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

BRIEF OF PETITIONERS

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August 18, 2010

DISCLOSURE OF CORPORATE AFFILIATIONS AND FINANCIAL INTEREST

Petitioner Daniel Chapter One is a nonprofit, nonstock corporation sole organized under the laws of the State of Washington, and no parent company or any publicly traded company owns any part of Daniel Chapter One. Petitioner James Feijo is an individual and is unrelated to any corporation within the intendment of Rule 26.1.

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

(A) Parties and Amici. Petitioners were the respondents in the case below, In the Matter of Daniel Chapter One, *et al.*, Docket No. 9329, before the Federal Trade Commission, and respondent herein, the Federal Trade Commission, was the complainant in the proceeding below.

(B) Ruling Under Review. The petitioners seek this Court's review of the Modified Final Order issued by the Federal Trade Commission on January 25, 2010, in FTC Docket No. 9329.

(C) Related Cases. On August 13, 2010, the United States filed a Complaint for Civil Penalties, Injunction, and Other Relief against the petitioners herein, alleging violations of the FTC's Modified Final Order. The case is pending in the

United States District Court for the District of Columbia (Civil No. 1:10-cv-01362-EGS).

/s/ Herbert W. Titus
Herbert W. Titus

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TABLE OF AUTHORITIES

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

MISCELLANEOUS

GLOSSARY OF ABBREVIATIONS

ALJ	Administrative Law Judge
ALJ Dec.	Initial Decision of the Administrative Law Judge
APA	Administrative Procedures Act
Commission	Federal Trade Commission
Comm. Op.	Opinion of the Commission
Compl.	Complaint
DCO	Daniel Chapter One and James Feijo, its Overseer
DSG	Dietary Supplement Guide
DSHEA	Dietary Supplement Health and Education Act of 1994
FDA	Food and Drug Administration
FTC	Federal Trade Commission
FTC Act	Federal Trade Commission Act
FoF	Findings of Fact
Four Challenged Products	Bio*Shark, 7 Herb Formula, GDU, and BioMixx
IRC	Internal Revenue Code
J.F. Tr.	James Feijo Testimony

Miller Report	Expert Report of Denis R. Miller, M.D.
Miller Tr.	Denis Miller Testimony
Order	Modified Final Order
P.F. Tr.	Patricia Feijo Testimony
RCW	Revised Code Washington
RFRA	Religious Freedom Restoration Act

JURISDICTIONAL STATEMENT

The Federal Trade Commission ("FTC" or "Commission") asserts jurisdiction under the section 5(b) of the Federal Trade Commission Act (15 U.S.C. § 45(b) ("FTC Act"), which empowers the Commission to issue a complaint for engaging in an unfair or deceptive act or practice in or affecting commerce under sections 5(a) and 12 of the FTC Act (15 U.S.C. §§ 45(a) and 52), committed by a corporation "organized to carry on business for its own profit or that of its members" under section 4 of the FTC Act (15 U.S.C. § 44).

On September 16, 2008, the FTC issued a complaint against petitioners, Daniel Chapter One, a nonprofit corporation sole, and its overseer, James Feijo (hereinafter collectively "DCO").

On January 25, 2010, after a hearing before an Administrative Law Judge, and an appeal to the Commission, the FTC issued its Modified Final Order ("Order") directing DCO to cease and desist from certain specified acts and practices and perform certain other acts. In the Matter of Daniel Chapter One, *et al.*, FTC Docket No. 9329.

This Court has jurisdiction pursuant to section 5(c) of the FTC Act (15 U.S.C. § 45(c)), which provides for judicial review of an FTC final order in any appropriate court of appeals of the United States. On March 17, 2010, DCO

timely filed its Petition for Review of the Order, which is a final order disposing of all parties' claims.

STATEMENT OF THE ISSUES

1. Whether the FTC erred, as a matter of law, in determining that DCO, a religious nonprofit corporation sole, was subject to the jurisdiction of the FTC under 15 U.S.C. section 44?

2. Whether the FTC is authorized by 15 U.S.C. sections 45(a) and 52 to have imposed on DCO the burden to substantiate its representations concerning health benefits of its dietary supplements by what the FTC unilaterally determines to be "competent and reliable scientific evidence"?

3. Whether the Dietary Supplement Health and Education Act of 1994 (Pub. L. 103-417, 108 Stat. 2860) ("DSHEA") is in conflict with the FTC's application of its standard of "competent and reliable scientific evidence" to DCO's health benefit representations with respect to its dietary supplements?

4. Whether the FTC's determination that DCO engaged in deceptive advertising because it failed to substantiate its health benefit representations by "competent and reliable scientific evidence" is arbitrary and capricious?

5. Whether the FTC's adoption and application of its "competent and reliable evidence" standard as the sole test of the lawfulness of DCO's health

benefit representations is an unconstitutional establishment of the religion of scientism in violation of the First Amendment?

6. Whether the First Amendment's commercial speech doctrine required the FTC to meet the three-part test set forth in Central Hudson Gas & Elec. Corp. v. Public Serv. Comm. Of New York, 447 U.S. 557, 566 (1980), which the FTC failed to meet?

7. Whether Parts II, III, and V.B of the FTC's Order substantially burden DCO's "exercise of religion" in violation of the Religious Freedom Restoration Act (42 U.S.C. §§ 2000bb-1, *et seq*.) ("RFRA")?

8. Whether Part V.B of the Order violates DCO's right of "speaker autonomy" as secured by the First Amendment?

STATUTES AND REGULATIONS

The pertinent constitutional provisions, statutes and regulations are set forth in the Addendum, *infra.*

STATEMENT OF THE CASE

DCO's petition for review challenges a final order issued by the FTC on January 25, 2010, against DCO in FTC Docket No. 9329.

The FTC Complaint (R. 2, A-23-61)[1] charged DCO with having engaged in deceptive acts or practices in violation of sections 5(a) and 12 of the FTC Act in connection with its advertising, promotion, and offering for sale four dietary supplement products: Bio*Shark, 7 Herb Formula, GDU, and BioMixx (hereinafter collectively "Four Challenged Products"). Specifically, the FTC charged that (i) DCO's ads created the overall net impression that the Four Challenged Products, either expressly or impliedly, were effective "in the treatment of cancer" or would "inhibit tumor growth," and (ii) DCO did not have, possess, or rely upon a "reasonable basis" that substantiated those claims. *See* Complaint ("Compl."), R. 2, ¶¶ 14-16, A-27.

The Complaint sought an order commanding DCO, *inter alia*, to cease and desist making any advertisement in connection with the sale of any dietary supplement, "unless the representation is "true, non-misleading, and at the time that it is made, [DCO] possess and rely upon competent and reliable scientific evidence that substantiates the representation." *See* Comp., Order Part II, A-30.

DCO filed pre-hearing motions to dismiss the case and for summary decision based, *inter alia,* on: (i) FTC's lack of jurisdiction of DCO under section

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[1] References to "R" are to the record as set forth in the docket entries provided by the FTC. Page references to "A-" are to the pages of the Appendix to the briefs.

44 of the FTC Act; (ii) FTC's lack of statutory authority under sections 5(a) and 12 of the FTC Act; (iii) violations of the constitutional guarantees of freedom of religion, freedom of speech, and due process of law; and (iv) violation of RFRA. *See* DCO Motions, R. 18, R. 40. The Administrative Law Judge ("ALJ") dismissed the RFRA claim as untimely, and denied all other motions on the merits. R. 27, R. 48, R. 49, R. 63, R. 103.

After discovery and hearing, the ALJ issued his Initial Decision ("ALJ Dec."), including 425 Findings of Fact ("FoF"), concluding that DCO's advertisements in connection with the Four Challenged Products were "misleading" because DCO had failed to substantiate that, at the time that the ads were made, it had possessed and relied upon the only type of "competent and reliable scientific evidence" that the FTC would accept — "controlled clinical studies" such as are required by the Food and Drug Administration ("FDA") for approval of a new pharmaceutical drug. ALJ Dec., pp. 99-107, A-265-273. The ALJ also denied all of DCO's constitutional defenses. From these rulings, DCO appealed to the Commission.

On December 18, 2009, the Commission affirmed, adopting all of the ALJ's findings of fact, as well as the ALJ's specific conclusion that DCO's ads in connection with the Four Challenged Products were misleading because DCO did

not possess or rely upon the kind of "controlled clinical studies" necessary for a new drug to obtain FDA approval. Opinion of the Commission ("Comm. Op."), pp. 18-22, A-316-320. Additionally, the Commission affirmed the ALJ's constitutional rulings, but unlike the ALJ, ruled on and denied DCO's RFRA defense on the merits. Comm. Op., pp. 10-18, 21-25, A- 308-16, A-319-23. On the same date, the Commission issued its initial final order. R. 134, A-324.

On January 25, 2010 — to correct an error in its initial final order — the Commission amended its December order, issuing a modified final order, which is the Order now subject to this petition for review. R. 138, A-334.

On March 17, 2010, pursuant to 15 U.S.C. section 45(c), DCO filed its timely petition for review.[2]

STATEMENT OF FACTS

A Christian Ministry

During the entire time period covered by the Complaint, DCO was engaged, as a nonprofit corporation sole, in a Christian spiritual and physical wellness ministry. *See* ALJ Dec., FoF 16-19, 28-29; A-273-75.

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[2] Pursuant to 15 U.S.C. § 45(g)(2)(A) and 16 C.F.R. § 3.56(b), DCO applied to the Commission for a stay of the Order. R. 139. On March 23, 2010, the application was denied. Pursuant to 15 U.S.C. § 45(g)(2)(B), F.R. App. P. 18, and D.C. Cir. R. 18, DCO filed an emergency motion with this Court for stay pending review of the Order. On April 1, 2010, the motion was denied.

Birthed in 1983 as a "house church,"[3] DCO "was created for the purpose of healing based on the [holy] scripture[s,] including Genesis 1:29." ALJ Dec., FoF 11, 16; A-173. Inspired by the first chapter of the book of Daniel — wherein it is recorded that "Daniel and men ... were expected to eat the king's very rich diet..., but instead ate and drank only pulse and water" — DCO embarked on a ministry based upon the "integration of spiritual and physical well being." ALJ Dec., FoF 17-18; A-173.

In 1986, DCO opened a health food store and began offering for sale dietary supplements to meet people's physical needs. ALJ Dec., FoF 12; A-173. By the mid-1990's, DCO — using the skills, training, and spiritual gifts of James and his wife, Patricia Feijo[4] — developed its own dietary products, including the Four Challenged Products — BioMixx, Bio*Shark, 7 Herb Formula, and GDU. ALJ Dec., FoF 13; A-173. By 1998, DCO had created the website,

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[3] *See, e.g.,* F. Viola, Pagan Christianity?: Exploring the Roots of Our Church Practices, pp. xxv-xxx, 1-46 (Tyndale House Pub.: 2002); F. Viola, Reimagining Church, pp. 15-18, 83-116 (David C. Cook Pub.: 2008); L. Ball, "House Church: Skip the Sermon, Worship at Home" (Associated Press: Jul. 21, 2010) ("House church is about relationships forged in small faith communities.") http://news.yahoo.com/s/ap/20100721/ap_on_re/us_rel_religion_today.

[4] *See* J. Feijo Testimony ("J.F. Tr.") 422, l. 5 - 434, l. 2; 437, l. 10 - 450, l. 3; A-137-145, A-147-156.

"www.danielchapterone.com," which became its major outlet for the marketing of DCO's dietary supplements. ALJ Dec., FoF 14; A-173.

Beginning in 2000, DCO launched a Monday through Friday, two-hour-per-day radio program, called "Daniel Chapter One Health Watch." ALJ Dec., FoF 36 and 108; A-175, A-182. Co-hosted by the Feijos, the program offered integrated spiritual and physical counseling on healing and well-being, as well as a "toll-free number that people can call to purchase the Four Challenged Products." ALJ Dec., FoF 100, 111; A-182-183. The Feijos counseled directly persons who called into the radio program, sharing their knowledge of the Challenged Products, personal testimonies, and the word of God. ALJ Dec., FoF 110, 213-14, 216; A-183, A-198.

From 1983 through 2002, DCO conducted its Christian spiritual and physical wellness ministry as an unincorporated house church, but operated its dietary supplement branch under the auspices of a for-profit corporation. ALJ Dec., FoF 22, 27; A-174. In 2002, three years before the beginning of the time period covered by the FTC Complaint, James Feijo reorganized DCO, including the house church, to function as a nonprofit corporation sole under the laws of the State of Washington. *See* ALJ Dec., FoF 28; A-174.

Under its new Articles of Incorporation as a corporation sole, DCO was authorized "[t]o do whatever will promote the Kingdom of God ... to provide for the comfort, happiness, and improvement of an indefinite number of natural men and women ... providing lawful advice, educating people in the fundamental principles of liberty ... as well as other worthwhile projects for the common good of Daniel Chapter One and its close associates...." ALJ Dec., FoF 29; A-175. Pursuant to this charter mandate, DCO was enabled under Washington state law as a united corporate body to operate its house church,[5] and to engage in commerce[6] in support of its overall religious mission promoting spiritual and physical health and wellness, all funds derived therefrom being held by James Feijo in his capacity as overseer[7] and trustee[8] for the work of the ministry.

Serving DCO full-time, the Feijos reside in, and operate the ministry from, two different properties, one of which is owned by DCO and the other by another corporation sole, Messiah Y'Shua Shalom, of which James Feijo is also the overseer and trustee. ALJ Dec., FoF 34, 55; A-175, A-177. The Feijos have

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[5] *See* Revised Code Washington ("RCW") 24.12.010; ALJ Dec., FoF 1; A-172.

[6] *See* RCW 24.12.020; ALJ Dec., FoF 8; A-172.

[7] *See* RCW 24.12.010; ALJ Dec., FoF 5; A-172.

[8] *See* RCW 24.12.030; ALJ Dec., FoF 6, 40; A-172, A-176.

nonexclusive use of two automobiles owned by DCO. ALJ Dec., FoF 56-57; A-175. From the proceeds of its sales of 150-200 dietary supplements,[9] DCO pays all ministry operating expenses (including personnel),[10] and "the Feijos' living expenses."[11]

In short, from 2002 when DCO was formed as a corporation sole, and throughout the period covered by the FTC Complaint, DCO has operated as a religious ministry, combining the teaching Biblical principles of spiritual and physical wellness and the promotion and sales of related products. *See* ALJ Dec., FoF 16-18, 29; A-173, A-175. *See also* J.F. Tr. 415, l. 23 - 423, l. 4; A-133-138.

Product Development

DCO's dietary supplements are created by means of "a combined spiritual and scientific approach that maintains the balance of bodily systems [termed] BioMolecular Nutrition." ALJ Dec., FoF 85; A-180. Through a publication entitled "BioGuide: The BioMolecular Nutrition Guide to Natural Health," DCO explains that the developed products combined "the spiritual and the physical," a combination that was missing in other products offered by nutritionists and

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[9] *See* ALJ Dec., FoF 8; A-172.

[10] *See* ALJ Dec., FoF 77, 83; A-179-80.

[11] *See* ALJ Dec., FoF 58; A-178.

biochemists. ALJ Dec., FoF 87; A-180. The BioGuide, in turn, contains "descriptions of DCO products, testimonies from people who have used DCO products and doctors who recommend[ed] the products, as well as Biblical passages." ALJ Dec., FoF 89; A-181.

In the development of the Four Challenged Products, DCO "did not conduct or direct others to conduct," nor were they "aware of, " any "scientific testing" of the effects of such products by means of the kinds of clinical studies required by the FDA for pharmaceutical drugs. *See* ALJ Dec., FoF 308-15, 327-28, 343-49; A-217-219, A-221-22. Such testing is "a particularly challenging and costly endeavor to undertake for testing herbal products, because it is difficult to extract and test a single chemical component from an herb, and because an herb may comprise thousands of chemical components." ALJ Dec., FoF 350; A-222.

Instead, DCO "relied upon a variety of materials, books, magazines, and articles ... which provided them with an understanding of how certain substances in the Four Challenged Products could be utilized to help healing." ALJ Dec., FoF 318; A-217.[12] Drawing on the Feijos' educational and professional experience,[13]

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[12] *See, e.g.,* ALJ Dec., FoF 225; A-200.

[13] Mr. Feijo holds both a bachelor's and a master's degree with emphasis on biology, and the sciences. Compl., Exh. B, A-46; J. F. Tr. 416, A-133. A graduate of the New England School of Homeopathy, Mrs. Feijo is an

and by God's inspiration, Mr. Feijo developed, for example, 7 Herb Formula based on research into "God-given nutrients [that] deal with health issues," producing thereby a more effective dietary supplement, as attested to by individual users calling into the DCO HealthWatch radio program. Compl., Exh. B, A-39. As was true of 7 Herb Formula, so it was with the three other products at issue — DCO relied upon research, and communicated "personal observations and customer testimonials" to substantiate their curative effects. ALJ Dec., FoF 316; A-217. *See, e.g.,* ALJ Dec., FoF 182-89, A-191-92; FoF 197-208, A-194-97; FoF 241-43, A-204-05; FoF 267-68, A-208-09; FoF 273-74, A-209-10. *See also* Compl., Exh. B, A-39 (7 Herb Formula); J.F. Tr. 442-44, A-151-52 (GDU); J.F. Tr. 444-49, A-152-55 (BioMixx); J.F. Tr. 449-51, A-156-57 (Bio*Shark).

In sum, the Four Challenged Products were developed on a Biblical foundation that nutrients extracted from their natural form in God's creation can help trigger the body to heal itself. J.F. Tr., 434 l. 3 - 435, l. 25; A-145-46. Thus, DCO's ministry offers a Biblically-based alternative to conventional medicine — an optional path to avoid dangerous and toxic pharmaceutical drugs that oftentimes harm rather than heal. *See* J.F. Tr. 435-37, 451; A-146-47, A-157.

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experienced homeopathic practitioner with a background in cancer research. Compl. Exh. B, A-46; Patricia Feijo Testimony ("P.F. Tr.") 346, l. 6 - 348, l. 8; A-126-27.

Testimonial Marketing

DCO reaches out to the general public[14] with its message of spiritual and physical wellness and products of natural healing through its Internet website,[15] printed publications,[16] personal counseling,[17] radio broadcasts,[18] call center, and stores and distributors.[19] Through these media, DCO presents information about the Four Challenged Products (*see* ALJ Dec., FoF 158; A-188) and personal testimonies of cancer sufferers who benefitted from one or more of the products. *See, e.g.,* ALJ Dec., FoF 179-219; A-189-99.

In support of the statement that Bio*Shark "can stop tumor growth," DCO urged readers of its webpage to "'Read our clients' testimonials...." ALJ Dec., FoF 221; A-199.[20] In support of the statements that 7 Herb Formula "purifies the blood," "promotes cell repair," "fights tumor formation," and "fights pathogenic

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[14] *See* ALJ Dec., FoF 82; A- 180.

[15] *See* ALJ Dec., FoF 32; A-175.

[16] *See* ALJ Dec., FoF 15; A-173.

[17] *See* ALJ Dec., FoF 19; A-174.

[18] *See* ALJ Dec., FoF 108-111; A-182-83.

[19] *See* ALJ Dec., FoF 84; A-180.

[20] *See also* ALJ Dec., FoF 231; A-200.

bacteria," DCO's website was linked to "Page shortcuts to testimonials about cancer." ALJ Dec., FoF 241; A-204.[21] In support of its statement that "7 Herb Formula battles cancer," DCO cited the testimony of a father healed of prostate cancer. ALJ Dec., FoF 253; A-206. In its webpage ad for GDU, DCO encouraged the reader to "Read our clients testimonials on using this anti-inflammatory," linking the reader up to a testimonial entitled "Breast Mass" and another denoted "Nancy — cured Breast Cancer in 3 months." ALJ Dec., FoF 265, 267-68; A-208-09.[22] In support of the statement that, if one suffers from any type of cancer, he should take BioMixx, DCO's webpage included a "testimonial, accompanied by a photograph of a smiling woman" with the headline, "*Tracey was given no hope!*" ALJ Dec., FoF 283-84; A-211-12. *See also* ALJ Dec., FoF 290, 292; A-213.

Entirely missing from any of these advertisements was any representation, express or implied, that any health claim made as to any of the Four Challenged Products was backed up by (i) clinical trials, randomized, controlled, or otherwise, or (ii) even by "competent and reliable scientific evidence."[23] Generally, DCO

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[21] *See also* ALJ Dec., FoF 243; A-204-05.

[22] *See also* ALJ Dec., FoF 273, 274, 276; A-209-210.

[23] DCO's occasional references to scientific studies were never presented in such a way as to encourage specific reliance upon them as support for DCO's product claims. For example, DCO's webpage ad for Bio*Shark stated

marketed the Four Challenged Products by providing personal testimonies witnessing to the effectiveness of those products with the message that each person has the right to choose one's own medical treatment. ALJ Dec., FoF 266, A-208. To assist that free choice, DCO provided descriptions of each product, listing its ingredients and specific uses. *See* Compl., Exhs. A-D, A-36-61. Additionally, DCO placed warnings on the Internet, including disclaimers, along with the statements that "[t]he information on this website is [:] [i] intended to provide a record, and testimony about God and His creation, and (ii) designed to support the relationship that exists between a patient/site visitor and his/her health care provider." *See* Compl., Exhs. A-C, A-36-58.

The FTC Attack

On September 18, 2008, by a press release entitled, "FTC Sweep Stops Peddlers of Bogus Cancer Cures," the FTC announced that it had initiated "11 law enforcement actions, including the one against DCO, challenging deceptive advertising of bogus cancer cures," including "**some complaints** ... that the

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that "[s]cientists recognize the benefit of starving a tumor to limit its growth," but that "[t]hese scientists are trying to replicate what God has already presented to us so that they can claim rights to it, patent it and make a lot of money." ALJ Dec., FoF 231, A-202. *See also* ALJ Dec., FoF 276, A-210.

companies ... **falsely touted clinical or scientific proof** for their products."[24] However, the FTC never charged that DCO had "falsely touted clinical or scientific proof" for the Four Challenged Products. *See* Compl., ¶¶ 1-16, A-23-27. Nevertheless, the FTC sought to prevent DCO from making health-related representations about any products unless DCO "possessed and relied upon competent and reliable scientific evidence," even if the representation would otherwise be "true and nonmisleading." *Id.*, Order ¶¶ I and II, A-29-30.

At the hearing before the ALJ, the FTC adduced **no evidence** of any person who was **harmed** by one of DCO's products, **nor** any person who had filed a **complaint** against DCO. And **no** person testified that he had been **misled, or deceived.** The FTC never disproved any of the personal testimonies shared by DCO, or challenged the statements that DCO's products have helped people in the treatment of cancer even after conventional methods had been tried and failed, and they were sent home by their doctors to die.

SUMMARY OF ARGUMENT

Misapplying both section 44 of the FTC Act and Internal Revenue Code ("IRC") section 501(c)(3), and ignoring Washington state law, the FTC erroneously exercised jurisdiction over DCO, a nonprofit religious corporation,

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[24] http://www.ftc.gov/opa/2008/09/boguscures.shtm (emphasis added).

having mistakenly concluded that DCO was "organized to carry on business for its own profit or that of its members."

Additionally, the FTC acted outside its statutory authority, imposing the FDA standard of "controlled clinical studies" governing approval of new pharmaceutical drugs to DCO's dietary supplements. Sections 5(a) and 12 of the FTC Act prohibit deceptive acts and practices and false advertising, not the marketing of dietary supplements even if the FTC believes them unsafe or inefficacious. Yet, the Complaint against DCO did not allege, nor did the FTC prove, that DCO's actual representations as to the efficacy of the dietary supplements challenged in this case were, in fact, false.

Instead, invoking its contrived "reasonable basis" theory, the FTC layered its case against DCO. First, the FTC substituted its "overall net impression" of what DCO actually said about the cancer/tumor health-benefits of its dietary supplements. Second, the FTC required DCO to substantiate the FTC's impressions of DCO's health benefit claims on the theory DCO had implied that — at the time that DCO had made its health benefit claims — DCO possessed and relied upon a "reasonable basis" to substantiate the FTC's "overall net impression" of those claims.

When DCO presented expert testimony that there was such a "reasonable basis," the FTC raised the bar, insisting that — since DCO had made health benefit claims for its products — it was required to substantiate those claims by "competent and reliable scientific evidence." And then, in a final *coup de grace*, the FTC insisted that — since DCO's health benefit claims concerned tumors and cancer — DCO could substantiate its claims only by evidence of efficacy that would satisfy the FDA "controlled clinical studies" test for new pharmaceutical drugs.

While the FTC required DCO to meet this "high" standard, it did not require itself to show that DCO represented that its cancer/tumor health claims were based on such "controlled clinical studies," and therefore, were deceptive and misleading. Rather, the FTC imposed the FDA standard because it claimed authority under the FTC Act to set health and safety policy for dietary supplements. But the FTC Act does not authorize the FTC to set such policy. Indeed, the FTC is in conflict with the Dietary Supplement Health and Education Act of 1994 when setting any such policy in connection with dietary supplements.

Furthermore, the FTC utterly failed to lay a factual predicate to support its application of the FDA standard of "controlled clinical studies" to dietary supplements. To the contrary, the FTC's adoption of that standard was

undermined by its own factual findings that it was neither suitable nor feasible. Undeterred by evidence, the FTC imposed the FDA standard on a foundation of religious faith — "scientism" — in violation of the First Amendment prohibition against laws respecting an establishment of religion.

At no point in the administrative proceedings did the FTC attempt, or succeed, in proving DCO's product representations to be actually misleading. Rather, the FTC merely charged and found that DCO's representations were presumed to be misleading, having failed to meet a pre-determined scientific standard. Contrary to the FTC's ruling, DCO's representations are entitled to First Amendment protection under the "commercial speech" doctrine as applied in Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999).

DCO is also entitled to the protection of the Religious Freedom Restoration Act and the First Amendment insofar as the FTC's final order substantially burdens its "exercise of religion" and violates the well-established rule of "speaker autonomy."

STANDING

DCO has standing because the Order mandates that DCO cease and desist from certain acts and perform other acts, which has caused, and will continue to

cause, DCO actual injury-in-fact, which injury can be redressed in this Court. *See* Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992).

ARGUMENT

I. THE FTC FAILED TO ESTABLISH JURISDICTION OVER DANIEL CHAPTER ONE, A NONPROFIT RELIGIOUS CORPORATION.

The FTC "has only such jurisdiction as Congress conferred upon it." Community Blood Bank v. FTC, 405 F.2d 1011, 1015 (8th Cir. 1969). "[I]f the jurisdiction of the Commission is challenged, it bears the burden of establishing its jurisdiction." *Id.* At the hearing and on appeal, DCO challenged the jurisdiction of the FTC on the ground that DCO is **not** a corporation that is "organized to carry on business **for its own profit or that of its members**" — within the meaning of 15 U.S.C. section 44 (emphasis added). The FTC erred by applying an erroneous legal standard to the question of jurisdiction, having misapplied the rule of Community Blood Bank. The standard of review is *de novo.* Skidmore v. Swift & Co., 323 U.S. 134, 137 (1944). *See also* Community Blood Bank, 405 F.2d at 1015-22.

A. The FTC Applied an Erroneous Legal Standard.

The Complaint charged that DCO had engaged in deceptive practices since 2005. Compl., ¶ 5, A-24. However, the FTC found that DCO had been

"organized" as a nonprofit corporation sole since 2002, having been so incorporated under the laws of Washington state. ALJ Dec., FoF 28; A-174; Comm. Op., p. 4, A-302. According to Washington state law, a corporation sole, by definition, is a church or religious society organized by a single overseer with the duty of holding all corporate property in "trust for the use, purpose, benefit, and behoof of his religious denomination, society or church." *See* RCW §§ 24-12.010 -24.12.030.

Article 3 of DCO's Articles of Incorporation dedicates DCO "to do whatever will promote the Kingdom of God," including "educating people in the fundamentals of liberty." ALJ Dec., FoF 29; A-175. In an effort to circumvent DCO's express Christian purpose,[25] as well as the statutory constraints placed on it by Washington state law, the FTC claimed that "DCO bears **none** of the substantive indicia of a corporation that is truly organized **only for charitable purposes.**" ALJ Dec., p. 71, A-237; Comm. Op., p. 8, A-306 (emphasis added).

Without citing any authority, the ALJ apparently mistakenly assumed that only entities that have obtained a "Section 501(c)(3) tax exemption" are not organized to carry on business for its own profit or that of its members, and therefore, are beyond FTC jurisdiction. *See* ALJ Dec., pp. 71-72, A-237-38.

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[25] *See* Matthew 6:33; Mark 1:14; Luke 4:4, John 3:3, and Acts 1:3.

However, 15 U.S.C. section 44 does not reference IRC section 501(c)(3), and even under that test, churches have automatic IRC section 501(c)(3) status, without the need to apply for such status. *See* IRC § 508(c)(1)(A). The ALJ also mistakenly assumed that, because DCO had not provided explicitly in its Articles for nonprofit distribution of its assets upon dissolution, it would not qualify for section 501(c)(3) tax-exempt status. *See* ALJ Dec., pp. 70-72, A-236-38; Comm. Op., p. 8, A-306. The IRS does not require absolutely that such a provision appear in the articles of incorporation of an organization exempt under IRC section 501(c)(3) if the entity's assets would, upon dissolution, be so distributed by operation of state law. *See* PPC's 990 Deskbook, p. 18-8 (18th ed. Thomson-Reuters: Jan. 2010).

The FTC made no attempt whatsoever to examine whether the DCO Articles and Washington state law created an express and enforceable trust that DCO's assets were required to be so distributed upon dissolution of DCO. *See* In re Catholic Bishop of Spokane, 329 Bankr. Rep. 304, 325-26 (E.D. Wash. 2005). Rather, the FTC assumed that DCO had the burden of showing compliance with 26 U.S.C. section 501(c)(3) in order to demonstrate that the FTC had no jurisdiction over it under 15 U.S.C. section 44. Under the FTC Act, however, it is

the FTC's burden to establish that DCO has been "organized to carry on business for its own profit," not DCO's burden to prove otherwise.

B. The FTC Erroneously Assumed that DCO's Receipt of Income Established FTC Jurisdiction over DCO.

Purporting to apply the rule in Community Blood Bank, the FTC erroneously ruled that DCO was subject to FTC jurisdiction because "by engaging in commercial activities, DCO operates a commercial enterprise," not a religious or charitable ministry. *See* Comm. Op., p. 7, A-305. No such dichotomy exists. Under Washington law, a corporation sole is authorized to "transact[] business" without negating or violating the corporation's charitable purpose. *See* Catholic Bishop, 329 Bankr. Rep. at 327-28. Indeed, the history and modern use of the corporation sole form strongly establish their essential "ecclesiastical" nature and purpose, while at the same time engaging in supportive commercial activities. *See* J. O'Hara, "The Modern Corporation Sole," 93 *Dickinson L. Rev.* 23, 33, 35 (1988).

The FTC incorrectly presumed otherwise — that DCO was a corporation organized **for profit** simply because DCO was engaged in money-generating sales of its products. *See* Comm. Op., pp. 4-8, A-304-07. That was the same error that the FTC made in Community Blood Bank, wherein the FTC claimed jurisdiction

over a "corporation engaged in business only for charitable purposes [if it] receives income in excess of expenses." *See id.*, 405 F.2d at 1016. However, Community Blood Bank expressly rejected that argument, ruling that "even though a corporation's income exceeds its disbursements its nonprofit character is not necessarily destroyed." *Id.,* 405 F.2d at 1017. Instead, the court adopted the rule that an entity's nonprofit character is lost **only if it can be shown that** either the entity or its members "derived a profit **over and above** the ability to **perpetuate or maintain** [its] existence." *Id.*, 405 F.2d at 1019 (emphasis added). DCO "'does not cease to be a nonprofit corporation merely because it has income.'" *See id.,* 405 F.2d at 1020.

C. The FTC Failed to Establish that DCO's Income Was Distributed to DCO's Sole Member and Overseer, Mr. Feijo, for His Individual Profit and Gain.

In the alternative, the FTC has claimed that it has jurisdiction over DCO because Mr. Feijo, as overseer, "distributed [DCO] funds to himself and his wife for their benefit." Comm. Op., p. 8, A-306. In support of this finding, the FTC observed that the Feijos lived in two homes and used two cars, each of which was owned by "DCO or its affiliate," and DCO "was the source of all of [the Feijos'] living expenses." *Id.* But the legal test whether the FTC has jurisdiction over DCO as a nonprofit organization is not whether the Feijos utilized DCO's assets,

or even benefitted from DCO's payment of their expenses as they ministered. Rather, the question is whether Mr. Feijo "derived a profit" for his personal "pecuniary gain," that is, whether DCO was "merely [a] vehicle through which a pecuniary profit could be realized for [himself and his wife]." *See* Community Blood Bank, 405 F.2d at 1017.

Notably absent from the Commission's ruling was any finding about the specific use to which the two corporation sole properties and the two DCO cars were put, and the reason for reimbursement of certain expenses of the Feijos. *See* Comm. Op., p. 8, A-306. Under the rule of Community Blood Bank, it is incumbent upon the FTC to prove that such use and payments were for the Feijos' "personal profit, benefit, or advantage[,]" and not for the purpose of perpetuating and maintaining DCO's religious services and programs. *See id.*, 405 F.2d at 1021. The record shows that the Feijos, as the sole officers of DCO, were fully and exclusively engaged in a ministry which included spiritual and nutritional counseling, health education, marketing DCO products, producing its publications, maintaining its website, and hosting its daily radio program. *See* ALJ Dec., FoF 5-19, 37-41; A-173-74, A-176. *See also* Comm Op., pp. 2, 4-6, A-300, A-302-04.

As the court pointed out in Community Blood Bank, the **FTC has the burden** to show that the Feijos' use of DCO properties and receipt of payment for

certain expenses were "infected with commercial intent," instead of the intent of "promoting [DCO's] program in the public interest." *See id.*, 405 F.2d at 1022. The FTC failed to meet this burden and failed, therefore, as a matter of law, to establish jurisdiction over DCO under section 44 of the FTC Act.

II. THE FTC EXCEEDED ITS STATUTORY AUTHORITY BY MISUSE OF ITS "REASONABLE BASIS" THEORY AND TEST.

Sections 5(a) and 12 of the FTC Act (15 U.S.C. §§ 45(a) and 52), respectively, make unlawful "deceptive acts or practices" and "false" advertisements "in or affecting commerce." The FTC believes that it may enforce these prohibitions under either its (i) "'falsity' theory" or (ii) "'reasonable-basis' theory." *See* ALJ Dec., p. 99, A-265. Tracking the statutory language, the falsity theory appropriately requires "the government [to] carry the burden of proving that the express or implied message conveyed by the ad is false." *Id.*, n.4, A-265. Under its reasonable basis construct, however, the FTC circumvents the FTC Act's requirement that it prove deception or falsity, as the FTC claims that it need only establish that an ad's "**net overall impression**" "carr[ied] ... the express or implied representation that the advertiser had a **reasonable basis** substantiating the claims at the time the claims were made." *Id.* at 99, A-266 (emphasis added). Once this foundation has been established, then the burden shifts to the advertiser

to produce the "substantiation they relied on for their product claim," after which the FTC has "the burden of establishing that [the] purported substantiation is inadequate." *Id.* at 100, A-266.

Moreover, in this case, the FTC has manipulated the reasonable basis theory to require DCO not just to substantiate that its implied product claims are "reasonable," but also that its implied claims are supported by "competent and reliable scientific evidence," that is , by the FDA standard of "controlled clinical studies." *See* ALJ Dec., pp. 103-04, A-269-70. The FTC has imposed this burden on DCO without first establishing the factual predicate required by its reasonable basis theory, namely, that the "overall net impression" of DCO's ads carried the express or implied representation that DCO's product claims were based on such "controlled clinical studies." Because the FTC has bypassed this step, it has misused its own "reasonable basis" theory to further a public health policy unauthorized by the FTC Act, and thereby, has exercised a power **not** conferred by Congress as unambiguously stated in sections 5(a) and 12 of the FTC Act, and as reinforced by the Dietary Supplement Health and Education Act of 1994.

Because the language of sections 5(a) and 12 unquestionably limit the FTC's authority to protecting the consumer from "fraud, deception, and unfair

business practices in the marketplace,"[26] the standard of review governing the FTC's authority in this case is not governed by the principle of deference to a reasonable administrative interpretation of the empowering statute, but by *de novo* review by this Court. *See* General Dynamics Land Systems, Inc. v. Cline, 540 U.S. 581, 600 (2004).

A. Requiring DCO to Substantiate Its Product Claims by "Controlled Clinical Studies" Is outside FTC's Statutory Authority.

The FTC never claimed that DCO actually made any false representation respecting any of the Four Challenged Products. *See* ALJ Dec., p. 99, A-265; Comm. Op., p. 12, A-310. Rather, the FTC alleged that DCO's statements about the Four Challenged Products created the **overall net impression** that (i) each product was effective in the treatment of cancer or inhibited or eliminated tumor growth and (ii) that DCO implied that it possessed and relied upon a **reasonable basis** that substantiated that overall net impression. *See* Compl. ¶¶ 6-15, A-24-27 (emphasis added). Alleging further that DCO's claims were, in fact, unsubstantiated by any "reasonable basis," the FTC charged DCO with having

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[26] Federal Trade Commission, "Protecting America's Consumers" http://www.ftc.gov.bcp/index.shtml.

engaged in "unfair or deceptive acts or practices, in or affecting commerce in violation of Sections 5(a) and 12 of the FTC Act." Compl. ¶ 17, A-27.

At the hearing, DCO presented evidence through five expert witnesses. Two of DCO's expert witnesses specifically testified that there was a "reasonable basis" for DCO's claims as to 7 Herb Formula, GDU, and BioMixx. *See* ALJ Dec., FoF 387, 397; A-227-28. Yet, the ALJ entirely disregarded their opinions because they did not address whether "there is **competent and reliable scientific evidence"** to support DCO's claims about the efficacy of the four challenged products. *See* ALJ Dec., FoF 388-89, 398-400; A-227-29 (emphasis added). However, the FTC Complaint did not charge DCO with having implied that its claims were based upon "competent and scientific evidence," but charged only that DCO's ads implied that it had a "reasonable basis" for its claims. Compl. ¶¶ 14-15, A-27. And, the ALJ did not require that FTC counsel first establish that DCO's advertisements implied that its product claims rested on "competent and reliable scientific evidence," as the reasonable basis theory purports to require. Instead, the ALJ ruled that a general standard of "reasonableness" did not apply, because DCO's statements were "health-related" and, for that reason alone, they "require[d] a high level of substantiation" — which the ALJ determined to be "competent and reliable scientific evidence." *See* ALJ Dec., p. 102, A-268.

Indeed, the ALJ — not finished in raising the bar — then ruled that DCO's health-related claims must meet an even higher standard of substantiation. Because DCO's claims gave the overall net impression "that the Challenged Products prevent, treat or cure cancer, inhibit tumors, and ameliorate the adverse effects of radiation and chemotherapy," the ALJ insisted that DCO must show that its claims were supported by "**controlled clinical studies**" of the kind required by the FDA for the approval of a new pharmaceutical drug. *See* ALJ Dec., p. 103, A-269. *See also* Expert Report of Denis R. Miller, M.D. ("Miller Report"), pp. 7-12, A-76-81. And again, the ALJ did not require FTC counsel to establish that the net overall impression of DCO's claims implied that they rested on such "controlled clinical studies," as the reasonable basis theory purports to require. Instead, the ALJ justified the higher standard of "controlled clinical studies" on the ground that "the evidence shows that foregoing a proven cancer treatment in favor of an ineffective treatment would be injurious to a patient's health." ALJ Dec., p. 103, A-269.

On appeal, the Commission affirmed, ruling that DCO has "not produced anything to show that they possessed and relied on any competent and reliable scientific evidence to support the overall net impressions conveyed by the advertisements at issue." Comm. Op., p. 18, A-316. In its affirmance, the

Commission explained that none of DCO's expert witnesses were qualified to offer an opinion concerning whether DCO had a "reasonable basis substantiating their representations." *See id.* Rather, the Commission agreed with the ALJ that only the FTC witness — a medical doctor and oncologist — was qualified to testify as to the whether there was a "reasonable basis" for DCO's claims, and adopted, as its own, the FTC witness' definition of "competent and reliable scientific evidence." Comm. Op., pp. 18, 22, A-316, A-320.

> As stated in his report, the FTC expert witness explained that:
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> > to **constitute competent and reliable scientific evidence**, a product that purports to treat, cure, or prevent cancer must have **efficacy and safety demonstrated through controlled clinical studies**. **My understanding** of what constitutes competent and reliable scientific evidence is **consistent with the FDA's regulations** that define the criteria for adequate and well-controlled clinical investigations, which are set forth at 21 C.F.R. sec. 314.126. [Miller Report, pp. 7-8, A-76-77 (emphasis added).]

The criteria set forth in the cited Code of Federal Regulations section is the standard promulgated by the FDA governing approval to market a new pharmaceutical drug, a matter totally outside the authority of the FTC. Yet, Dr. Miller applied, and the FTC erroneously adopted, that FDA pharmaceutical standard to determine whether DCO engaged a "deceptive act or practice" under

section 5(a) of the FTC Act with respect to a dietary supplement, as if the FTC, like the FDA, were empowered by statute to protect the public health and safety.

The FTC is "charged with the enforcement of no policy except the policy of the law." *See* Humphrey's Executor v. United States, 295 U.S. 602, 624 (1935). On their face, sections 5(a) and 12 of the FTC Act authorize the FTC **only** to protect consumers from deceptive or misleading advertising, **not** to protect the public health and safety — areas in which the FTC commissioners have no education or expertise.[27]

B. As applied here, the FTC's "Reasonable Basis Theory" Is Not a Rule of Law, but a Flexible Health Policy.

The FTC claims that its "reasonable basis theory," as applied here, is established by "Commission and federal case law." Comm. Op., p. 11, A-309. However, neither of the two cases cited by the Commission in its Opinion demonstrates how the text of either section 5 or section 12 of the FTC Act could possibly be construed to require health care marketing representations to meet the FTC-contrived standard of "reasonableness" as employed in this case. Rather, it

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[27] All four members of the Commission that decided the appeal in this case were lawyers. None had any experience or educational background that would qualify them as versed in health policy. Rather, they came to the Commission primarily with backgrounds in antitrust and consumer protection. *See* http://www.ftc.gov/commissioners/index.shtml.

appears that, in the absence of clear challenge, the two courts simply assumed that the FTC's "reasonableness" construct generally is authorized by law. *See* FTC v. Pantron I, 33 F.3d. 1088 (9th Cir. 1994); Thompson Medical Co., Inc. v. FTC, 791 F.2d 189 (D.C. Cir. 1986). While the parties in these (and other) cases have "concede[d] the validity of the reasonable basis theory," along with its "competent-and-reliable-scientific-evidence" offspring,[28] DCO vigorously contests their application in this case.

The FTC standard of "competent and reliable scientific evidence" is not derived from the statutory language, but comes from the "reasonable basis theory," itself. *See* FTC v. National Urological Group, Inc., 2008 U.S. Dist. LEXIS 44145, *44-*45 (N.D. Ga. 2008). And the "reasonable basis theory" appears to have been created "because it does not require the FTC to prove that [a] message was false in order to prevail." *See* FTC v. Garvey, 383 F.3d 891, 901 (9th Cir. 2004). **If the FTC** is **not required** to shoulder its statutory burden of having to prove an advertisement to be, in fact, "false" or "deceptive," it is difficult to imagine how the FTC could fail to prevail on its reasonable basis theory in virtually every case. *See* Pantron I, 33 F.3d at 1096 n.23.

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[28] *See, e.g.,* American Home Products Corp. v. FTC, 695 F.2d 681, 693, 710 (9th Cir. 1982).

The "reasonable basis/scientific evidence" standard is not bound by any agency rule, having never been promulgated under the Administrative Procedure Act ("APA"). Rather, as FTC Commissioner J. Thomas Rosch has explained, the FTC aborted its effort to adopt a regulation because "there did not appear to be a way to develop workable rules."[29] Instead, the FTC resorted to the publication of an industry guide purportedly to explain its policy governing health claims about dietary supplements. FTC Guide, *Dietary Supplements: An Advertising Guide for Industry* (hereinafter "DSG") (Apr. 2001).[30] Industry guides are "administrative interpretations of the law intended to help advertisers comply with the [FTC] Act; [but] they are **not binding law themselves,"** — as the FTC admits[31] and as the rule in Chevron v. Natural Resources Defense Council, 467 U.S. 837 (1984) states. *See* National Railroad P. Corp. v. Morgan, 536 U.S. 101, 120, n.6 (2002).

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[29] J. T. Rosch, "Self-Regulation and Consumer Protection: A Complement to Federal Law Enforcement," (hereinafter "Rosch") pp. 10-11 (Sept. 23, 2008). This article is provided to the public on the FTC website, http://www.ftc.gov/.

[30] http://www.ftc.gov/bcp/edu/pubs/business/adv/bus09.shtm.

[31] "FTC Publishes Final Guides Governing Endorsements, Testimonials" ("Testimony Guide"), p. 2 (Oct. 5, 2009) (emphasis added). http://www.ftc.gov/opa/2009/10/endortest.shtm.

Indeed, the DSG explains that the "require[ment] [that] claims about the efficacy or safety of dietary supplements ... be supported with 'competent and reliable scientific evidence'" is **not a fixed legal standard**, but is "'**flexible.**'" *See* Comm. Op., p. 16, A-314 (emphasis added). As the court noted in American Home Products, since "the Commission has chosen not to bind itself in advance to rules as to the interpretation of the phrase 'reasonable basis,'" any order issued by the FTC is deliberately "imprecise." *Id.*, 695 F.2d at 710. Thus, the DSG states that the standard is only "**typically** require[d] [of] claims about the efficacy and safety of dietary supplements." DSG, p. 9 (emphasis added). Further, the evidentiary standard is "sufficiently flexible" so that it may be raised or lowered depending upon the FTC's assessment of the type of product or claim, the cost/feasibility of developing substantiation of the claim, the risk of harm, and the opinions of experts. *Id*., pp. 8-9, 25. In short, the DSG is not anchored to the enforcement of its statutorily-granted authority to protect the public from consumer fraud but, as this case demonstrates, to facilitate the FTC's exercise of powers completely outside its statutory authority.

C. The FTC Action in this Case Conflicts with the Dietary Supplement Health and Education Act.

In 1994, Congress enacted the Dietary Supplement Health and Education Act ("DSHEA"), limiting the power of the FDA over dietary supplements. As the FDA itself acknowledges, DSHEA does not require that dietary supplements "need approval from FDA before they are marketed":

> [T]he manufacturer is responsible for ensuring that its dietary supplement products are safe before they are marketed. 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. Under DSHEA, once the product is marketed, **FDA has the responsibility for showing that a dietary supplement is "unsafe," before it can take action to restrict the product's use or removal from the marketplace**. [U.S. Food and Drug Administration, "Food: Overview of Dietary Supplements," p. 2 http://www.fda.gov/Food/Dietary Supplements/Consumer Information/ucm110417.htm (emphasis added).]

As psychiatrist Dr. Stephen Barrett of "Quackwatch" bemoans, the DSHEA places on the FDA the burden of proof that a dietary supplement is **unsafe** before it can take any action.[32] In this case, however, the FTC has imposed the FDA "controlled clinical studies" standard on DCO on the ground that DCO's "products **could be** harmful." *See* Comm. Op., p. 20, A-318 (emphasis added). According

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[32] S. Barrett, M.D., "How the Dietary Supplement Health and Education Act of 1994 Weakened the FDA," p. 3 http://www.quackwatch.org/02ConsumerProtection/dshea.html.

to the FTC Press Release announcing the filing of the complaint against DCO, DCO had received **a "warning letter" from the FDA** that DCO's were "not proven to be safe and effective for their labeled use."[33] Instead of the FDA launching a complaint against DCO, the **FTC stepped in**, thereby circumventing the burden that DSHEA would have placed on the FDA. Indeed, as Commissioner Rosch stated five days after the issuance of the FTC Press Release, the FTC's action against DCO was part of a "**collaborative undertaking**" by the FTC and the FDA. Rosch, p. 16 (emphasis added). With the FDA so limited by Congress, the baton was handed off to the FTC to do what the FDA could not.

In a detailed review of the history of legislation and regulations governing dietary supplements, the DSHEA-created Commission on Dietary Supplement Labels documented that from 1906, when the first Pure Food and Drug Act became law, through 1998, when it issued its report, Congress looked to the FDA as the administrative agency directly concerned about health claims for drugs and food, including dietary supplements. *See* DSHEA Commission Final Report, Chapter II (Nov. 1997) http://www.health.gov/dietsupp/chs.htm. The DSHEA Commission recognized that the FTC's jurisdiction over dietary supplements was

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[33] "FTC Sweep Stops Peddlers of Bogus Cancer Cures" (hereinafter "FTC Press Release"). http://www.ftc.gov/opa/2008/09/boguscures.shtm.

only incidental to its "authority to regulate advertisements for **all** consumer products." *Id.* at Chapter III. Thus, the DSHEA does not envision, much less countenance, the enhanced role to set dietary supplement health and safety policy that the FTC has unlawfully seized for itself in this case.

III. THE FTC ORDER IS ARBITRARY AND CAPRICIOUS, BEING THE PRODUCT OF A BLIND ADHERENCE TO THE RELIGION OF SCIENTISM.

The FTC case against DCO rests entirely on the report and testimony of one man, Dr. Denis R. Miller. He was, the Commission stated, "the **only** witness qualified as an expert in cancer research and cancer treatment" and "the **only expert** witness who offered an opinion as to whether there was competent and reliable scientific evidence to support [DCO's] representations." Comm Op., p. 22, A-320 (emphasis added). According to the Commission, it was Dr. Miller's opinion, and only Dr. Miller's opinion, that carried the FTC's burden to establish that DCO's substantiation of their claims in relation to the Four Challenged Products was inadequate. For it was Dr. Miller's report and testimony that convinced the FTC that DCO's claims were not substantiated by "competent and reliable scientific evidence." Comm. Op., pp. 18-19, A-316-17.

Insofar as the FTC decision is based on Dr. Miller's report and testimony, the decision is erroneous, with Dr. Miller's report and testimony resting on an

unsupported factual predicate, and falling short of the applicable standard of review governing the sufficiency of the Commission's findings of facts under 15 U.S.C. section 45(c). Insofar as the FTC decision rests upon Dr. Miller's personal faith in "controlled clinical studies," the Commission's decision constitutes an unconstitutional establishment of religion, the standard of review as to which is *de novo*. *See* United States v. Bajakajian, 524 U.S. 321, 336-37 (1998).

A. Dr. Miller's Opinion Rests upon the Unsupported Assumption that the FDA Standard for Approval of New Pharmaceutical Drugs Applies to Herbal Products.

Dr. Miller is a pediatric hematologist/oncologist, but no longer practices medicine.[34] He works as Senior Medical Director of PAREXEL Clinical Research Services, assisting pharmaceutical companies to comply with FDA procedures and standards applicable to the approval of new toxic pharmaceutical drugs (known as "investigational new drugs") in the area of hematology and oncology. Dr. Miller summarized his report as follows: "there is no **competent and reliable scientific evidence** to substantiate the [DCO] claims that the products at issue treat, cure, and prevent cancer." Miller Report, p. 7, A-76 (emphasis added). He stated "it is **my opinion** that to constitute **competent and reliable scientific evidence**, a product that purports to treat, cure, or prevent cancer **must** have its efficacy and

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[34] Denis Miller Testimony ("Miller Tr.") Tr. 1/47-48, 157.

safety demonstrated through **controlled clinical studies**" (*id.*) which, in turn, must follow a "**clinical trial protocol**" including 11 specified and detailed elements. *Id.*, pp. 8-10, A-77-79 (emphasis added).

Dr. Miller assumed *sub silentio* that FDA standards requiring controlled clinical tests for approval of new toxic pharmaceuticals applies to herbal remedies.[35] The Chantilly Report[36] found, however, that:

> Herbalists may apply under existing guidelines for approval of new pharmaceutical drugs but **this burden is unrealistic**, because the total cost of bringing a new pharmaceutical drug to market in the United States is estimated $140 million to $500 million... [**H]erbal remedies are not viable candidates for the existing drug approval process**: pharmaceutical companies will not risk a loss of [hundreds of millions of dollars], and herbal companies lack the financial resources even to seek approval. [*Id.*, p. 197 (emphasis added).[37]]

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[35] While Dr. Miller may be exceptionally knowledgeable about FDA approval procedures for new toxic drugs, he revealed at the hearing that he had little familiarity with herbal products, unable to answer the ALJ's question as to the difference between an **herb** and a **plant.** Miller Tr., pp. 168, l. 16 - 169, l. 3; A-115.

[36] Alternative Medicine: Expanding Medical Horizons: A Report to the National Institutes of Health on alternative medical systems and practices in the United States (Sept. 1992), also known as the "Chantilly Report." Commissioned by the Office of Alternative Medicine created by Congress in 1991, the Chantilly Report was designed to provide "a baseline of information on the state of alternative medicine in the United States." *Id.* at vii.

[37] *See also* World Health Organization, A Practical Guide for Health Researchers (Dec. 2004) (hereinafter "WHO Guide"), p. 43.

Dr. Miller agreed that the FDA approval process is "a complicated, lengthy, and expensive process" where "[o]f any 5000 promising agents discovered in the laboratory and entering nonclinical [test tube and animal] testing, 5 enter Phase I and one is approved [by the FDA to be marketed]." *Id*., p. 9. But that did not deter him in setting the FDA "controlled clinical studies" as the bar over which herbal remedies must hurdle. Nor did it deter the ALJ from adopting Dr. Miller's "controlled clinical studies" as the measure by which to determine whether DCO's health claims for its herbal products were to be substantiated.

Yet, the ALJ also acknowledged:

> Testing to prove that a drug is a safe and effective treatment of disease is **a particularly costly** endeavor to undertake for testing herbal products, because it is difficult to extract and test a **single** chemical component from an herb, and because an herb may contain **thousands** of chemical components. [ALJ Dec., FoF 350; A-222 (emphasis added).]

Nevertheless, ignoring this finding, the ALJ imposed the "controlled clinical studies" standard upon DCO, in total disregard of the FTC's own industry guide — DSG — that claimed that the "competent and reliable scientific evidence" standard was flexible, depending upon the FTC's assessment of a number of factors, including the cost and feasibility of developing substantiation of the claim.

DSG, pp. 8-9, 25. In short, the ALJ imposed the FDA pharmaceutical drug standard on nutritional supplements regardless of its suitability or feasibility.[38]

But, as the government's Chantilly Report strongly states:

> [C]onventional researchers typically and **inappropriately** demand application of ... prospective randomized clinical trials ... when they are **not appropriate**. This demand occurs despite the availability of a range of suitable methods from which to choose and the possibility that new methods will have to be identified to fit the situation. [Chantilly Report, p. 290 (emphasis added).]

B. By Adopting Dr. Miller's Standard as Its Own, the FTC Has Established the Religion of Scientism.

By adopting Dr. Miller's standard for its own,[39] the FTC has, in effect, ruled out any cancer or tumor treatment approach that did not conform to "conventional

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[38] Former Sloan-Kettering Cancer Center employee Ralph Moss, Ph.D., explained how remedies which cannot be patented are not approved by the FDA:

> [I]n the thirty-five years that I've been studying the situation, the FDA has never approved any nontoxic drug, herb, vitamin, or anything like that for cancer. The rule seems to be that nothing of a nonpatented, less profitable nature gets through the FDA system. The only things that get through are these synthetic patented agents that are generally **very toxic** and **ineffective**. They are so ineffective that the FDA keeps lowering the bar and allowing things to be approved on **lower and lower standards** of **effectiveness** and lower and lower standards of **safety**. [Suzanne Somers, Knockout, Crown Publishers (2009), p. 46 (emphasis added).]

[39] *See* Comm. Op., pp. 18, 22, A-316, A-320.

anticancer therapy," leaving **absolutely no** room for "alternative medicine." *Id.* Indeed, in Dr. Miller's — and hence in the FTC's world:

> "There cannot be two kinds of medicine — conventional and alternative... Alternative treatments should be subjected to scientific testing no less rigorous than that required for conventional treatments." [*Id.*, p. 12.]

Dr. Miller's rejection of alternative medicine, and the FTC's adoption of that view, is based **not** on "competent and reliable scientific evidence," but on his personal faith in the kind of medicine that he practices and seeks to protect. Indeed, Dr. Miller testified that he would "opt for what I am told and believe and have faith in my physician." Miller Tr. p. 214, l. 9. According to the Bible, however, God's people are to put their faith in "Yawweh Rofekha, the Lord who heals you."[40] Exodus 15:26.

The Chantilly Report warns that "[c]onventional physicians" create **"belief barriers"** leading to the conclusion that there is but "'*one true' medical profession"* — that "there should be only one representative voice for the whole of medicine," and that "only members of their profession ... should be allowed to control all aspects of medical practice." Chantilly Report, p. xliv (italics original,

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[40] King Asa died because "[t]hough his disease was severe, in his illness he did not seek help from the Lord, but only from physicians." 2 Chronicles 16:12-13.

bold added). In essence, this is Dr. Miller's view. Although Dr. Miller attempts to empirically justify his position — "There is only medicine that works and medicine that may or may not work"[41] — his explanation makes no sense. Even conventional medicine may or may not work. There is no medicine that works — all of the time.[42] By subscribing to the notion that conventional cancer treatments work perfectly,[43] Dr. Miller has unwittingly revealed that his opposition to alternative medicine is faith-based.

According to the Chantilly Report, "the root of this conflict is the fact that alternative and mainstream medical scientists often have two diametrically

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[41] Miller Report, p. 12, A-81.

[42] Albert Einstein is quoted to have said: "As far as the laws of mathematics refer to reality, they are not certain, and as far as they are certain, they are not reality. There is no certainty in science. There are probabilities. What is certain about science is the uncertainty." WHO Guide, p. 95.

[43] Although oncologists, like Dr. Miller, use chemotherapy liberally to treat their patients, they see problems with their methods more clearly when they consider using it for themselves. "In 1968, McGill Cancer Center scientists sent a questionnaire to 118 doctors who treated non-small-cell lung cancer.... More than three-quarters of them recruited patients and then helped carry out trials of toxic drugs for lung cancer." They were asked which of current trials they themselves would choose. Sixty-four of the 79 respondents would not consent to be in a trial containing cisplatin, a common chemotherapy drug, and 58 found all the trials unacceptable based on the ineffectiveness of chemotherapy and its unacceptable degree of toxicity. R. Moss, Ph.D., Questioning Chemotherapy, p. 40 (Equinox Press: 2000).

opposed views ... **on the nature of life itself**." Chantilly Report, p. xlv (emphasis added). According to 20th century scientific philosopher, Thomas Kuhn, the Report states, "scientific doctrines rest not just on facts, but more fundamentally on **paradigms** (i.e., broad views of how those facts should be organized)." *Id.* Those who break out from established paradigms are treated as "**scientific outcasts**." Such are those like the Feijos, who promote health and wellness through herbal remedies that are considered by government agencies like the FDA "to be worthless or potentially dangerous." *See* Chantilly Report, p. 185. By adopting the FDA standard of "controlled clinical studies," the FTC has virtually locked out herbal remedies, disallowing claims based upon history, general science, and the revelation of God. Thus, DCO's reliance upon Biblical revelation and personal testimonies as the source of their representations about the efficacy of their products is disallowed.[44] *See* ALJ Dec., p. 105, A-271.

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[44] Dr. Miller dismisses testimonials, which he calls "anecdotal reports," as "not reliable and competent, lack statical robustness, are short on scientific quality or validity ... the weakest form of evidence...." Miller Report pp. 11-12, A-80-81. On the other hand, divine revelation and personal testimony are the primary methodologies of truth. Matthew 16:1-17. For example, followers of Jesus at that time, and Biblical Christians today, believe the testimony of a man blind from birth that he had his sight restored merely from washing in the pool of Siloam. The fact that the politically-powerful Pharisees of that time would not accept that testimony did not make it untrue. *See* John 9:10-11, 25.

But the FTC has no proof that its empirical methodology is the only legitimate path to truth. Rather, it has simply taken its hyper-secular views and imposed them upon an otherwise viewpoint-neutral statute, and in the process has violated the Supreme Court's *per se* rule against viewpoint discrimination laid down in Rosenberger v. University of Virginia, 515 U.S. 819 (1995). As the Rosenberger Court stated, "[w]hen the government targets not subject matter, but particular views taken by speakers on a subject, the violation of the First Amendment is all the more blatant." *Id.*, 515 U.S. at 828. By discriminating against DCO's religious approach to truth, the FTC's policy on permissible advertising in this case is no different from the school district policy which prohibited the showing of a film on family values because the film's "religious perspective" did not conform to the school district's secular educational philosophy. *See* Good News Club v. Milford Central School, 533 U.S. 98, 107-08 (2001).

In United States v. Ballard, 322 U.S. 78 (1944), the United States Supreme Court ruled that the First Amendment guarantees of freedom of religion precluded the prosecution of a mail fraud indictment based upon allegations that the defendant was promoting false beliefs. Among the promoted beliefs that the government had contended to be false was "the power to heal persons of ailments

and diseases ... normally classified as curable, and also of diseases which are ordinarily classified by the medical profession as being incurable." *Id.*, 322 U.S. at 80. At issue in the case, the Court concluded, was "the truth or verity of ... religious doctrines," which, in turn, the Court ruled to be a "forbidden domain" into which the government may not enter. *Id.*, 322 U.S. at 86-87.

Dr. Miller's testimony that medical truth is to be found only in "competent and reliable scientific evidence"[45] is a manifestation of a world view based on the superiority of western natural science.[46] The notion that following one way will lead to all truth is properly described as a religion. *See* John 14:6. Scientism is

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[45] Dr. Miller's personal faith that clinical trials are the only objective sources of truth could be based in the fact he makes his living navigating FDA clinical trial protocols. Dr. Miller is employed by Parexel, a global bio/pharmaceutical services company whose practices have raised questions. *See generally* "What Did Parexel Tell the Participants in the TGN 1423 Trial?," Health Care Renewal, Apr. 13, 2006, http://hcrenewal.blogspot.com/2006/04/what-did-parexel-tell-participants-in.html; J. Edwards, "AstraZeneca's Sex-for-Studies Seroquel Scandal: Did Research Chief Bias the Science?" BNET, Feb. 25, 2009, http://www.bnet.com/blog/drug-business/astrazeneca-8217s-sex-for-studies-seroquel-scandal-did-research-chief-bias-the-science/768.

[46] Scientism appears to be a narrow, largely Western phenomenon which tolerates no religious or cultural diversity, imposing one standard of truth on all peoples around the world. If allowed to control American medicine, it would penalize those who have come to the United States bringing their wisdom to our melting pot. Scientism gives no place to branches of medicine derived from around the world, such as homeopathy (Germany), acupuncture (China), traditional folk medicine, American Indian medicine, etc. *See generally* Chantilly Report, pp. xv-xxiii.

the view that truth can be best, if not only, known from the results of the application of a supposedly scientific methodology.[47] For the FTC to require that all in the healing arts must adopt the standard of "competent and reliable scientific evidence" is to require the adoption of scientism — which would be an unconstitutional Establishment of Religion, violative of the prohibition contained in the First Amendment to the U.S. Constitution.

IV. THE FTC ACTION AND ORDER UNCONSTITUTIONALLY ABRIDGED DCO'S FREEDOM OF SPEECH.

Invoking the Supreme Court's "commercial speech" doctrine, DCO contended that the FTC's action against it violated DCO's freedom of speech. The FTC rejected DCO's defense solely on the ground that the "commercial speech" three-part test does not apply because DCO's advertisements were "misleading, DCO's having not substantiated their "net overall impression" by "competent and reliable scientific evidence." *See* ALJ Dec., pp. 115-16, A-281-82; Comm. Op., p. 14, A-312.

DCO's constitutional claim, including the underlying facts, is subject to *de novo* review by this Court. *See, e.g.,* Peel v. Attorney Registration and Disciplinary Comm., 496 U.S. 91 (1990).

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[47] *See generally* T. Sorel, Scientism: Philosophy and the Infatuation with Science (Routledge 1991), pp. 1-40.

A. The Supreme Court's "Commercial Speech" Doctrine Applies to this Case.

The FTC neither alleged in its Complaint, nor proved at the hearing, that DCO's advertisements respecting the Four Challenged Products — or even the "overall net impressions" of those ads — were, in fact, false, misleading, or otherwise deceptive. *See* ALJ Dec., p. 99, n.4, A-265. Rather, as the Commission observed, "the ALJ focused on whether the advertisements at issue were deceptive or misleading under the 'reasonable basis' theory because the Complaint only made 'reasonable basis' allegations." Comm. Op., p. 12, A-310. Under the reasonable basis theory, the ALJ, in turn, concluded that DCO's advertising was misleading because DCO had not substantiated its claims by "competent and reliable scientific evidence," *i.e.,* "controlled clinical studies" of the kind conducted by the FDA in the FDA's approval process for new pharmaceutical drugs. *See* ALJ Dec., pp. 103-107, A-269-73. On appeal, the Commission affirmed. Comm. Op., pp. 11-14, A-309-12.

Under the FTC's reasonable basis theory — as provided by "Commission and federal case law" — DCO's product advertisements were deemed "deceptive unless properly substantiated." *See* Comm. Op., p. 11, A-309. Relying solely upon the FTC expert witness' personal opinion that "in order 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," the Commission affirmed the ALJ finding that DCO had failed to substantiate its advertising claims. Comm. Op., pp. 18-22, A-316-20. Having reached that finding, the Commission concluded, "no further analysis [of DCO's "commercial speech" claim] is necessary." Comm. Op., p. 14, A-312.

In Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), marketers of dietary supplements made claims similar to DCO's representations here — that their products would help people in their battle against cancer. *Compare* Pearson, 164 F.3d at 652, *with* ALJ Dec., pp. 83-95, A-249-61. In Pearson, as here, the FTC's agency counterpart, the FDA, found such claims to be misleading because, as here, they did not meet a pre-determined "scientific" standard. *Compare* Pearson, 164 F.3d at 652-55, *with* ALJ Dec., pp. 99-106, A-265-72. In Pearson, the agency, as here, ruled that the health claims made were "entirely outside the protection of the First Amendment." *Compare* Pearson, 164 F.3d at 655, *with* ALJ Dec., pp. 115-16, A-281-82. In Pearson, this Court rejected the FDA's position as "almost frivolous," based as it was upon a "paternalistic assumption" that "claims lacking 'significant scientific agreement' are inherently misleading." *Id.*, 164 F.3d at 655.

So too here, this Court should reject the FTC's ruling that DCO's health claims were completely outside the protection of the First Amendment because the FTC ruling, like the FDA's, is based upon a paternalistic assumption that DCO's claims "are difficult or impossible for consumers to evaluate for themselves." *See* ALJ Dec., p. 102, A-268. Rather, as the Pearson Court ruled, "consumer ... difficulty in independently verifying health claims on dietary supplements" provides support only for the proposition that such claims are "potentially misleading." *Id.*, 164 F.3d at 655. And, as the Pearson Court further ruled, "[u]nder *Central Hudson*, we are obliged to evaluate a government scheme to regulate potentially misleading commercial speech by applying a three-part test," the very test that the FTC declined to follow.

B. The FTC Case against DCO Fails the Commercial Speech "Three-Part Test."

Because the FTC ruled that the First Amendment commercial speech doctrine did not apply at all, there is nothing in the record to demonstrate that the FTC met the three-part test of Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of New York, 447 U.S. 557 (1980). For that reason alone, the FTC's order should be overturned.

In order to satisfy Central Hudson, the FTC must first establish that it has a "substantial" interest in applying the FDA standard of "controlled clinical tests" as the standard by which it is to measure whether DCO's ads were "misleading." *See id.*, 447 U.S. at 566. In its Complaint, the FTC has "not assert[ed] that [DCO's ads] *threaten* consumer's health and safety." *Compare* Pearson, 164 F.3d at 656 (italics original) *with* Complaint ¶ 14, A-27. Rather, the FTC's concern is to protect consumers from allegedly misleading "efficacy" claims. *See* Comm. Op., pp. 12 and 20, A-310, A-318. Thus, the only substantial interest that the FTC has demonstrated, according to the record, is to "ensur[e] the accuracy of commercial information in the marketplace" as to the efficacy of DCO's dietary supplements. *See* Edenfield v. Fane, 507 U.S. 761, 769 (1993).

The next questions under Central Hudson, then, are (i) whether the FTC's action in this case "directly advances the government" interest in the prevention of consumer fraud as to **efficacy**, and (ii) whether the fit between that end and the means chosen is "reasonable." *See* Pearson, 164 F.3d at 656. As the FTC's expert witness explained, the FDA "controlled clinical test" standard is designed not only to test a proposed new pharmaceutical drug for efficacy, but for safety. Miller Report, p. 7, A-76. Indeed, according to the FTC witness, Phase I of the FDA clinical test is designed to test for "safety." *Id.* at 9, A-8. Not until Phase II is the

proposed new drug tested for "efficacy." *Id.* Even at that stage, safety remains the primary testing goal. Thus, the FDA "controlled clinical studies" standard is not a "reasonable" fit here, where the sole aim is the efficacy of DCO's Four Challenged Products.

Moreover, because accurate information about efficacy of the products is the FTC's object, there was no "reason" for the FTC to dismiss outright DCO's disclaimer efforts — as it did — without giving any consideration as to whether those disclaimers could be modified in order to meet the FTC's concern that consumers be better informed as to the products' efficacy. *See* Comm. Op., pp. 10-11, A-308-09. The Pearson Court rejected the FDA's argument that it was not "obliged to utilize the disclaimer approach, because the commercial speech doctrine does not embody a preference for disclosure over outright suppression." *Id.*, 164 F.3d at 657. In this case, the FTC simply observed that DCO's disclaimers were ineffective, ambiguous, and inconspicuous. Comm. Op., p. 15, A-313. The commercial speech doctrine does not permit the FTC so to evade the "First Amendment preference for disclosure over suppression." *See* Pearson, 164 F.3d at 58.

V. THE FTC ERRONEOUSLY DISMISSED DCO'S RELIGIOUS FREEDOM RESTORATION ACT AND FIRST AMENDMENT "SPEAKER AUTONOMY" CLAIMS.

The Order directs DCO to cease and desist making any cancer or tumor treatment or cure claim in any advertisement offering for sale or distribution any dietary supplement or any other program, service or product **unless** the representation is **true, non-misleading,** and, at the time that it is made, [DCO] **possess[es] and rel[ies]** upon competent and reliable scientific evidence that substantiates the representation." FTC Order, Part II, A-325 (emphasis added). Part III of the Order extends this prohibition to any such claim about "the efficacy, performance, or health-related benefits" of any kind — cancer, tumor or otherwise. *Id.*, Part III, A-326.

Additionally, the Order requires that DCO mail to all consumers, who purchased one or more of the Four Challenged Products on or after January 1, 2005 to the date of service of the Order, an "exact copy" of an FTC-composed letter and envelope. *Id.,* Part V.B, A-326. The envelope must show DCO's address as the return address and the letter must be printed on DCO letterhead and must state that the FTC has: (i) found that DCO's ads were "deceptive because they were not substantiated by competent and reliable scientific evidence"; and (ii) "issued an Order prohibiting DCO making these claims in the future." *Id.*

Additionally, the letter must advise that DCO is "required to send ... the **following information from the FTC** about the scientific evidence on these products":

> • there is no "scientific evidence" that any of the ingredients in [the Four Challenged Products] are effective when used for prevention, treatment or cure of cancer.
>
> • It is important that you talk to your doctor or health care provider before using **any herbal product** ...
>
> • **Some herbal** products may interfere or affect your cancer or **other medical treatment,** may keep your **medicines** from doing what they are supposed to do, or could be **harmful** when taken with other **medicines** ...
>
> • It is also important that you talk to your doctor or health care provider before you decide to take **any herbal product** instead of taking cancer treatments that **have been scientifically proven to be safe and effective in humans.**
> [Order, Attachment A, A-330 (emphasis added).]

The cease and desist order mandating that DCO possess and rely upon competent and reliable scientific evidence violates RFRA by substantially burdening DCO's exercise of religion. *See* 42 U.S.C. § 2000bb-1(a). The FTC-mandated letter also violates RFRA section 2000bb-1(a), as well as the free exercise of religion and freedom of speech guarantees of the First Amendment. These are mixed questions of law and fact for which the standard of review is *de novo*. *See* Gonzales v. O Centro Espirita Beneficente Uniao Do Vegetal, 546 U.S.

418, 434 (2006) (RFRA). *See also* Hurley v. Irish-American Gay, Lesbian and Bisexual Group of Boston, 515 U.S. 557 (1995) (freedom of speech).

A. Parts II and III of the Order Substantially Burden DCO's Exercise of Religion in Violation of the Religious Freedom Restoration Act.

The Commission summarily dismissed DCO's RFRA claim on the ground that the "Order imposes no burden on Respondents' exercise of religion; it only applies to their commercial advertising." Comm. Op., p. 24, A-322. This ruling is based upon a false factual predicate — one that artificially separates the sale of DCO's products from the research and development of those products and from the relationship of those sales to the overall DCO ministry.

The Commission acknowledged that DCO's "Bio-guide: The BioMolecular Nutrition Guide to Natural Health ... was prepared by James Feijo, describ[ing] 'two aspects of BioMolecular Nutrition, the **spiritual and the physical'** [to] **promote all four Challenged Products**." Comm. Op., p. 5, A-303 (emphasis added). *See also* ALJ Dec., FoF 85, 87; A-179-80. Additionally, the ALJ found — and the Commission did not disagree — that the BioGuide "descriptions of DCO products, [included] testimonies from people who have used [them] as well as Biblical passages." ALJ Dec., FoF 89; A-181.

Additionally, the ALJ acknowledged the Feijos' uncontradicted testimony that "DCO was created for the purpose of healing based on the scripture of Daniel Chapter One and other Biblical verses, including Genesis 1:29 where it is written that God said he created all things for our food for healing." ALJ Dec., p. 68, A-234. The ALJ also acknowledged the Feijos' testimony "that DCO's ministry activities include ... performing healings and reaching out to others to inform them about [DCO's] perspectives on the **integration of spiritual and physical well being."** *Id.* (emphasis added). Thus, the ALJ accepted DCO's "claim that [the Feijos] have created a combined **spiritual and scientific approach** that maintains the balance of bodily systems." *Id.* Indeed, it was through prayer that God led the Feijos to "start the [DCO] healing ministry," and it was in reliance on God's inspiration and the application of Biblical principles that the Four Challenged Products were developed. *See* Statement of Facts, pp. 10-13, *supra.*

In order to comply with portions of the Order, DCO must, in addition to making only true and nonmisleading claims for its products, **possess and rely upon competent and reliable scientific evidence.** Such an order would substantially burden DCO's exercise of religion. According to 42 U.S.C. sections 2000bb-2 and 2000cc-5, "exercise of religion ... includes **any** exercise of religion, whether or not compelled by, or central to, a system of religious belief." Religion,

by definition, concerns matters of the spirit. The Christian faith, in particular, teaches the interrelation between a person's spiritual and physical health, with an emphasis upon the Biblical principle that God is the source not only of the salvation of man's soul but the healing of man's body. *See* Isaiah 53:5 and 1 Peter 2:24. That principle lay at the heart of the DCO ministry, as reflected in its very name and its operation.

Enforcement of Parts II and III of the FTC Order would require DCO to change its allegiance from God and the Bible to "the expertise of professionals in the relevant area," as determined by the FTC. *See* FTC Order, Part I.A, p. 1, A-324. Instead of relying on prayer, testimony, and the application of Biblical principles, DCO would be required to "possess and rely" on "tests, analyses, research, or other evidence ... that has been ... conducted and evaluated in an objective manner by persons qualified to do so," as determined by the FTC. *Id.* Such an order would destroy the DCO ministry, even if its claims for the products covered by Parts II and III are otherwise, in fact, "true and nonmisleading."

B. Part V.B of the FTC Order Would Substantially Burden DCO's Exercise of Religion.

The Commission denied that the mandated letter "compel[s]" DCO to discontinue its "religious ministry," or forces DCO to "repudiate" its religious

"faith," or otherwise "punish[es]" DCO "for their political or religious beliefs." Comm. Op., p. 25, A-323. But none of these conclusions — even if they are true — is responsive to the question presented by RFRA: whether the mandated letter "substantially burdens [DCO's] exercise of religion."

According to RFRA, the Order cannot substantially burden **any** "exercise of religion," whether compelled by or central to a system of religious belief. 42 U.S.C. § 2000cc-5(7). According to the Supreme Court, exercise of religion is not limited to the positive expression of "belief and profession," but includes "abstention from physical acts." *See* Employment Division, Dept. of Human Resources v. Smith, 494 U.S. 872, 877 (1990).

The FTC Order would require DCO to sign and mail a letter containing the views of the FTC, thereby forcing DCO to identify itself with a message with which it profoundly disagrees. Although the letter states at the outset that DCO is sending "information from the FTC about the **scientific evidence on [the[] Four Challenged]** products," the letter is **not** so limited. *See* FTC Order, Attachment A, A-330.

Instead, an entire paragraph is devoted to **counseling** in connection with **herbal products generally.** First the recipient is told that "it is important to **talk to your doctor or health care** provider before using **any** herbal product in order

to ensure that all aspects of your medical treatment work together." Next, the recipient is advised that "[s]ome **herbal products** may interfere or affect your cancer or other medical treatment, may keep your medicines from doing what they are supposed to do, or could be harmful when taken with other medicines, or in high doses." Finally, the recipient is counseled "to talk to your doctor or health care provider before you decide to take **any herbal product** instead of taking **cancer treatments** that have been **scientifically proven to be safe and effective** in humans."[48] *Id.*

Although the Commission found "DCO's activities included **spiritual counseling**" (Comm. Op., p. 2, A-300), the letter is completely devoid of any such spiritual content. FTC Order, Attachment A, A-330. Further, the letter would require DCO to embrace the FTC's **secular belief** that conventional cancer treatments have been "**scientifically proven,"** directly contrary to DCO's deeply held religious beliefs. The mandated letter violates RFRA.

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[48] To DCO, mailing of the FTC's letter would be "false" and "deceptive." As to cancer treatments being "safe," even Dr. Miller conceded chemotherapy was highly toxic, often causing irreversible organ damage. Tr. 1/221-22. As to being "effective," oncologist Guy B. Faguet, M.D.'s study of "three decades of disappointing progress in cancer treatment" concludes that "disease eradication is currently achievable in only 11 of over 200 human malignancies and meaningful survival prolongation is possible for another few...." Guy B. Faguet, The War on Cancer (Springer 2008), pp. xiii-xiv.

C. Part V.B of the FTC Order Violates the Well-Established First Amendment Principle of Speaker Autonomy.

DCO has repeatedly voiced its moral, ethical, and religious objections to being forced to sign and send the Attachment A letter. *See* ALJ Dec., p. 121, A-323; Comm. Op., p. 25, A-323. By design, the Order mandates that DCO use its private property as a vehicle for the FTC's infomercial, or suffer a crushing "civil" sanction of up to $16,000 for each of the many hundreds of letters unsent. *See* 15 U.S.C. § 45(m).

This principle of "speaker autonomy" — the right "to choose the content of his own message" — is a "fundamental rule of protection under the First Amendment." *See* Hurley v. Irish-American Gay, Lesbian and Bisexual Group of Boston, 515 U.S. 557, 573 (1995). In Wooley v. Maynard, 430 U.S. 705 (1977), the petitioner filed an affidavit wherein he stated that he "refused to be coerced by the State into advertising a slogan which [he found] morally, ethically, religiously and politically abhorrent." *Id.*, 430 U.S. at 713. The Court ruled that government may not "require" persons to "use their private property ... for the State's ideological message — or suffer a penalty" for noncompliance. *Id.*, 430 U.S. at 715. In Pacific Gas and Electric Company v. California P.U.C., 475 U.S. 1 (1986), the Supreme Court ruled that a state agency could not require a company to send a

"billing envelope[] to distribute the message of another." *See id.*, 475 U.S. at 17. Likewise, the FTC should not be allowed to force DCO to deliver the government's message with which it disagrees: "For to compel a man to furnish contributions of money for the propagation of opinions with which he disagrees is sinful and tyrannical." Virginia Act for Establishing Religious Freedom (1785), reprinted in 5 The Founders Constitution 84 (P. Kurland & R. Lerner, eds.: Liberty Press: 1987).

CONCLUSION

For the foregoing reasons, the petition for review should be granted and the FTC's Order reversed.

Respectfully submitted,

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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 13,926 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 14.0.0.756 in 14-point Times New Roman.

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ADDENDUM

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UNITED STATES CONSTITUTION

First Amendment

Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.

STATUTES

Federal Trade Commission Act

15 U.S.C. § 44. Definitions

(Sec. 4 of the FTCA)

The words defined in this section shall have the following meaning when found in this subchapter, to wit:

* * *

"Corporation" shall be deemed to include any company, trust, so-called Massachusetts trust, or association, incorporated or unincorporated, which is organized to carry on business for its own profit or that of its members, and has shares of capital or capital stock or certificates of interest, and any company, trust, so-called Massachusetts trust, or association, incorporated or unincorporated, without shares of capital or capital stock or certificates of interest, except partnerships, which is organized to carry on business for its own profit or that of its members.

* * *

15 U.S.C. § 45. Unfair methods of competition unlawful; prevention by Commission

(Sec. 5 of the FTCA)

(a) Declaration of unlawfulness; power to prohibit unfair practices; inapplicability to foreign trade

(1) Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.

(2) The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations, except banks, savings and loan institutions described in section 57a(f)(3) of this title, Federal credit unions described in section 57a(f)(4) of this title, common carriers subject to the Acts to regulate commerce, air carriers and foreign air carriers subject to part A of subtitle VII of Title 49, and persons, partnerships, or corporations insofar as they are subject to the Packers and Stockyards Act, 1921, as amended [7 U.S.C.A. § 181 et seq.], except as provided in section 406(b) of said Act [7 U.S.C.A. § 227(b)], from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce.

(3) This subsection shall not apply to unfair methods of competition involving commerce with foreign nations (other than import commerce) unless--

(A) such methods of competition have a direct, substantial, and reasonably foreseeable effect--

(i) on commerce which is not commerce with foreign nations, or on import commerce with foreign nations; or

(ii) on export commerce with foreign nations, of a person engaged in such commerce in the United States; and

(B) such effect gives rise to a claim under the provisions of this subsection, other than this paragraph.

If this subsection applies to such methods of competition only because of the operation of subparagraph (A)(ii), this subsection shall apply to such conduct only for injury to export business in the United States.

(4)(A) For purposes of subsection (a) of this section, the term "unfair or deceptive acts or practices" includes such acts or practices involving foreign commerce that--

(i) cause or are likely to cause reasonably foreseeable injury within the United States; or

(ii) involve material conduct occurring within the United States.

(B) All remedies available to the Commission with respect to unfair and deceptive acts or practices shall be available for acts and practices described in this paragraph, including restitution to domestic or foreign victims.

(b) Proceeding by Commission; modifying and setting aside orders

Whenever the Commission shall have reason to believe that any such person, partnership, or corporation has been or is using any unfair method of competition or unfair or deceptive act or practice in or affecting commerce, and if it shall appear to the Commission that a proceeding by it in respect thereof would be to

the interest of the public, it shall issue and serve upon such person, partnership, or corporation a complaint stating its charges in that respect and containing a notice of a hearing upon a day and at a place therein fixed at least thirty days after the service of said complaint. The person, partnership, or corporation so complained of shall have the right to appear at the place and time so fixed and show cause why an order should not be entered by the Commission requiring such person, partnership, or corporation to cease and desist from the violation of the law so charged in said complaint. Any person, partnership, or corporation may make application, and upon good cause shown may be allowed by the Commission to intervene and appear in said proceeding by counsel or in person. The testimony in any such proceeding shall be reduced to writing and filed in the office of the Commission. If upon such hearing the Commission shall be of the opinion that the method of competition or the act or practice in question is prohibited by this subchapter, it shall make a report in writing in which it shall state its findings as to the facts and shall issue and cause to be served on such person, partnership, or corporation an order requiring such person, partnership, or corporation to cease and desist from using such method of competition or such act or practice. Until the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time, or, if a petition for review has been filed within such time then until the record in the proceeding has been filed in a court of appeals of the United States, as hereinafter provided, the Commission may at any time, upon such notice and in such manner as it shall deem proper, modify or set aside, in whole or in part, any report or any order made or issued by it under this section. After the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time, the Commission may at any time, after notice and opportunity for hearing, reopen and alter, modify, or set aside, in whole or in part, any report or order made or issued by it under this section, whenever in the opinion of the Commission conditions of fact or of law have so changed as to require such action or if the public interest shall so require, except that (1) the said person, partnership, or corporation may, within sixty days after service upon him or it of said report or order entered after such a reopening, obtain a review thereof in the appropriate court of appeals of the United States, in the manner provided in subsection (c) of this section; and (2) in the case of an order, the Commission shall reopen any such order to consider whether such order (including any affirmative relief provision contained in such order) should be altered, modified, or set aside, in whole or in part, if the person, partnership, or corporation involved files a request with the Commission which makes a

satisfactory showing that changed conditions of law or fact require such order to be altered, modified, or set aside, in whole or in part. The Commission shall determine whether to alter, modify, or set aside any order of the Commission in response to a request made by a person, partnership, or corporation under paragraph [FN1] (2) not later than 120 days after the date of the filing of such request.

(c) Review of order; rehearing

Any person, partnership, or corporation required by an order of the Commission to cease and desist from using any method of competition or act or practice may obtain a review of such order in the court of appeals of the United States, within any circuit where the method of competition or the act or practice in question was used or where such person, partnership, or corporation resides or carries on business, by filing in the court, within sixty days from the date of the service of such order, a written petition praying that the order of the Commission be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Commission, and thereupon the Commission shall file in the court the record in the proceeding, as provided in section 2112 of Title 28. Upon such filing of the petition the court shall have jurisdiction of the proceeding and of the question determined therein concurrently with the Commission until the filing of the record and shall have power to make and enter a decree affirming, modifying, or setting aside the order of the Commission, and enforcing the same to the extent that such order is affirmed and to issue such writs as are ancillary to its jurisdiction or are necessary in its judgement to prevent injury to the public or to competitors pendente lite. The findings of the Commission as to the facts, if supported by evidence, shall be conclusive. To the extent that the order of the Commission is affirmed, the court shall thereupon issue its own order commanding obedience to the terms of such order of the Commission. If either party shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Commission, the court may order such additional evidence to be taken before the Commission and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Commission may modify its findings as to the facts, or make new findings, by reason of the additional evidence so taken, and it shall file such modified or new findings, which, if supported by evidence, shall be conclusive, and its recommendation, if any, for the modification or setting aside of its original order, with the return of

such additional evidence. The judgment and decree of the court shall be final, except that the same shall be subject to review by the Supreme Court upon certiorari, as provided in section 1254 of Title 28.

(d) Jurisdiction of court

Upon the filing of the record with it the jurisdiction of the court of appeals of the United States to affirm, enforce, modify, or set aside orders of the Commission shall be exclusive.

(e) Exemption from liability

No order of the Commission or judgement of court to enforce the same shall in anywise relieve or absolve any person, partnership, or corporation from any liability under the Antitrust Acts.

(f) Service of complaints, orders and other processes; return

Complaints, orders, and other processes of the Commission under this section may be served by anyone duly authorized by the Commission, either (a) by delivering a copy thereof to the person to be served, or to a member of the partnership to be served, or the president, secretary, or other executive officer or a director of the corporation to be served; or (b) by leaving a copy thereof at the residence or the principal office or place of business of such person, partnership, or corporation; or (c) by mailing a copy thereof by registered mail or by certified mail addressed to such person, partnership, or corporation at his or its residence or principal office or place of business. The verified return by the person so serving said complaint, order, or other process setting forth the manner of said service shall be proof of the same, and the return post office receipt for said complaint, order, or other process mailed by registered mail or by certified mail as aforesaid shall be proof of the service of the same.

(g) Finality of order

An order of the Commission to cease and desist shall become final--

(1) Upon the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time; but the Commission may thereafter modify or set aside its order to the extent provided in the last sentence of subsection (b).

(2) Except as to any order provision subject to paragraph (4), upon the sixtieth day after such order is served, if a petition for review has been duly filed; except that any such order may be stayed, in whole or in part and subject to such conditions as may be appropriate, by--

(A) the Commission;

(B) an appropriate court of appeals of the United States, if (i) a petition for review of such order is pending in such court, and (ii) an application for such a stay was previously submitted to the Commission and the Commission, within the 30-day period beginning on the date the application was received by the Commission, either denied the application or did not grant or deny the application; or
(C) the Supreme Court, if an applicable petition for certiorari is pending.
(3) For purposes of subsection (m)(1)(B) of this section and of section 57b(a)(2) of this title, if a petition for review of the order of the Commission has been filed--
(A) upon the expiration of the time allowed for filing a petition for certiorari, if the order of the Commission has been affirmed or the petition for review has been dismissed by the court of appeals and no petition for certiorari has been duly filed;
(B) upon the denial of a petition for certiorari, if the order of the Commission has been affirmed or the petition for review has been dismissed by the court of appeals; or
(C) upon the expiration of 30 days from the date of issuance of a mandate of the Supreme Court directing that the order of the Commission be affirmed or the petition for review be dismissed.
(4) In the case of an order provision requiring a person, partnership, or corporation to divest itself of stock, other share capital, or assets, if a petition for review of such order of the Commission has been filed--
(A) upon the expiration of the time allowed for filing a petition for certiorari, if the order of the Commission has been affirmed or the petition for review has been dismissed by the court of appeals and no petition for certiorari has been duly filed;
(B) upon the denial of a petition for certiorari, if the order of the Commission has been affirmed or the petition for review has been dismissed by the court of appeals; or
(C) upon the expiration of 30 days from the date of issuance of a mandate of the Supreme Court directing that the order of the Commission be affirmed or the petition for review be dismissed.
(h) Modification or setting aside of order by Supreme Court
If the Supreme Court directs that the order of the Commission be modified or set aside, the order of the Commission rendered in accordance with the mandate of the Supreme Court shall become final upon the expiration of thirty days from the time it was rendered, unless within such thirty days either party has instituted proceedings to have such order corrected to accord with the mandate, in which event the order of the Commission shall become final when so corrected.
(i) Modification or setting aside of order by Court of Appeals

If the order of the Commission is modified or set aside by the court of appeals, and if (1) the time allowed for filing a petition for certiorari has expired and no such petition has been duly filed, or (2) the petition for certiorari has been denied, or (3) the decision of the court has been affirmed by the Supreme Court, then the order of the Commission rendered in accordance with the mandate of the court of appeals shall become final on the expiration of thirty days from the time such order of the Commission was rendered, unless within such thirty days either party has instituted proceedings to have such order corrected so that it will accord with the mandate, in which event the order of the Commission shall become final when so corrected.

(j) Rehearing upon order or remand

If the Supreme Court orders a rehearing; or if the case is remanded by the court of appeals to the Commission for a rehearing, and if (1) the time allowed for filing a petition for certiorari has expired, and no such petition has been duly filed, or (2) the petition for certiorari has been denied, or (3) the decision of the court has been affirmed by the Supreme Court, then the order of the Commission rendered upon such rehearing shall become final in the same manner as though no prior order of the Commission had been rendered.

(k) "Mandate" defined

As used in this section the term "mandate", in case a mandate has been recalled prior to the expiration of thirty days from the date of issuance thereof, means the final mandate.

(l) Penalty for violation of order; injunctions and other appropriate equitable relief

Any person, partnership, or corporation who violates an order of the Commission after it has become final, and while such order is in effect, shall forfeit and pay to the United States a civil penalty of not more than $10,000 for each violation, which shall accrue to the United States and may be recovered in a civil action brought by the Attorney General of the United States. Each separate violation of such an order shall be a separate offense, except that in a case of a violation through continuing failure to obey or neglect to obey a final order of the Commission, each day of continuance of such failure or neglect shall be deemed a separate offense. In such actions, the United States district courts are empowered to grant mandatory injunctions and such other and further equitable relief as they deem appropriate in the enforcement of such final orders of the Commission.

(m) Civil actions for recovery of penalties for knowing violations of rules and cease and desist orders respecting unfair or deceptive acts or practices;

jurisdiction; maximum amount of penalties; continuing violations; de novo determinations; compromise or settlement procedure

(1)(A) The Commission may commence a civil action to recover a civil penalty in a district court of the United States against any person, partnership, or corporation which violates any rule under this chapter respecting unfair or deceptive acts or practices (other than an interpretive rule or a rule violation of which the Commission has provided is not an unfair or deceptive act or practice in violation of subsection (a)(1) of this section) with actual knowledge or knowledge fairly implied on the basis of objective circumstances that such act is unfair or deceptive and is prohibited by such rule. In such action, such person, partnership, or corporation shall be liable for a civil penalty of not more than $10,000 for each violation.

(B) If the Commission determines in a proceeding under subsection (b) of this section that any act or practice is unfair or deceptive, and issues a final cease and desist order, other than a consent order, with respect to such act or practice, then the Commission may commence a civil action to obtain a civil penalty in a district court of the United States against any person, partnership, or corporation which engages in such act or practice--

(1) after such cease and desist order becomes final (whether or not such person, partnership, or corporation was subject to such cease and desist order), and

(2) with actual knowledge that such act or practice is unfair or deceptive and is unlawful under subsection (a)(1) of this section.

In such action, such person, partnership, or corporation shall be liable for a civil penalty of not more than $10,000 for each violation.

(C) In the case of a violation through continuing failure to comply with a rule or with subsection (a)(1) of this section, each day of continuance of such failure shall be treated as a separate violation, for purposes of subparagraphs (A) and (B). In determining the amount of such a civil penalty, the court shall take into account the degree of culpability, any history of prior such conduct, ability to pay, effect on ability to continue to do business, and such other matters as justice may require.

(2) If the cease and desist order establishing that the act or practice is unfair or deceptive was not issued against the defendant in a civil penalty action under paragraph (1)(B) the issues of fact in such action against such defendant shall be tried de novo. Upon request of any party to such an action against such defendant, the court shall also review the determination of law made by the Commission in the proceeding under subsection (b) of this section that the act or practice which

was the subject of such proceeding constituted an unfair or deceptive act or practice in violation of subsection (a) of this section.
(3) The Commission may compromise or settle any action for a civil penalty if such compromise or settlement is accompanied by a public statement of its reasons and is approved by the court.
(n) Standard of proof; public policy consideration
The Commission shall have no authority under this section or section 57a of this title to declare unlawful an act or practice on the grounds that such act or practice is unfair unless the act or practice causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition. In determining whether an act or practice is unfair, the Commission may consider established public policies as evidence to be considered with all other evidence. Such public policy considerations may not serve as a primary basis for such determination.
[FN1] So in original. Probably should be “clause”.

15 U.S.C. § 52. Dissemination of false advertisements
(Sec. 12 of the FTCA)
(a) Unlawfulness
It shall be unlawful for any person, partnership, or corporation to disseminate, or cause to be disseminated, any false advertisement--
(1) By United States mails, or in or having an effect upon commerce, by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly the purchase of food, drugs, devices, services, or cosmetics; or
(2) By any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase in or having an effect upon commerce, of food, drugs, devices, services, or cosmetics.
(b) Unfair or deceptive act or practice
The dissemination or the causing to be disseminated of any false advertisement within the provisions of subsection (a) of this section shall be an unfair or deceptive act or practice in or affecting commerce within the meaning of section 45 of this title.

(x)

Dietary Supplement Health and Education Act of 1994
Public Law 103-417
(Oct. 25, 1994)
An Act

To amend the Federal Food, Drug, and Cosmetic Act to establish standards with respect to dietary supplements, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; REFERENCE; TABLE OF CONTENTS.

(a) SHORT TITLE- This Act may be cited as the 'Dietary Supplement Health and Education Act of 1994'.
(b) REFERENCE- Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.
(c) TABLE OF CONTENTS- The table of contents of this Act is as follows:

SEC. 2. FINDINGS.

Congress finds that--

(1) improving the health status of United States citizens ranks at the top of the national priorities of the Federal Government;
(2) the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies;
(3)(A) there is a link between the ingestion of certain nutrients or dietary supplements and the prevention of chronic diseases such as cancer, heart disease, and osteoporosis; and
(B) clinical research has shown that several chronic diseases can be prevented simply with a healthful diet, such as a diet that is low in fat, saturated fat, cholesterol, and sodium, with a high proportion of plant-based foods;
(4) healthful diets may mitigate the need for expensive medical procedures, such as coronary bypass surgery or angioplasty;
(5) preventive health measures, including education, good nutrition, and appropriate use of safe nutritional supplements will limit the incidence of chronic diseases, and reduce long-term health care expenditures;
(6)(A) promotion of good health and healthy lifestyles improves and extends lives while reducing health care expenditures; and
(B) reduction in health care expenditures is of paramount importance to the future of the country and the economic well-being of the country;
(7) there is a growing need for emphasis on the dissemination of information linking nutrition and long-term good health;
(8) consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements;
(9) national surveys have revealed that almost 50 percent of the 260,000,000 Americans regularly consume dietary supplements of vitamins, minerals, or herbs as a means of improving their nutrition;
(10) studies indicate that consumers are placing increased reliance on the use of nontraditional health care providers to avoid the excessive costs of traditional medical services and to obtain more holistic consideration of their needs;
(11) the United States will spend over $1,000,000,000,000 on health care in 1994, which is about 12 percent of the Gross National Product of the United States, and this amount and percentage will continue to increase unless significant efforts are undertaken to reverse the increase;
(12)(A) the nutritional supplement industry is an integral part of the economy of the United States;

(B) the industry consistently projects a positive trade balance; and
(C) the estimated 600 dietary supplement manufacturers in the United States produce approximately 4,000 products, with total annual sales of such products alone reaching at least $4,000,000,000;
(13) although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers;
(14) dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare; and
(15)(A) legislative action that protects the right of access of consumers to safe dietary supplements is necessary in order to promote wellness; and
(B) a rational Federal framework must be established to supersede the current ad hoc, patchwork regulatory policy on dietary supplements.

SEC. 3. DEFINITIONS.

(a) DEFINITION OF CERTAIN FOODS AS DIETARY SUPPLEMENTS- Section 201 (21 U.S.C. 321) is amended by adding at the end the following:
‘(ff) The term ‘dietary supplement’--
‘(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
‘(A) a vitamin;
‘(B) a mineral;
‘(C) an herb or other botanical;
‘(D) an amino acid;
‘(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
‘(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);
‘(2) means a product that--
‘(A)(i) is intended for ingestion in a form described in section 411(c)(1)(B)(i); or
‘(ii) complies with section 411(c)(1)(B)(ii);
‘(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and
‘(C) is labeled as a dietary supplement; and
‘(3) does--

‘(A) include an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262) and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 402(f); and
‘(B) not include--
‘(i) an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262), or
‘(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,
which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary’s discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this Act.
Except for purposes of section 201(g), a dietary supplement shall be deemed to be a food within the meaning of this Act.’.
(b) EXCLUSION FROM DEFINITION OF FOOD ADDITIVE- Section 201(s) (21 U.S.C. 321(s)) is amended--
(1) by striking ‘or’ at the end of subparagraph (4);
(2) by striking the period at the end of subparagraph (5) and inserting ‘; or’; and
(3) by adding at the end the following new subparagraph:
‘(6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.’.
(c) FORM OF INGESTION- Section 411(c)(1)(B) (21 U.S.C. 350(c)(1)(B)) is amended--
(1) in clause (i), by inserting ‘powder, softgel, gelcap,’ after ‘capsule,’; and
(2) in clause (ii), by striking ‘does not simulate and’.

SEC. 4. SAFETY OF DIETARY SUPPLEMENTS AND BURDEN OF PROOF ON FDA.

Section 402 (21 U.S.C. 342) is amended by adding at the end the following:

‘(f)(1) If it is a dietary supplement or contains a dietary ingredient that--
‘(A) presents a significant or unreasonable risk of illness or injury under--
‘(i) conditions of use recommended or suggested in labeling, or
‘(ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use;
‘(B) is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury;
‘(C) the Secretary declares to pose an imminent hazard to public health or safety, except that the authority to make such declaration shall not be delegated and the Secretary shall promptly after such a declaration initiate a proceeding in accordance with sections 554 and 556 of title 5, United States Code, to affirm or withdraw the declaration; or
‘(D) is or contains a dietary ingredient that renders it adulterated under paragraph (a)(1) under the conditions of use recommended or suggested in the labeling of such dietary supplement.
In any proceeding under this subparagraph, the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated. The court shall decide any issue under this paragraph on a de novo basis.
‘(2) Before the Secretary may report to a United States attorney a violation of paragraph (1)(A) for a civil proceeding, the person against whom such proceeding would be initiated shall be given appropriate notice and the opportunity to present views, orally and in writing, at least 10 days before such notice, with regard to such proceeding.’.

SEC. 5. DIETARY SUPPLEMENT CLAIMS.

Chapter IV (21 U.S.C. 341 et seq.) is amended by inserting after section 403A the following new section:
‘DIETARY SUPPLEMENT LABELING EXEMPTIONS

‘SEC. 403B. (a) IN GENERAL- A publication, including an article, a chapter in a book, or an official abstract of a peer-reviewed scientific publication that appears in an article and was prepared by the author or the editors of the publication, which is reprinted in its entirety, shall not be defined as labeling when used in connection with the sale of a dietary supplement to consumers when it--
‘(1) is not false or misleading;

‘(2) does not promote a particular manufacturer or brand of a dietary supplement;
‘(3) is displayed or presented, or is displayed or presented with other such items on the same subject matter, so as to present a balanced view of the available scientific information on a dietary supplement;
‘(4) if displayed in an establishment, is physically separate from the dietary supplements; and
‘(5) does not have appended to it any information by sticker or any other method.
‘(b) APPLICATION- Subsection (a) shall not apply to or restrict a retailer or wholesaler of dietary supplements in any way whatsoever in the sale of books or other publications as a part of the business of such retailer or wholesaler.
‘(c) BURDEN OF PROOF- In any proceeding brought under subsection (a), the burden of proof shall be on the United States to establish that an article or other such matter is false or misleading.’.

SEC. 6. STATEMENTS OF NUTRITIONAL SUPPORT.

Section 403(r) (21 U.S.C. 343(r)) is amended by adding at the end the following:
‘(6) For purposes of paragraph (r)(1)(B), 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 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. If the manufacturer of a dietary supplement proposes to make a statement described in the first sentence of this subparagraph in the labeling of the dietary supplement, the manufacturer shall notify the Secretary no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made.’.

SEC. 7. DIETARY SUPPLEMENT INGREDIENT LABELING AND NUTRITION INFORMATION LABELING.

(a) MISBRANDED SUPPLEMENTS- Section 403 (21 U.S.C. 343) is amended by adding at the end the following:
‘(s) If--
‘(1) it is a dietary supplement; and
‘(2)(A) the label or labeling of the supplement fails to list--
‘(i) the name of each ingredient of the supplement that is described in section 201(ff); and
‘(ii)(I) the quantity of each such ingredient; or
‘(II) with respect to a proprietary blend of such ingredients, the total quantity of all ingredients in the blend;
‘(B) the label or labeling of the dietary supplement fails to identify the product by using the term ‘dietary supplement’, which term may be modified with the name of such an ingredient;
‘(C) the supplement contains an ingredient described in section 201(ff)(1)(C), and the label or labeling of the supplement fails to identify any part of the plant from which the ingredient is derived;
‘(D) the supplement--
‘(i) is covered by the specifications of an official compendium;
‘(ii) is represented as conforming to the specifications of an official compendium; and
‘(iii) fails to so conform; or
‘(E) the supplement--
‘(i) is not covered by the specifications of an official compendium; and
‘(ii)(I) fails to have the identity and strength that the supplement is represented to have; or
‘(II) fails to meet the quality (including tablet or capsule disintegration), purity, or compositional specifications, based on validated assay or other appropriate methods, that the supplement is represented to meet.’.
(b) SUPPLEMENT LISTING ON NUTRITION LABELING- Section 403(q)(5)(F) (21 U.S.C. 343(q)(5)(F)) is amended to read as follows:
‘(F) A dietary supplement product (including a food to which section 411 applies) shall comply with the requirements of subparagraphs (1) and (2) in a manner which is appropriate for the product and which is specified in regulations of the Secretary which shall provide that--

‘(i) nutrition information shall first list those dietary ingredients that are present in the product in a significant amount and for which a recommendation for daily consumption has been established by the Secretary, except that a dietary ingredient shall not be required to be listed if it is not present in a significant amount, and shall list any other dietary ingredient present and identified as having no such recommendation;
‘(ii) the listing of dietary ingredients shall include the quantity of each such ingredient (or of a proprietary blend of such ingredients) per serving;
‘(iii) the listing of dietary ingredients may include the source of a dietary ingredient; and
‘(iv) the nutrition information shall immediately precede the ingredient information required under subclause (i), except that no ingredient identified pursuant to subclause (i) shall be required to be identified a second time.’.
(c) PERCENTAGE LEVEL CLAIMS- Section 403(r)(2) (21 U.S.C. 343(r)(2)) is amended by adding after clause (E) the following:
‘(F) Subclause (i) clause (A) does not apply to a statement in the labeling of a dietary supplement that characterizes the percentage level of a dietary ingredient for which the Secretary has not established a reference daily intake, daily recommended value, or other recommendation for daily consumption.’.
(d) VITAMINS AND MINERALS- Section 411(b)(2) (21 U.S.C. 350(b)(2)) is amended--
(1) by striking ‘vitamins or minerals’ and inserting ‘dietary supplement ingredients described in section 201(ff)’;
(2) by striking ‘(2)(A)’ and inserting ‘(2)’; and
(3) by striking subparagraph (B).
(e) EFFECTIVE DATE- Dietary supplements--
(1) may be labeled after the date of the enactment of this Act in accordance with the amendments made by this section, and
(2) shall be labeled after December 31, 1996, in accordance with such amendments.

SEC. 8. NEW DIETARY INGREDIENTS.

Chapter IV of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end the following:
‘NEW DIETARY INGREDIENTS

‘SEC. 413. (a) IN GENERAL- A dietary supplement which contains a new dietary ingredient shall be deemed adulterated under section 402(f) unless it meets one of the following requirements:
‘(1) The dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered.
‘(2) There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the Secretary with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.
The Secretary shall keep confidential any information provided under paragraph (2) for 90 days following its receipt. After the expiration of such 90 days, the Secretary shall place such information on public display, except matters in the information which are trade secrets or otherwise confidential, commercial information.
‘(b) PETITION- Any person may file with the Secretary a petition proposing the issuance of an order prescribing the conditions under which a new dietary ingredient under its intended conditions of use will reasonably be expected to be safe. The Secretary shall make a decision on such petition within 180 days of the date the petition is filed with the Secretary. For purposes of chapter 7 of title 5, United States Code, the decision of the Secretary shall be considered final agency action.
‘(c) DEFINITION- For purposes of this section, the term ‘new dietary ingredient’ means a dietary ingredient that was not marketed in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October 15, 1994.’.

SEC. 9. GOOD MANUFACTURING PRACTICES.

Section 402 (21 U.S.C. 342), as amended by section 4, is amended by adding at the end the following:

‘(g)(1) If it is a dietary supplement and it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations, including regulations requiring, when necessary, expiration date labeling, issued by the Secretary under subparagraph (2).
‘(2) The Secretary may by regulation prescribe good manufacturing practices for dietary supplements. Such regulations shall be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology. No standard of current good manufacturing practice may be imposed unless such standard is included in a regulation promulgated after notice and opportunity for comment in accordance with chapter 5 of title 5, United States Code.’.

SEC. 10. CONFORMING AMENDMENTS.

(a) SECTION 201- The last sentence of section 201(g)(1) (21 U.S.C. 321(g)(1)) is amended to read as follows: ‘A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.’.
(b) SECTION 301- Section 301 (21 U.S.C. 331) is amended by adding at the end the following:
‘(u) The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under section 413.’.
(c) SECTION 403- Section 403 (21 U.S.C. 343), as amended by section 7, is amended by adding after paragraph (s) the following:
‘A dietary supplement shall not be deemed misbranded solely because its label or labeling contains directions or conditions of use or warnings.’.

SEC. 11. WITHDRAWAL OF THE REGULATIONS AND NOTICE.

The advance notice of proposed rulemaking concerning dietary supplements published in the Federal Register of June 18, 1993 (58 FR 33690-33700) is null and void and of no force or effect insofar as it applies to dietary supplements. The Secretary of Health and Human Services shall publish a notice in the Federal

Register to revoke the item declared to be null and void and of no force or effect under subsection (a).

SEC. 12. COMMISSION ON DIETARY SUPPLEMENT LABELS.

(a) ESTABLISHMENT- There shall be established as an independent agency within the executive branch a commission to be known as the Commission on Dietary Supplement Labels (hereafter in this section referred to as the 'Commission').
(b) MEMBERSHIP-
(1) COMPOSITION- The Commission shall be composed of 7 members who shall be appointed by the President.
(2) EXPERTISE REQUIREMENT- The members of the Commission shall consist of individuals with expertise and experience in dietary supplements and in the manufacture, regulation, distribution, and use of such supplements. At least three of the members of the Commission shall be qualified by scientific training and experience to evaluate the benefits to health of the use of dietary supplements and one of such three members shall have experience in pharmacognosy, medical botany, traditional herbal medicine, or other related sciences. Members and staff of the Commission shall be without bias on the issue of dietary supplements.
(c) FUNCTIONS OF THE COMMISSION- The Commission shall conduct a study on, and provide recommendations for, the regulation of label claims and statements for dietary supplements, including the use of literature in connection with the sale of dietary supplements and procedures for the evaluation of such claims. In making such recommendations, the Commission shall evaluate how best to provide truthful, scientifically valid, and not misleading information to consumers so that such consumers may make informed and appropriate health care choices for themselves and their families.
(d) ADMINISTRATIVE POWERS OF THE COMMISSION-
(1) HEARINGS- The Commission may hold hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Commission considers advisable to carry out the purposes of this section.
(2) INFORMATION FROM FEDERAL AGENCIES- The Commission may secure directly from any Federal department or agency such information as the Commission considers necessary to carry out the provisions of this section.
(3) AUTHORIZATION OF APPROPRIATIONS- There are authorized to be appropriated such sums as may be necessary to carry out this section.

(e) REPORTS AND RECOMMENDATIONS-
(1) FINAL REPORT REQUIRED- Not later than 24 months after the date of enactment of this Act, the Commission shall prepare and submit to the President and to the Congress a final report on the study required by this section.
(2) RECOMMENDATIONS- The report described in paragraph (1) shall contain such recommendations, including recommendations for legislation, as the Commission deems appropriate.
(3) ACTION ON RECOMMENDATIONS- Within 90 days of the issuance of the report under paragraph (1), the Secretary of Health and Human Services shall publish in the Federal Register a notice of any recommendation of Commission for changes in regulations of the Secretary for the regulation of dietary supplements and shall include in such notice a notice of proposed rulemaking on such changes together with an opportunity to present views on such changes. Such rulemaking shall be completed not later than 2 years after the date of the issuance of such report. If such rulemaking is not completed on or before the expiration of such 2 years, regulations of the Secretary published in 59 FR 395-426 on January 4, 1994, shall not be in effect.

SEC. 13. OFFICE OF DIETARY SUPPLEMENTS.

(a) IN GENERAL- Title IV of the Public Health Service Act is amended by inserting after section 485B (42 U.S.C. 287c-3) the following:
'Subpart 4--Office of Dietary Supplements

'SEC. 485C. DIETARY SUPPLEMENTS.

'(a) ESTABLISHMENT- The Secretary shall establish an Office of Dietary Supplements within the National Institutes of Health.
'(b) PURPOSE- The purposes of the Office are--
'(1) to explore more fully the potential role of dietary supplements as a significant part of the efforts of the United States to improve health care; and
'(2) to promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions.
'(c) DUTIES- The Director of the Office of Dietary Supplements shall--
'(1) conduct and coordinate scientific research within the National Institutes of Health relating to dietary supplements and the extent to which the use of dietary

supplements can limit or reduce the risk of diseases such as heart disease, cancer, birth defects, osteoporosis, cataracts, or prostatism;
‘(2) collect and compile the results of scientific research relating to dietary supplements, including scientific data from foreign sources or the Office of Alternative Medicine;
‘(3) serve as the principal advisor to the Secretary and to the Assistant Secretary for Health and provide advice to the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs on issues relating to dietary supplements including--
‘(A) dietary intake regulations;
‘(B) the safety of dietary supplements;
‘(C) claims characterizing the relationship between--
‘(i) dietary supplements; and
‘(ii)(I) prevention of disease or other health-related conditions; and
‘(II) maintenance of health; and
‘(D) scientific issues arising in connection with the labeling and composition of dietary supplements;
‘(4) compile a database of scientific research on dietary supplements and individual nutrients; and
‘(5) coordinate funding relating to dietary supplements for the National Institutes of Health.
‘(d) DEFINITION- As used in this section, the term ‘dietary supplement’ has the meaning given the term in section 201(ff) of the Federal Food, Drug, and Cosmetic Act.
‘(e) AUTHORIZATION OF APPROPRIATIONS- There are authorized to be appropriated to carry out this section $5,000,000 for fiscal year 1994 and such sums as may be necessary for each subsequent fiscal year.’.
(b) CONFORMING AMENDMENT- Section 401(b)(2) of the Public Health Service Act (42 U.S.C. 281(b)(2)) is amended by adding at the end the following:
‘(E) The Office of Dietary Supplements.’.

TITLE 42--THE PUBLIC HEALTH AND WELFARE
CHAPTER 21B--RELIGIOUS FREEDOM RESTORATION

42 U.S.C. Sec. 2000bb. Congressional findings and declaration of purposes

(a) Findings
The Congress finds that--
(1) the framers of the Constitution, recognizing free exercise of religion as an unalienable right, secured its protection in the First Amendment to the Constitution;
(2) laws "neutral" toward religion may burden religious exercise as surely as laws intended to interfere with religious exercise;
(3) governments should not substantially burden religious exercise without compelling justification;
(4) in Employment Division v. Smith, 494 U.S. 872 (1990) the Supreme Court virtually eliminated the requirement that the government justify burdens on religious exercise imposed by laws neutral toward religion; and
(5) the compelling interest test as set forth in prior Federal court rulings is a workable test for striking sensible balances between religious liberty and competing prior governmental interests.

(b) Purposes
The purposes of this chapter are--
(1) to restore the compelling interest test as set forth in Sherbert v. Verner, 374 U.S. 398 (1963) and Wisconsin v. Yoder, 406 U.S. 205 (1972) and to guarantee its application in all cases where free exercise of religion is substantially burdened; and
(2) to provide a claim or defense to persons whose religious exercise is substantially burdened by government.

42 U.S.C. Sec. 2000bb-1. Free exercise of religion protected

(a) In general
Government shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability, except as provided in subsection (b) of this section.

(b) Exception

Government may substantially burden a person's exercise of religion only if it demonstrates that application of the burden to the person--
(1) is in furtherance of a compelling governmental interest; and
(2) is the least restrictive means of furthering that compelling governmental interest.

(c) Judicial relief
A person whose religious exercise has been burdened in violation of this section may assert that violation as a claim or defense in a judicial proceeding and obtain appropriate relief against a government. Standing to assert a claim or defense under this section shall be governed by the general rules of standing under article III of the Constitution.

42 U.S.C. Sec. 2000bb-2. Definitions
As used in this chapter--
(1) the term "government" includes a branch, department, agency, instrumentality, and official (or other person acting under color of law) of the United States, or of a covered entity;
(2) the term "covered entity" means the District of Columbia, the Commonwealth of Puerto Rico, and each territory and possession of the United States;
(3) the term "demonstrates" means meets the burdens of going forward with the evidence and of persuasion; and
(4) the term "exercise of religion" means religious exercise, as defined in section 2000cc-5 of this title.

42 U.S.C. Sec. 2000bb-3. Applicability
(a) In general
This chapter applies to all Federal law, and the implementation of that law, whether statutory or otherwise, and whether adopted before or after November 16, 1993.

(b) Rule of construction
Federal statutory law adopted after November 16, 1993, is subject to this chapter unless such law explicitly excludes such application by reference to this chapter.

(c) Religious belief unaffected

Nothing in this chapter shall be construed to authorize any government to burden any religious belief.

42 U.S.C. Sec. 2000bb-4. Establishment clause unaffected

Nothing in this chapter shall be construed to affect, interpret, or in any way address that portion of the First Amendment prohibiting laws respecting the establishment of religion (referred to in this section as the "Establishment Clause"). Granting government funding, benefits, or exemptions, to the extent permissible under the Establishment Clause, shall not constitute a violation of this chapter. As used in this section, the term "granting", used with respect to government funding, benefits, or exemptions, does not include the denial of government funding, benefits, or exemptions.

42 Sec. 2000cc-5. Definitions

In this chapter:

* * *

(7) Religious exercise

(A) In general

The term "religious exercise" includes any exercise of religion, whether or not compelled by, or central to, a system of religious belief.

(B) Rule

The use, building, or conversion of real property for the purpose of religious exercise shall be considered to be religious exercise of the person or entity that uses or intends to use the property for that purpose.

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 August 18, 2010, the foregoing 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:

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