.

B. The FTC Action Violates DCO's First Amendment Religious Freedoms.

The FTC begins its defense against DCO's Establishment Clause claim with the disclaimer that, contrary DCO's contention, "the Commission did not 'adopt[] Dr. Miller's standard" that there is no room for "alternative medicine" — there being only one medicine that works. *See* FTC Br., p. 55. The administrative record proves otherwise.

At the close of his direct examination, in response to FTC Complaint Counsel's question seeking a summary answer of Dr. Miller's testimony,[19] Dr. Miller replied:

> My opinion ... is that there are no competent and reliable evidence or data to support any of the alleged beneficial effects of any of these four DCO products in the treatment of cancer.... And the other thing that **influenced me very much** was an editorial[20] ... in the New

---

[19] Tr., p. 143, ll. 1-5, A-109.

[20] Dr. Miller was referencing an article co-authored by Marcia Angell, M.D. cited in his report. A-81. He was apparently not influenced, however, by Dr. Angell's criticisms of the pharmaceutical industry (including how it "uses its immense wealth and power to co-opt nearly every institution that might stand in its way — including the U.S. Congress, the Food and Drug Administration (FDA), and the medical profession itself", as well as the operations of "contract research organizations" such as the one for which Dr. Miller works). *See* M. Angell, M.D.,

> England Journal of Medicine [that] [t]here is **not** a thing of **two kinds of medicine**. There's not conventional medicine and alternative medicine. There is **one medicine**, medicine that works. The other medicine may or may not work, but to show that it works you have to go through the process [of controlled clinical studies] that we've talked about all day today. [Tr., p. 143, ll. 13-17, 19-21, 144, ll.1-6, A-109 (footnote added, emphasis added).]

The ALJ, in turn, adopted Dr. Miller's views as his own:

> The need to substantiate a claim of anti-cancer activity with competent and scientific evidence is the same whether the purported agent is a herbal medicine or a conventional pharmaceutical agent. "**There [are] not ... two kinds of medicine**. There's not conventional medicine and alternative medicine. There's **one medicine**, medicine that works. The other medicine may or may not work, but to show that it works you have to go through the process.... (Miller Tr., 144). [ALJ Dec., FoF 354 (emphasis added).]

And, citing this very ALJ finding, the Commission applied Dr. Miller's singular world view of medicine to this case:

> [Dr. Miller] testified that ... the need to substantiate a claim by **clinical studies** (*i.e.,* on humans) was the **same** whether the purported agent was a **herbal** medicine or a more conventional **pharmaceutical** agent. IDF 354. [Comm. Op., p. 18, A-316 (emphasis added).]

By so endorsing and applying Dr. Miller's testimony, the FTC has established the religion of scientism to rule the advertising of nutritional supplements.

The Truth About the Drug Companies: How they Deceive Us and What to Do About it (Random House, 2005), p. x, chapters 1, 2, 7 and 11. Nor was Dr. Miller influenced by scholarly critiques of the controlled clinical trial. *See, e.g.,* H. Coulter, Ph.D., The Controlled Clinical Trial, An Analysis (Center for Empirical Medicine, 1991).

The FTC brief protests mightily that it has done no such thing — that "the Commission has **in no way** ruled out 'alternative medicine'" — that "[**n]othing** it has done restricts the marketing of alternative medicines." *See* FTC Br., pp. 55-56 (emphasis added). That is blatantly untrue. The FTC has issued an Order that forbids DCO from making any representation — even if true and nonmisleading — that any of its nutritional supplement products benefit one's health **unless** DCO "**possess[es] and rel[ies]** upon competent and reliable scientific evidence [*i.e.,* "controlled clinical studies"] that **substantiates** the representation." *See* Order, Parts II and III, A-335-36 (emphasis added).

Amazingly, the FTC claims that DCO has brought this ban onto its own head because DCO had previously failed to state that its product claims were based on "subjective statements of belief and healing, and that nothing it claimed about its products was based on science." *See* FTC Br., p. 56. Indeed, the FTC has asserted that:

> [I]t might have been possible, in its advertising, for DCO to clarify its claims so that all reasonable consumers would understand that its claims were based on **Biblical teachings and nothing else**. If DCO had crafted its advertisements in this manner, and also ensured that other aspects of the advertisements did not convey any misleading impression ... then its advertising would not have been deceptive, so long as it was clear that the claim was **based on theology rather than science.** [FTC Br., pp. 36-37 (emphasis added).]

Under the Order issued in this case, however, there is no room for Biblically-based representations, even if true and nonmisleading. Science trumps theology. Not only must DCO "possess" what the FTC views to be competent and reliable scientific evidence for any advertised health-related benefit, it must "rely" on that evidence in order to comply with the Order. The FTC appears blind to its anti-Biblical prejudice. Yet, the very essence of "scientism" is the foreclosure of all other sources of truth other than those that are based upon the empirical method. As one history professor, Walter W. Davis, has written in a telling chapter entitled "Science and Humanism: The Rise of a New Deity,"[21] with the rise of "empirical experimentalism and a new confidence in man's ability to promote human progress through science"[22]:

> All knowledge was experientially apprehended; there were no revealed, no self-evident truths. [*Id.* at 145.]

Under the FTC Order there is no room for the marketing of any of DCO's dietary supplements or herbal products on any basis other than "science" as unilaterally determined by the FTC. To suggest otherwise, as the FTC brief does, is belied by the requirement of Parts II and III of the Order that DCO not only

---

[21] W. Davis, Eastern & Western History, Thought & Culture, p. 141 (Univ. Press of America: 1993).

[22] *Id.*

possess, but rely on, competent and reliable scientific evidence. The FTC's constraints on DCO are unconstitutional. *See* United States v. Ballard, 322 U.S. 78 (1944).

C. By Demanding that DCO Pay Homage to the FTC, as Required by Part V.B of the Order, the FTC Has Violated the First Amendment and RFRA.

Not content with an Order that would require only DCO's external obedience to Parts II and III of the Modified Final Order, the FTC demands DCO's internal obeisance, by commanding the sending of the letter required by Part V.B of that Order. The FTC brief argues that the FTC had cleansed the letter so as to "ensure that DCO is *not* required to repudiate any of its beliefs or 'embrace the FTC' **secular belief,**" but admits that the required letter "must recite that *the FTC* has found its past advertising claims to be deceptive, and that 'the FTC requires that we send you the following information *from the FTC* about scientific evidence on these products.'" FTC Br., pp. 59-60 (bold and italics in original).

As the FTC brief concedes, "DCO is being required to deliver the message," and the message to be delivered is exclusively that of the FTC. *See* FTC Br., p. 60. The FTC brief's sole professed justification for DCO being so ordered is "to ensure that [the letter] actually gets to the consumers in question...." *Id.* But

DCO has already furnished the names and addresses of the consumers for the period required by Part V.A of the Order. If the FTC really were concerned that the letter actually get to the consumers in question, then the FTC, itself, would already have sent the letter.

The truth is that the FTC insists upon DCO sending the required letter because it wants DCO to pay the FTC homage — to "bow the knee." *See* 1 Kings 19:18. As DCO has repeatedly informed the FTC, it cannot render such obeisance to the FTC without violating the First Commandment. *See* Exodus 20:3-5; Deuteronomy 5:7-9. To require DCO to do so violates the "speaker autonomy" principle of the First Amendment,[23] as well as the establishment and free exercise guarantees of the First Amendment, and substantially burdens DCO's exercise of religion in violation of the Religious Freedom Restoration Act.[24]

---

[23] The FTC brief argues that the "speaker autonomy" rule does not apply because the letter must be viewed "in the context of a commercial transaction." FTC Br., p. 54, n.24. To the contrary, the Supreme Court unhesitatingly applied the rule to a gas and electric company's "billing envelope." *See* Pacific Gas and Electric Co. v. California P.U.C., 475 U.S. 1, 17 (1986).

[24] *See* Pet. Br., pp. 55-60.

Respectfully submitted,

/s/ Herbert W. Titus

*Herbert W. Titus
William J. Olson
John S. Miles
Jeremiah L. Morgan
WILLIAM J. OLSON, P.C.
370 Maple Ave. W., Ste. 4
Vienna, Virginia 22180-5615
(703) 356-5070
wjo@mindspring.com
Attorneys for Petitioners

*Counsel of Record
October 1, 2010

CERTIFICATE OF COMPLIANCE

It is hereby certified, pursuant to Rule 32(a)(7)(C), Federal Rules of Appellate Procedure, that the foregoing brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 6,949 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using WordPerfect 13.0.0.568 in 14-point Times New Roman.

/s/ Herbert W. Titus
Herbert W. Titus
Counsel of Record for Petitioners

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

DANIEL CHAPTER ONE, a corporate sole, and JAMES FEIJO individually, and as an officer of Daniel Chapter One, Petitioners, v. FEDERAL TRADE COMMISSION, Respondent.	)	No. 10-1064

CERTIFICATE OF SERVICE

I hereby certify that on October 1, 2010, the foregoing Reply Brief of Petitioners was served upon respondent, the Federal Trade Commission, by the Court's Case Management/Electronic Case Files system upon the following attorneys for respondent:

John F. Daly, Esquire
Federal Trade Commission
(FTC) General Counsel
600 Pennsylvania Ave., NW
Washington, DC 20580
jdaly@ftc.gov

Lawrence DeMille-Wagman, Esquire
Federal Trade Commission
(FTC) Office of Policy Planning
600 Pennsylvania Ave., NW
Washington, DC 20580
lwagman@ftc.gov

/s/ Herbert W. Titus

Herbert W. Titus
WILLIAM J. OLSON, P.C.
370 Maple Ave. W., Ste. 4
Vienna, Virginia 22180-5615
(703) 356-5070
wjo@mindspring.com