No. 10-1064

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

DANIEL CHAPTER ONE, and JAMES FEIJO,
Petitioners,

v.

FEDERAL TRADE COMMISSION,
Respondent.

On Petition for Review from the Federal Trade Commission

BRIEF FOR RESPONDENT FEDERAL TRADE COMMISSION

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties and Amici

All parties and intervenors appearing below and in this Court are listed in the brief of petitioners Daniel Chapter One and James Feijo, filed with this Court on August 18, 2010.

B. Ruling Under Review

The ruling under review is the Federal Trade Commission's Modified Final Order ("Order"), issued on January 25, 2010, 20102010 WL 387917, (F.T.C.), Docket No. 9329. JA332-341.[1] The opinions supporting this order are the Commission's Opinion of December 18, 2009, 2009 WL 5160000, (F.T.C.), Docket No. 9329, JA299-331, and the Initial Decision of Chief Administrative Law Judge D. Michael Chappell, issued on August 5, 2009, 2009 WL 2584873, (F.T.C.), Docket No. 9329, JA160-298.

C. Related Cases

On August 13, 2010, the United States brought an enforcement action against DCO for violations of the Modified Final Order, seeking civil penalties, injunctive, and other relief, pursuant to 15 U.S.C. § 45(l). This enforcement action, Civ. No. 1:10-cv-01362-EGS, is currently pending before Judge Emmet G. Sullivan in the United States

[1] "JA" refers to the parties' Joint Appendix filed concurrently with Petitioners' Brief. "Br." refers to Petitioners' Brief. "IDF" refers to findings of fact contained in the Initial Decision.

District Court for the District of Columbia, who issued an order on September 14, 2010, staying the case pending resolution of this appeal.

/s/ Lawrence DeMille-Wagman
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STATUTES

MISCELLANEOUS

GLOSSARY

"ALJ"	Administrative Law Judge
"Br."	Brief of Petitioners, Daniel Chapter One and James Feijo
"CX"	Exhibits presented by the Federal Trade Commission, Complaint Counsel in the Administrative Proceedings
"Commission"	Federal Trade Commission
"DCO"	Daniel Chapter One
"DSHEA"	Dietary Supplement Health and Education Act of 1994
"FDA"	Food and Drug Administration
"FTC"	Federal Trade Commission
"HOJ"	Hearing on Jurisdiction
"IDF"	Initial Decision Finding of Fact
"IRC"	Internal Revenue Code
"JA"	Joint Appendix
"Order"	FTC's Modified Final Order of January 25, 2010
"RFRA"	Religious Freedom Restoration Act
"RX"	Exhibits presented by DCO, Respondents in the proceedings below
"Tr."	Transcript

JURISDICTIONAL STATEMENT

Jurisdiction for this Court's review of the Federal Trade Commission's ("FTC" or "Commission") Modified Final Order of January 25, 2010 ("Order"), lies under Section 5(c) of the FTC Act, 15 U.S.C. § 45(c). The Petition for Review was timely filed on March 17, 2010.

STATEMENT OF ISSUES PRESENTED FOR REVIEW

1) Whether the Commission properly exercised jurisdiction over Daniel Chapter One ("DCO"), where DCO operates as a commercial enterprise, and where DCO's principal, James Feijo ("Feijo") treats DCO's funds as his own.

2) Whether the Commission correctly held that DCO's advertising, which falsely represented that it had substantiation for claims that four of its challenged products could prevent, treat, or cure cancer, violated the FTC Act.

3) Whether the Commission's Order violates any of DCO's or Feijo's rights to freedom of speech or religion.

STATUTES AND REGULATIONS INVOLVED

Pertinent statutory provisions and regulations are reproduced in the addendum to the Petitioner's brief.

STATEMENT OF THE CASE

This case concerns deceptive advertising claims made by DCO that its nationally-marketed dietary supplements could cure or inhibit cancer. On September

16, 2008, the FTC issued the Complaint in this matter. JA23-61. Administrative proceedings were held before Chief Administrative Law Judge D. Michael Chappell ("ALJ") under Section 5(b) of the FTC Act, 15 U.S.C. § 45(b), and as provided for in Commission Rule of Practice 3.42, 16 C.F.R. § 3.42. The ALJ found DCO and Feijo liable under Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, and recommended entry of a cease and desist order. JA171.

Following its own de novo review, the Commission unanimously denied DCO's appeal and affirmed the ALJ's decision. JA299-323. The Commission concluded that: it had jurisdiction over petitioners because DCO operates a multi-million dollar commercial enterprise and Feijo treats DCO's funds as his own, JA302-306; DCO's advertising claimed that the challenged products could prevent, treat, or cure cancer, and that DCO had a reasonable basis to support its cancer-cure claims, JA307-310; DCO lacked substantiation for its cancer-cure claims, JA316-20; and DCO's constitutional and other defenses were meritless, JA310-323.

Based on these findings, the Commission issued an order (i) prohibiting DCO from making any of the claims challenged in the Commission's complaint unless such claim is true and DCO possessed competent and reliable scientific evidence to support that claim; (ii) requiring DCO to notify past purchasers of the challenged products of the FTC's ruling, and (iii) prohibiting DCO from making any efficacy- or health-

related claim regarding any future product sold unless the claim was true and supported by competent and reliable scientific evidence. JA324-329. On January 25, 2010, the Commission denied DCO's Petition for Reconsideration and issued the Order, which was modified solely to clarify the time periods relevant for enforcement of the order. JA332-41. This appeal followed. This Court denied DCO's emergency motion for a stay pending review of the Order on April 1, 2010.

STATEMENT OF THE FACTS[2]

A. DCO's Commercial and Financial Operations

Opened as a health food store in 1986, DCO was incorporated in 1990 as a for-profit corporation for the purpose of marketing dietary supplements. IDF12, 22, 23, JA173-74. Since at least 1993, DCO has marketed dietary supplements – including the four challenged products, Bio*Shark, 7 Herb Formula, GDU, and BioMixx – from its headquarters in Rhode Island. IDF13, 27, JA173-74. Feijo was responsible for the development, creation, production, and pricing of DCO's products. IDF37, JA176. By 1998, DCO was making sales nationwide through its website. IDF14, JA173. It operated a call center with a toll-free number, and a warehouse. IDF33, JA175.

[2] The ALJ's findings of fact were adopted by the Commission, JA301, and stand undisputed on this appeal.

At some point, DCO's corporate status was revoked, IDF26, JA174, and in 2002, it reorganized itself as a "corporation sole" under the laws of the State of Washington.[3] IDF28, JA174. DCO's articles of incorporation as a corporation sole state its purpose:

> to do whatever will promote the Kingdom of God, All Righteousness, and the principals [sic] of Liberty and Justice to provide for the comfort, happiness and improvement of an indefinite number of natural men and women, with special forerunner emphases upon the firm practice and lawful operation of the law * * * as well as other worthwhile projects for the common good of Daniel Chapter One and its close associates * * *.

IDF29, JA175. There is no provision in the Articles of Incorporation that DCO restrict its activities to charitable or nonprofit purposes. IDF30, JA175.

Even after its reorganization as a corporation sole, DCO continued to market dietary supplements to the general public, IDF80, JA180, using several websites, IDF103, JA182, a radio show (hosted by Feijo and his wife), IDF108-11, JA182-83, and various publications, IDF85-98, JA180-81. The "About Us" section on the DCO Website describes DCO as a "health food store" or "health food supplement store."

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[3] The corporation sole is a corporate structure that, under Washington state law, allows the "presiding elder" of any church to assume the rights of a corporation. *See* Wash. Rev. Code § 24.12.010. According to DCO, it operates as a "house church." IDF11, JA173. That is, it has no established doctrine or set location, and meets on an ad hoc basis in various locations. *Id.* DCO has no operational ties to the State of Washington. Neither DCO nor Feijo maintains a presence at the mailing address listed as the principal location on DCO's Articles of Incorporation. CX31; J. Feijo, HOJ Tr. 93-94.

IDF32, JA175. The radio show and publications provide consumers with DCO's toll-free number to order DCO products. IDF99-102, JA181-82. DCO also sells its products through distributors and stores in Florida, Georgia, Missouri, and Pennsylvania. IDF117, JA183. In addition to its commercial ventures, DCO carries out ministry activities in furtherance of its stated mission of healing based on biblical verses. IDF16-18, JA173-74.

Feijo is the "overseer" of DCO and trustee of all its assets, and his wife Patricia Feijo, the only other corporate officer, serves as Secretary. IDF5-7, JA172. DCO has a number of bank accounts, and has maintained surpluses in the hundreds of thousands of dollars in these accounts for extended periods of time. IDF42-45, JA176. Some accounts are described as "Business Partners" accounts. IDF42, JA176. The corporation has a policy of not maintaining records and Feijo does not keep track of expenditures. IDF47, 50, JA177. From late 2006 to early 2008, the Business Partners Money Market Fund showed a balance of over $1 million, but in February 2008, over $800,000 was withdrawn from this account. IDF45, JA176.

Feijo does not have his own individual bank account and treats DCO's assets as his own. IDF76, JA179, JA303. DCO pays all the Feijos' living expenses. IDF58, JA178, JA303. Although DCO did not maintain records of total funds spent on the Feijos' expenses, IDF59, JA178, it is undisputed that the Feijos use DCO's funds to:

(i) pay for their two homes, one of which is in Florida on country club land with a pool in the back; (ii) pay for the two Cadillacs that they use; and (iii) bankroll discretionary entertainment expenses. IDF58, 61-70; JA178-79, JA303.[4] For example, between December 2005 and March 2009, DCO's American Express Business Gold Card (to which Feijo is a signatory), was charged almost $10,000 for golf expenses, IDF67, JA178; about $14,000 in restaurant expenses (including restaurants such as P.F. Chang's and the Cheesecake Factory) IDF68, JA178-79, CX48; and just over $1,000 to buy cigars, IDF70, JA179.

The Feijos financed their country-club lifestyle with the roughly $2 million per year generated by DCO's sales of 150 to 200 dietary supplement products. IDF9, 10, JA173, JA303. About twenty to thirty percent of DCO's sales revenue comes from the four challenged products, with sales totaling approximately $400,000 to $600,000 per year from 2006 to 2008. IDF80, JA180, JA303. These revenues derive from a substantial markup: DCO sells a bottle of 100 Bio*Shark capsules (which lasts consumers from two to three weeks) for a price of $30.95. IDF126-27, JA185 However, it purchases that bottle for $3.15 from a wholesaler. IDF128, JA185. It sells a 120-capsule bottle of GDU (which lasts consumers from one to three weeks)

[4] Just like DCO, the Feijos also do not maintain records. IDF59, JA178. Nor do they file tax returns with regard to the money they receive from DCO; and James Feijo stopped paying individual income taxes prior to DCO's incorporation as a corporation sole. IDF60, 78, JA178-79.

for $29.95, and it purchases that bottle for $3.28 from its wholesaler. IDF139-41, JA186. It sells a three-pound container of BioMixx for $40.95, but pays only $11.50 for that container. IDF144-45, JA187. Finally, DCO itself formulates the 32-ounce bottles of 7 Herb Formula. DCO charges $70.95 for each bottle, which will last a consumer from eight to sixteen days. IDF135-36, JA185-86. Overall, DCO's product acquisition costs are less than one-third the sales price. IDF83, JA180, JA303.

DCO sells the challenged products through a variety of channels, including publications, a call center, over the Internet, and through stores and distributors. IDF84, 158, JA180, 188. The Feijos have also promoted the challenged products during the DCO radio program and counseled listeners who identify themselves as cancer patients to take those products. IDF108-11, JA182-83. During the program, the Feijos have provided listeners with DCO's toll-free number to use for purchase of DCO's products. IDF111, JA183, JA304.

DCO's publications are fourfold: BioGuide: the BioMolecular Nutrition Guide to Natural Health ("BioGuide"); the BioMolecular Nutrition Product Catalog ("Product Catalog"); a newsletter entitled "How to Fight Cancer is Your Choice!!!" ("Newsletter"), and "The Most Simple Guide to the Most Difficult Diseases: The Doctors' How-To Quick Reference Guide" ("Most Simple Guide"). JA303-04. All four publications describe and promote the four challenged products. *Id.* The

publications also cross-reference one another, and all except the Product Catalog promote DCO's radio program. *Id*. Each publication likewise promotes DCO's call center and the toll-free number to access it, as well as DCO's principal website address. JA304. The Newsletter, the BioGuide, and the Most Simple Guide were all available through DCO's website. IDF163, 169, 172, JA188-89.

DCO's publications sometimes reference DCO's ministry and the spiritual aspects of DCO's approach to nutrition – *see, e.g.*, JA303 (BioGuide describes both the spiritual and physical aspects of BioMolecular Nutrition); JA47 (website for 7 Herb Formula stating DCO is "blessed that God has revealed this formula"); JA50 (website for Bio*Shark stating scientists are "trying to replicate what God has already presented to us" and "have been looking for a drug to patent that can do the same thing as shark cartilage"). Yet many, if not most, of DCO's sales materials make no reference to religion or spirituality, or do so only within buried disclaimers. *See, e.g.*, JA37-38 (product description for Bio*Shark); JA52-54 (product description for 7 Herb Formula); JA56-58 (product description for GDU); JA61(description of BioMixx contained in DCO's Cancer Newsletter). There is no mention of a DCO ministry in the BioMolecular Nutrition Product Catalog. JA303. And the DCO Cancer Newsletter is, according to Feijo, "strictly all about the products for cancer." IDF195, JA194.

DCO contracts with various distributors to sell its products, including natural food stores and chiropractic centers. IDF116-119, JA183. Doctors and stores that carry DCO's merchandise receive products at discounts below retail price, and can charge significant mark-ups. IDF120-21, JA184. These distributors receive a brochure from DCO which promises financial benefits such as "boost[ed] sales" and "earnings potential," and represents that DCO is "the ONLY nutrition company where the owners personally tell thousands of people to visit your office or store." IDF122, JA184, JA304. DCO also runs an Internet-based affiliate marketing program wherein participants, who do not have to be religious entities, work on commission from sales generated by DCO-sponsored links that they agree to place on their own websites. IDF123-24, JA184.

The principal DCO website invited visitors to shop at DCO's "On-Line Store" and to "Buy Now." IDF103-106, JA182, JA304. When a consumer purchased the challenged products directly from DCO's website, there was no indication that the consumer needed to be part of a religious community to obtain the challenged products. IDF149,150, JA187. Any consumer entering the term "cancer" in a Google Internet search could be directed to the DCO website. IDF162 JA188, JA303. In its sales materials, DCO compares its products and organization to "other brands," or "other companies." IDF137-38; JA186, JA236. Consumers who purchase online are

charged shipping and handling fees, offered coupons for their next online order, and provided with volume discounts. IDF112-115, JA183, JA304. Over a thousand people have purchased the challenged products, including people who do not belong to any DCO religious community and people who do not believe in God. IDF81-82, JA180, JA303.

B. DCO's Advertising Claims That The Challenged Products Can Prevent, Treat, or Cure Cancer, and the Absence of Scientific Substantiation for Such Claims

DCO's advertising represented that the four challenged products could prevent, treat, or cure cancer. Bio*Shark is a capsule whose primary ingredient is shark cartilage. IDF126, JA185, JA37.[5] DCO advertises that Bio*Shark "stops tumor growth." IDF223, 233-34, JA200, 202-03, JA37. The 7 Herb Formula is a liquid tea concentrate concocted of, *inter alia*, Turkey rhubarb root, sheep sorrel, Siberian ginseng, and cat's claw. IDF134, JA185, JA52-53. DCO advertises that 7 Herb Formula will "decrease cell mutation" and "fight * * * tumor formation." IDF237, JA203, JA52. GDU capsules contain, *inter alia*, bromelain, turmeric, quercetin, feverfew, and boron. IDF139, JA186, JA56-57. DCO claims that GDU helps the body "digest * * * unwanted tumors and cysts," and "can aid the body in eliminating a tumor." IDF263, 276, JA208, 210, JA56. BioMixx is a powder that contains

[5] The Commission attached examples of DCO advertising to its administrative complaint. *See* JA23-35 (complaint) and JA36-61 (copies of DCO advertisements).

goldenseal, echinacea, and ginseng. IDF143, JA186, JA61. DCO touts BioMixx as able to "assist the body in fighting cancer." IDF293, JA214, JA61. The challenged products are said, *inter alia*, to "stop tumor growth," "fight [] tumor formation," "battle[] cancer," and "eliminate[] pre-cancerous growth." IDF180, 182, 184, 221-23, 226, 229, 233-34, 238-41, 253, 266, 283, JA190-191, 199-201, 202-204, 206, 208, 211.

DCO's advertising is replete with testimonials that tout the products' success in treating cancer. *See, e.g.,* IDF184, JA191 (after taking 7 Herb Formula and BioMixx, the consumer claimed to have gone into remission from leukemia and three inoperable tumors); IDF243, JA204-05, JA50 (consumer who took 7 Herb Formula experienced "massive tumor shrinkage"); IDF268, JA209 (consumer who took GDU "cured breast cancer in 3 months"); JA43 (consumer's brain stem tumor "has completely disappeared" and other tumors have shrunk from use of challenged products).

DCO's "Cancer News webpage" refers to specific cures and products - "Dad's throat cancer cured - 7 Herb and more," "Nancy- - Cured Breast Cancer in 3 months - 7 Herb and GDU," and "Robert- Prostate cured from [DCO] products." IDF187, JA192, JA40-41. Respondents urge consumers who "suffer from any type of cancer" "**to buy the products**" they describe as "**Daniel Chapter One's Cancer solutions**,"

assuring consumers that **"How to fight cancer is your choice!"** IDF180 (bold in original), JA190, JA40-41. Overall, DCO's advertisements and promotional materials appear in a variety of media, repeatedly cross-reference one another, and continually represent, in a mutually-reinforcing fashion, that the challenged products are effective in preventing, treating, or curing cancer or tumors. JA307.[6] The undisputed net impressions from DCO's advertisements are that the challenged products prevent, treat, or cure cancer. IDF 306, JA216, JA308.

In answering the Commission's complaint, DCO alleged that it possessed and relied upon a reasonable basis to substantiate the representations made for the challenged products at the time the representations were made. IDF307, JA216, JA65 (Answer ¶ 16). Yet DCO presented no evidence that they, the product manufacturers,

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[6] The Commission alleged that DCO made the following health and disease claims about the Challenged Products:

a. Bio*Shark inhibits tumor growth;
b. Bio*Shark is effective in the treatment of cancer;
c. 7 Herb Formula is effective in the treatment or cure of cancer;
d. 7 Herb Formula inhibits tumor formation
e. GDU eliminates tumors;
f. GDU is effective in the treatment of cancer;
g. BioMixx is effective in the treatment of cancer; and
h. BioMixx heals the destructive effects of radiation and chemotherapy.

JA27 (Complaint ¶ 14). The Commission likewise alleged that DCO "represented, either expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 14." *Id.* (Complaint ¶ 16).

or anyone else, had ever carried out scientific testing of the effects of the challenged products. IDF308-15, JA217, JA316. Instead, DCO claimed to have relied on personal observations, customer testimonials, and a variety of books, magazines, and articles about how certain substances in the challenged products could be utilized. IDF316-318, JA217. One of the experts hired by DCO to evaluate DCO's substantiation claims herself recognized that, because the challenged products had not been tested, their effectiveness in the prevention, treatment, or cure of cancer is not known. IDF364, JA224.

C. The Administrative Proceedings

The Commission's administrative complaint alleged that DCO's advertising represented, *inter alia*, that Bio*Shark is effective for the treatment of cancer, that 7 Herb Formula inhibits the formation of tumors, that GDU eliminates tumors, and that BioMixx is effective in the treatment of cancer. The complaint further alleged that DCO lacked a reasonable basis to substantiate those claims. JA23-27, JA167.

DCO moved to dismiss the complaint, arguing that it was a nonprofit religious ministry outside the Commission's jurisdiction. After an evidentiary hearing on this motion, the ALJ concluded that jurisdiction did exist, denied DCO's motion to dismiss the complaint for lack of jurisdiction, and rejected the argument that DCO operated solely as a nonprofit religious ministry outside the Commission's jurisdiction. JA169,

JA234-44. The ALJ likewise rejected DCO's second motion to dismiss, and declined to decide the case summarily. JA169. The ALJ then conducted two-and-a-half days of trial regarding the allegations in the Commission's complaint. Over seventy exhibits were admitted into evidence and eleven witnesses testified. *Id*.

The Commission presented the testimony of expert witness Dr. Miller, a board-certified pediatric hematologist/oncologist, with over forty years of experience including management experience at facilities such as Memorial Sloan-Kettering Cancer Center. IDF320-21, JA218. The ALJ concluded that Dr. Miller was qualified to give expert opinions regarding cancer, cancer research, and research methodology. IDF326, JA218. Based on his review of the relevant scientific literature and the materials DCO relied upon for substantiation, Dr. Miller testified that no competent and reliable scientific evidence substantiated DCO's cancer-cure claims. IDF328, 362-386, JA224-27; *see also* JA70-108 (Miller Report). Dr. Miller also reviewed thirty of DCO's testimonials and concluded that there was insufficient documentation to establish that any of the testimonialists actually had cancer. IDF353, JA222.

Although DCO proffered five experts, none was a medical doctor, none had specialized training regarding cancer or cancer treatment, and none had conducted clinical studies regarding cancer. IDF335-337, JA220. One DCO expert had "no idea" of the ingredients contained in the challenged products. IDF412, JA230, JA317

(Roy). Two others were ignorant of the concentration of the ingredients contained in the challenged products. JA317, IDF330, 394, JA219, 228 (Duke); IDF395, 401, JA228-229 (Lamont). A fourth expert extolled the benefits of another DCO product ("Prepost") unrelated to this case and never once mentioned the challenged products. IDF334, JA220, RX21 (Lehr). The final expert, a manufacturer of "nutraceuticals," stated that he believed 7 Herb Formula was safe, but offered no opinion as to whether it could treat or cure cancer. IDF333, JA220, RX6 (Dews). None of DCO's experts reviewed the advertisements at issue. IDF338, 342, JA220-21.

On August 5, 2009, the ALJ issued a 124-page Initial Decision, containing 425 detailed findings of fact, and 29 conclusions of law in which he concluded that: DCO had engaged in a business for profit, DCO had advertised that the four challenged products could cure or inhibit cancer, and DCO's commercial speech was deceptive because DCO did not have a reasonable basis for those claims. JA171, JA160-298. The ALJ recommended entry of an order prohibiting DCO from making any of the claims challenged in the Commission's complaint unless such claim is true and DCO possesses competent and reliable scientific evidence to support that claim. He also recommended that DCO be required to notify past purchasers of the challenged products that there was no scientific evidence supporting the cancer-cure claims that DCO had made. Finally, he recommended that DCO be prohibited from making any

efficacy- or health-related claim regarding any product that it sold unless that claim was true and DCO possessed competent and reliable scientific evidence to back up that claim. JA291-298.

As provided by Commission Rule 3.52, 16 C.F.R. § 3.52, DCO appealed the Initial Decision to the Commission. A unanimous Commission denied DCO's appeal. JA299. The Commission first rejected DCO's contention that DCO was a nonprofit corporation exempt from the Commission's jurisdiction. Drawing on established precedent, the Commission recognized that, even if an entity is organized as a nonprofit, such "status insulates an entity from FTC jurisdiction when the entity is engaged in business for 'only charitable purposes.'" JA305 (quoting *Community Blood Bank v. FTC*, 405 F.2d 1011, 1022 (8th Cir. 1969)). It found that "DCO bears none of the substantive indicia of a corporation that is truly organized only for charitable purposes," and that DCO did not devote its profits to any charitable purpose, but used them instead to support a lavish lifestyle for Feijo. JA306.

The Commission next rejected DCO's contentions that its cancer-cure claims were protected by the First Amendment, JA311-314. In so doing the Commission concluded that the "primary purpose and effect of [the] representations concerning the four Challenged Products was to sell those products," JA311, and that, because DCO's commercial speech was deceptive, it was not entitled to any First Amendment

protection. The Commission recognized that DCO "g[ot] things backward" by insisting that the FTC identify a substantial interest in order to justify restricting their advertisements. JA312. The threshold inquiry to afford commercial speech First Amendment protection, under *Central Hudson*, is that "'it at least must concern lawful activity and not be misleading.'" *Id.* (quoting *Central Hudson Gas & Elec. Co. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980)). The Commission found meritless DCO's arguments – based on flawed readings of other statutes – that it could not be held liable for deceptive advertisement, JA313-14, and concluded that DCO's assertions that the advertisements at issue were intended only to promote spiritual complements to traditional cancer care were "at odds with almost all of the advertisements themselves." JA314. The Commission then rejected DCO's arguments that the ALJ failed to accord it due process, JA315, and that it had substantiation for its cancer-cure claims, JA316-320.

In addressing DCO's substantiation arguments, the Commission rejected DCO's claim that, to interpret the advertising, "extrinsic evidence" was required, because the nature of the claims was facially obvious. JA319. The Commission further found "irrelevant" DCO's assertion that the Commission's substantiation standard required placebo-controlled, double-blind studies, because DCO "had not possessed or relied upon *any* adequate substantiation for [its] claims." *Id.* (emphasis

in original). Finally, the Commission rejected DCO's contention that the remedy recommended by the ALJ was arbitrary or capricious, or violated its constitutional rights. JA320-323. The Commission revised the ALJ's proposed Order only "in the interest of brevity," JA323, and subsequently issued the Order here at issue to clarify the pertinent dates for enforcement. JA332-341. This Order includes remedial provisions substantially identical to the relief initially recommended by the ALJ. *Compare* JA332-341 *with* JA291-298.

On February 25, 2010, DCO filed a motion with the Commission seeking a stay pending resolution of a petition for review. The Commission denied that motion on March 22. On March 17, 2010, DCO filed its petition for review with this Court. This Court denied DCO's emergency motion for a stay pending review of the Order on April 1, 2010.[7]

STANDARD OF REVIEW

Review of the Commission's legal analysis is de novo, "although even in considering such issues the courts are to give some deference to the Commission's

[7] In an action currently before the United States District Court for the District of Columbia, the United States has alleged that DCO is violating the Order by continuing to deceptively advertise the challenged products, and by failing to provide past customers with the notice required by Part V of the Order. *See* Civ. No. 1:10-cv-01362-EGS. On September 14, 2010, Judge Sullivan issued an order denying the government's request for injunctive relief (relying on a purported lack of jurisdiction) and staying the enforcement action pending resolution of the instant appeal.

informed judgment." *FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 454 (1986). The "findings of the Commission as to the facts, if supported by evidence, shall be conclusive." 15 U.S.C. § 45(c); *Polygram Holding, Inc. v. FTC*, 416 F.3d 29, 33 (D.C. Cir. 2005). In determining whether a factual finding is supported by the evidence, the Court's role is "not to reweigh the evidence de novo to determine how [it] would have resolved the matter * * * [but] only to determine if the Commission's finding is supported by substantial evidence on the record as a whole." *Thompson Med. Co. v. FTC*, 791 F.2d 189, 196 (D.C. Cir. 1986). The Court's role in reviewing the remedy is likewise "limited," as "'[t]he Commission is the expert body to determine what remedy is necessary to eliminate the unfair or deceptive trade practices which have been disclosed * * * and courts will not interfere except where the remedy selected has no reasonable relation to the unlawful practices found to exist.'" *Warner-Lambert Co. v. F.T.C.*, 562 F.2d 749, 762 (D.C. Cir. 1977) (quoting *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 612-13 (1946)).

SUMMARY OF ARGUMENT

The Commission correctly applied governing precedent to undisputed facts in concluding that jurisdiction was proper, holding DCO liable for violating the FTC Act, and rejecting DCO's constitutional challenges.

The Commission did not err in asserting jurisdiction. Abundant and uncontroverted evidence established that, irrespective of DCO's formal non-profit status and religious trappings, DCO also operates a multi-million-dollar commercial enterprise, the proceeds of which inure directly to the benefit of James Feijo. Both the for-profit nature of DCO's operations, and the use of DCO's profits for Feijo's private gain serve to establish jurisdiction under the FTC Act. (Part I)

Nor did the Commission err in concluding that DCO's deceptive advertisements violated the FTC Act. Claims that the four challenged products could prevent, treat, or cure cancer were pervasive and apparent from the face of DCO's advertising. And, the implied representation that DCO could substantiate its cancer-cure claims was part and parcel of the express representations that the challenged products could treat or cure cancer. Indeed, in answering the FTC's complaint, DCO admitted to representing to consumers that it had a reasonable basis for the cancer-cure claims that it made. (Part II.A)

The Commission engaged in an exhaustive and fact-intensive examination before determining that DCO's implicit representation that it could substantiate its cancer-cure claims was false. DCO failed to limit or specify the nature of the substantiation it claimed for its cancer-cure claims. In such circumstances, consumers expect an advertiser to possess scientific evidence to support a representation that a

product can cure or treat a disease (such as cancer). Overwhelming evidence supports the Commission's determination that DCO's cancer-cure claims lacked a "reasonable basis," and, in particular, that DCO nowhere possessed the competent and reliable scientific evidence needed to support its generalized health-related efficacy claims. DCO failed to demonstrate that it had a reasonable basis for its cancer-cure claims. (Part II.B)

Contrary to DCO's broadside attack, the substantiation requirement imposed in this case is not a form of back-door regulation of dietary supplements, nor does it entail a novel shift of the burden of proof. On the contrary, the Commission's ruling is a straightforward application of long-established principles of deception law under the FTC Act. The Commission determined that DCO had implicitly represented that it had substantiation for its health-related efficacy claims, and then determined that this representation was false. The Commission properly addresses such issues in a flexible manner, in case-by-case adjudiction, and is not required to promulgate rules to effectuate the anti-deception provision of Section 5 of the FTC Act. (Part II.C) Furthermore, the Commission's resulting Order is not at odds with the Dietary Supplement Health and Education Act. Nothing in that statute immunizes false advertisements from liability under the FTC Act. (Part II.D)

The Commission's Order does not impinge on DCO's freedom of speech or religious freedom. Although truthful commercial speech enjoys some measure of First Amendment protection, deceptive speech does not. The Commission correctly recognized that the First Amendment provides no shield to the sort of deceptive advertising in which DCO engaged. Given the specific findings that DCO's claims were actually deceptive, DCO's heavy reliance upon *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) is unavailing. (Part III.A) Also without merit are DCO's contentions that the Commission's Order violates the First Amendment. To the limited extent that the Order could be read to curtail any non-deceptive commercial speech, it readily satisfies constitutional scrutiny under the *Central Hudson* standard. (Part III.B)

DCO's argument that the Commission has established the "religion of scientism" is likewise meritless and lacks grounding in the facts of this case. The Commission has not prohibited marketing of alternative medicines, but simply held DCO liable for its specific deceptive practices. (Part III.C) Finally, DCO has failed to demonstrate that the Commission's Order substantially burdens its exercise of religion. (Part III.D)

ARGUMENT

I. JURISDICTION IS PROPER BECAUSE DCO OPERATES A COMMERCIAL ENTERPRISE AND DCO'S PROFITS ARE USED FOR FEIJO'S PRIVATE GAIN

The fact that DCO may operate a religious ministry, or has formally donned nonprofit status, does not foreclose the FTC from exercising jurisdiction. Rather, the "jurisdictional touchstone" of the FTC Act is "profit." *California Dental Ass'n v. FTC*, 526 U.S. 756, 767-68 (1999). Engaging in some religious activity or styling oneself as a nonprofit does not protect an entity from FTC jurisdiction if that entity is actually engaged in business for other than "only charitable purposes." *Community Blood Bank*, 405 F.2d at 1022; *see also In re Ohio Christian Coll. (of Calvary Grace Christian Churches of Faith, Inc.)*, 80 F.T.C. 815, 848 (1972).

Uncontroverted and abundant evidence establishes that DCO did far more than engage in business for "only charitable purposes." As the Commission observed, "[w]hatever else may be said about DCO's religious status and activities, the findings of fact, supported by extensive evidence, establish that DCO conducted business for the purpose and with the effect of selling its products, including the four challenged products." JA305 (referencing over 100 findings of fact). Moreover, "the ALJ's

findings of fact, supported by ample evidence, show that the 'destination' of the profits of DCO's for-profit activities was James Feijo." JA306.[8]

The Commission correctly applied the governing legal standards to undisputed facts in concluding that jurisdiction was proper. Section 4 of the FTC Act does not insulate all entities with nonprofit status from the Commission's jurisdiction, and DCO misrepresents the proceedings below in stating that the Commission assumed that only Section 501(c)(3) tax-exempt status could protect DCO from the Commission's jurisdiction. Where, as here, overwhelming evidence demonstrated that DCO generated funds from commercial activities, and the use of such funds was not confined to charitable purposes, jurisdiction is proper.

A. In Determining Jurisdiction, The Commission Applied The Correct Legal Standard

In determining jurisdiction under the FTC Act, substance trumps form. *See Community Blood Bank*, 405 F.2d at 1018-19 (it is the reality of a corporation's actions, not its mere form, that determines whether a corporation is beyond the reach of the FTC Act). Yet in challenging the Commission's jurisdictional holding, DCO clings tightly to form over substance, ignores the evidence, and mischaracterizes the proceedings below.

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[8] The Commission's other jurisdictional holdings – that James Feijo is a person over whom the FTC has jurisdiction, and that DCO engages in interstate commerce – have not been challenged in this appeal.

In *California Dental*, the Supreme Court upheld the Commission's assertion of jurisdiction over a voluntary nonprofit association of local dental societies that was "exempt from federal income tax under 26 U.S.C. §501(c)(6)." 526 U.S. at 759. Even though the entity was formally a nonprofit, it "provide[d] substantial economic benefit" to its members. *Id*. In affirming jurisdiction, a unanimous Court observed that the "FTC Act is at pains to include not only an entity 'organized to carry on business for its own profit,' 15 U.S.C. § 44, but also one that carries on business for the profit 'of its members,' *ibid.*" *Id.* at 766.

The Court expressly noted that its decision in *California Dental* was "fully consistent" with the Eighth Circuit's decision in *Community Blood Bank*. 526 U.S. at 767 n.6. There, the Eighth Circuit had observed that Congress "did not intend to provide a blanket exclusion [from FTC jurisdiction] of all nonprofit corporations, for it was also aware that corporations ostensibly organized as not-for-profits, such as trade associations, were merely vehicles through which a pecuniary profit could be realized for themselves or their members." 405 F.2d at 1017. *Community Blood Bank* recognized "that the mere form of incorporation does not put [an entity] outside the jurisdiction of the Commission." *Id.* at 1019. The court further noted that "settled law" vested the Commission with jurisdiction "over organizations without shares of capital or certificates engaged in business for pecuniary profit." *Id.*

Denial of jurisdiction in *Community Blood Bank*, therefore, was premised not on the associations' nonprofit labels, but on a fact-intensive inquiry into the organizations' actual practices. Jurisdiction was denied because, *inter alia*, "any profit realized * * * [was] devoted exclusively to * * * charitable purposes," *id.*, and "uncontroverted evidence" supported the Commission's findings that "no part of any funds received by [the associations had] ever been distributed or inured to the benefit of any of their members, directors or officers * * * ," *id.*, at 1020.

Thus, the Commission did not "mistakenly assume[] that only entities that have obtained a Section 501(c)(3) tax exemption are * * * beyond FTC jurisdiction." DCO's Brief ("Br.") 21. Although a formal claim of tax exempt status may be one factor to consider in determining whether an entity truly is a nonprofit, it is not dispositive. Moreover, the Commission has repeatedly recognized that it is not bound by determinations made under other statutes. *See, e.g.*, JA238; *In re College Football Ass'n*, 117 F.T.C. 971, 994 (1994). Indeed, if mere tax exempt status were sufficient to remove an entity from the FTC's jurisdiction, the analysis in cases such as *California Dental* and *Community Blood Bank* would be superfluous.

In insisting that the Commission misapplied governing precedent, the logic of DCO's argument appears to be: 1) DCO operates a church; 2) it is therefore automatically exempt from federal taxes, notwithstanding its failure to claim 501(c)(3)

status[9]; and 3) because DCO is purportedly tax exempt, it is automatically immune from FTC jurisdiction. Br. 21-23. DCO further argues that the Commission failed to consider provisions of the Washington State Code regarding the legal requirements for corporations sole, which also establish DCO's tax-exempt status.[10] Br. 22-23. Not only are these arguments red herrings (as legal form is the beginning, not the end, of the jurisdictional inquiry), they are also premised on a misunderstanding of the law and a misrepresentation of the facts. DCO may operate a church, but it also operates a business that financially benefits James Feijo and his family.

The Commission, therefore, did not err in "look[ing] to the substance, rather than the form, of incorporation" in reviewing the ALJ's determination that jurisdiction

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[9] As the IRS has noted, although churches need not expressly claim 501(c)(3) status to be tax exempt, they are automatically exempt from taxes *only* if they meet the *substantive* requirements of 501(c)(3), including, *inter alia*, that the organization be organized and operated exclusively for religious, educational, scientific, or other charitable purposes, and that net earnings not inure to the benefit of any private individual or shareholder. *See* IRS Tax Guide for Churches and Religious Organizations, at 3, *available at* http://www.irs.gov/pub/irs-pdf/p1828.pdf.

[10] With respect to DCO's suggestion that its status as a corporation sole, in and of itself, is sufficient to insulate it from jurisdiction, the IRS has warned that corporations sole are often not used for their intended purpose and instead have become vehicles for tax evasion. *See, e.g.*, IRS Rev. Rul. 2004-27, I.R.B. 2004-12 (March 22, 2004), *available at* http://www.irs.gov/irb/2004-12_IRB/ar11.html. Indeed, Washington State recently passed a bill banning the formation of corporations sole after August 1, 2009, and, for the corporations sole currently registered with the state, requiring the filing of annual reports. *See* http://www.sos.wa.gov/corps/CorporationSoleLegislativeChanges.aspx.

was proper and concluding that "DCO bears none of the substantive indicia of a corporation that is truly organized only for charitable purposes." JA306. That determination is fully borne out by the evidence, which established both the commercial nature of DCO's activities and Feijo's handsome profit from those activities.

B. Overwhelming Evidence Demonstrates That DCO Runs a For-Profit Business And That James Feijo Personally Benefitted From DCO's Profits

Community Blood Bank suggests a two-part analysis for assessing whether the FTC Act provides jurisdiction over a nonprofit corporation. This analysis considers both the source of the corporation's income and the distribution of that income; either one can provide a basis for the Commission's jurisdiction. *College Football Ass'n*, 117 F.T.C. at 993-94. The Commission correctly applied this precedent, and concluded, based on undisputed findings of fact, that both prongs of the jurisdictional test were satisfied.

1. With respect to the first prong of the substantive jurisdictional inquiry, DCO's source of income, the Commission did not err in concluding that, irrespective of DCO's religious status and activities, "the findings of fact, supported by extensive evidence," made clear that DCO was actively engaged in the business of selling its products for profit, including the four challenged products. JA305. Petitioners assign error to the Commission's supposed presumption that DCO was organized for profit

"simply because DCO was engaged in money-generating sales of its products," which, they argue, was insufficient to permit the exercise of jurisdiction in *Community Blood Bank*. Br. 23-24. But the Commission correctly distinguished this case from *Community Blood Bank*, where jurisdiction was denied not because the nonprofit entities generated some income, but because the individual respondents were "'public-spirited volunteers' who derived no personal profit," and whose "'activities at all times were directed toward promoting a community-sponsored program in the public interest and at no time were infected with commercial intent.'" JA240 (quoting 405 F.2d at 1021-22).

DCO cannot, and does not, credibly argue that its activities were free from commercial intent. Tellingly, DCO was originally incorporated as a *for-profit* corporation from 1990 to 1997 and engaged in the same activities now at issue, selling the challenged products throughout the 1990s. IDF12-13, 22-23, 27, JA173-74. During 2006-2008, DCO generated approximately $2 million in annual sales, of which the challenged products accounted for some twenty or thirty percent. JA303. DCO has a toll-free phone number and operates a call center. IDF99, JA181, JA303-04; sells through distributors, IDF116-22, JA183-84; and runs an affilliate marketing program, IDF123-24, JA184. The DCO website invited consumers to shop at DCO's

"On-Line Store," JA304, and the "About Us" section on the website described the company as a "health food store" or "health food supplement store," IDF32, JA175.

There is no religious qualification to sell, or purchase, DCO's products. IDF124, JA184, IDF150, JA187, JA303. Extensive uncontested factual findings underpin the Commission's conclusion that jurisdiction was proper because DCO did not operate "only for charitable purposes." JA305 (quoting *Community Blood Bank*, 405 F.2d at 1022). The Commission did not exercise jurisdiction over DCO "merely because it ha[d] income," Br. 24 (quoting *Community Blood Bank*, 405 F.2d at 1020), but rather because it operated a multi-million-dollar enterprise that, whatever its religious trappings, was ultimately indistinguishable from a commercial concern.

2. The Commission likewise did not err in concluding that the second part of the jurisdictional analysis, the destination of DCO's income, independently establishes the Commission's jurisdiction. JA306. Even if DCO is nominally organized as a corporation sole to "promote the Kingdom of God," *see* IDF29, JA175, the Commission found, based on abundant evidence, that DCO actually operates for the profit (*i.e.*, "pecuniary" or "economic" benefit) of its sole member, Feijo. JA306. The reality is that Feijo, the overseer of DCO, treats DCO as his personal bank account. DCO's assets are under Feijo's complete control. IDF76, JA179, JA303. He makes frequent cash withdrawals from DCO's accounts but maintains no records as to how

that money is used. IDF47, JA177. Although DCO has a policy of not maintaining records, IDF50, 59, JA177-78, the evidence nonetheless shows that Feijo uses DCO's funds to pay for all his living expenses. IDF58, JA178. These include funds to pay for Feijo's two homes (one in Rhode Island, and one on a Florida country club), for his two Cadillacs, for his country club membership, for his wife's tennis club membership, and for a wide variety of other expenses (including $9,936 for golfing expenses, and $1,077 for cigars). IDF47, 55, 56, 58, 62, 63, 67, 70, JA177-79. While DCO may try to put forward an eleemosynary front, the backroom reality is otherwise. Because DCO's revenues provide a pecuniary benefit to Feijo, DCO is subject to the FTC Act.

DCO makes no effort to deny that Feijo enjoyed free access to DCO funds and lived well on them, but instead argues that the Commission was required to make "findings" regarding the nature of Feijo's use of the homes and vehicles (as well as, presumably, the country club memberships and cigars). Br. 25. The Commission had no need, however, to ascertain how many hours of the day the Feijos may have used their DCO-financed amenities for "ministry" purposes and how many for personal pursuits. As the ALJ properly concluded, "[i]t is sufficient for the purpose of finding jurisdiction that the economic benefits conferred are more than '*de minimis*' or 'merely presumed.'" JA241 (quoting *California Dental*, 526 U.S. at 767). And, as the

Commission observed, ample evidence supports the finding that "the 'destination' of the profits of DCO's for-profit activities was James Feijo." JA306.

The permeability between DCO and Feijo was thus like the situation presented in *Ohio Christian College*, which involved deceptive trade practices by a nonprofit religious college. There the Commission concluded that the corporate officers' "cavalier treatment of the corporate assets and finances" rendered their relationship to the supposedly charitable institution "strikingly similar to that existing between a closely-held commercial corporation and its officer-shareholders." 80 F.T.C. at 84. In particular, "[t]he individual respondent * * * ha[d] complete control over the purse strings, he set[] all salaries (including his own), determine[d] all allocation and expenditures, signs all checks and exercises plenary power over the affairs of the school." *Id.*

As the ALJ concluded, and the Commission agreed, the situation here is exactly parallel:

> Feijo treated the income and expenditures of DCO cavalierly. He claimed to keep no financial records, and to have no idea of how much money DCO had or how much money was spent on various aspects of its operations or for the support of the Feijos' living expenses. Moreover, since James Feijo had no individual account, he used DCO's assets at will, thereby treating those assets as his own. As in *Ohio Christian College*, such circumstances support jurisdiction over DCO."

JA242.

II. THE COMMISSION CORRECTLY HELD THAT THE CANCER-CURE CLAIMS THAT DCO MADE IN ITS ADVERTISING FOR THE CHALLENGED PRODUCTS VIOLATED THE FTC ACT

DCO launches a barrage of statutory arguments against the Commission's adjudication of this case, erroneously accusing it of bypassing steps in its analysis and shifting the burden of proof (Br. 26-27), of engaging in *ad hoc* "health policy" (Br. 32-24), and of usurping the regulatory role of the Food and Drug Administration (Br. 36-38). All of these shots miss the mark, however, for in truth this is a straight-forward case of deceptive advertising. Applying long-established legal principles about the assessment of advertising claims, and weighing the evidence concerning the specific claims made, the Commission found that DCO's advertisements were deceptive because they implicitly represented a level of substantiation that was, in fact, utterly lacking.

An essential first step in any deceptive advertising case is determining what claims the advertising makes. The Commission considers both the express and implied claims in the advertisement, *i.e.*, the entire net impression. *See*, *e.g.*, *FTC v. Kraft, Inc.*, 970 F.2d 311, 314, 318-19 (7th Cir. 1992). In this case, the Commission evaluated DCO's advertising for the challenged products, and correctly found that DCO represented that those products could prevent, treat, or cure cancer, and thus expressly or implicitly claimed that a reasonable basis existed for DCO's cancer-cure

claims. Next, the Commission assesses the accuracy of the claims made in the advertising: if any of the material claims is false or misleading, the advertising is deceptive. The Commission correctly determined the falsity of DCO's representations that it had a reasonable basis for its claims that the challenged products could prevent, treat, or cure cancer. Because there is no merit to any of the challenges that DCO raises with respect to the Commission's determination, this Court should affirm the Commission's Order.

A. The Commission Correctly Evaluated the Claims DCO Made in its Advertising for the Challenged Products

The Commission correctly concluded that, as alleged in its complaint, DCO had represented in its advertising that each of the four challenged products could prevent, treat, or cure cancer. JA307-08. These claims were apparent from the face of DCO's advertising for the challenged products: its advertising specifically stated that Bio*Shark "can stop tumor growth," JA37; its advertising for 7 Herb Formula advised that, "[i]f you suffer from any type of cancer, Daniel Chapter One suggests taking this product," JA40; its advertising for GDU claimed that the product can "help digest * * * unwanted tumors," JA56; its advertising for BioMixx claimed that it "is used to assist the body in fighting cancer," JA61; and on its website, it referred to all four of the challenged products as "Daniel Chapter One's cancer solutions," JA41.

Next, the Commission determined that, implicit in each of DCO's advertisements, was the claim that DCO had a reasonable basis for its cancer-cure claims. JA310. Again, DCO does not dispute that the Commission may determine what implied claims are made by an advertisement, or that an advertiser is liable if those implied claims are false.[11] *See Thompson Medical Co.,* 791 F.2d at 197 (the Commission may use its expertise to evaluate claims made by advertising, and this determination is due special deference). Nor does DCO dispute that it impliedly represented that it had a reasonable basis for making the cancer-cure claims. *See In re Thompson Medical Co.*, 104 F.T.C. 648, 819 n.52 (1984), *aff'd,* 791 F.2d 189 ("the representation 'X is true' carries with it the implied representation that 'The claim "X is true" is supported by a reasonable basis'").

[11] DCO seems to suggest that the Commission somehow erred because it relied on the "overall net impression" of DCO's advertising to conclude that it had represented that its products could cure cancer, and that it had a reasonable basis for that representation. Br. 27, 28. In fact, it has long been settled that, when the Commission analyzes advertising, it is not limited to considering the express words in the advertising, but may also consider images and context, *i.e.*, the overall net impression. *See Thompson v. FTC*, 791 F.2d at 197. This is so because statements that are literally true may, nonetheless, be deceptive. *FTC v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 41 (D.C. Cir. 1985); *see Kraft, Inc. v. FTC*, 970 F.2d at 318 n.4 (giving the example of an advertisement that depicts a car rolling past one gas station after another, and explaining how the net impression of the advertisement is that the car is inexpensive to operate). In any event, DCO's argument is irrelevant because it admitted in its answer that it made both representations. JA64-65.

that it represented that it had a reasonable basis for the cancer-cure claims that it made. JA65.

B. The Commission Correctly Determined that a Reasonable Basis for DCO's Cancer-cure Claims Must Consist of Competent and Reliable Scientific Evidence and that DCO Lacked a Reasonable Basis for its Claims

The Commission next found that DCO's implicit representation that it had a reasonable basis for its cancer-cure claims for the challenged products was false. To make this finding, the Commission had to determine what level of substantiation DCO impliedly represented that it possessed. Like all aspects of claim interpretation, this determination turns on an assessment of the actual advertisement, considering the likely impact on a consumer of all of its elements. Although cancer-cure claims are ones that a reasonable consumer would normally assume are backed up by scientific evidence, it is conceivable that DCO could have made clear to consumers that it did *not* have substantiation of that sort. For example, it might have been possible, in its advertising, for DCO to clarify its claims so that all reasonable consumers would understand that its claims were based on Biblical teachings and nothing else. If DCO had crafted its advertisements in this manner, and also ensured that other aspects of the advertisements did not convey any misleading impression,[12] then its advertising

[12] There are myriad ways in which advertisers can deceive, by implication and even by omission. For example, even if an advertiser made crystal-clear that its (continued...)

would not have been deceptive, so long as it was clear that the claim was based on theology rather than science.

DCO, however, did not qualify the level of substantiation that it possessed. In such circumstances, "and absent other evidence indicating what consumer expectations would be, the Commission assumes that consumers expect a 'reasonable basis' for claims." *Thompson Medical Co.*, 104 F.T.C. at 839-40. Accordingly, the Commission turned to the question of what level of substantiation is "reasonable," a question that turns on a number of factors, which must be evaluated on the record of particular claims. *Id.*

Here, the Commission started with the premise that, "under well-established precedent," "'health-related efficacy claims'" such as the ones that DCO made, must be substantiated by "'competent and reliable scientific evidence.'" JA318, quoting from the ALJ's Opinion (JA267), and citing, *inter alia*, *FTC v. National Urological Group, Inc.*, 645 F. Supp. 2d 1167, 1202 (N.D. Ga. 2008), *aff'd*, 356 Fed. App'x 358 (11th Cir. 2009) (claims regarding the safety and efficacy of dietary supplements "must be substantiated with competent and reliable scientific evidence"); *FTC v.*

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[12](...continued)
claims were affirmatively based on one limited study, its failure to disclose the existence of other studies debunking the claim could be deceptive. In all cases, the touchstone remains an assessment of the overall net impression of the advertisement on reasonable consumers, a sensitive factual inquiry.

Direct Marketing Concepts, Inc., 569 F. Supp. 2d 285, 300 (D. Mass. 2008), *appeal docketed*, No. 09-2172 (1st Cir. Aug. 27, 2009) (same); *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 961 (N.D. Ill. 2006), *aff'd*, 512 F.3d 858 (7th Cir. 2008) (requiring competent and reliable scientific evidence for a claim that a bracelet could provide significant relief from pain). Consumers are well aware that drug products that purport to treat disease are heavily regulated and subject to substantial pre-market testing. Thus, consumers would reasonably assume that, when DCO touts its products as a treatment for cancer, *i.e.*, as an alternative to products marketed by drug manufacturers, DCO has first subjected those products to scientific testing.[13]

Although DCO concedes that it represented that it possessed a reasonable basis for its cancer-cure claims, it complains that the ALJ (and the Commission) somehow "raised the bar" by requiring that it possess competent and reliable scientific evidence consisting of clinical tests supporting its claims. *See* Br. 27, 29-30. In fact, there was no raising of the bar. DCO's acknowledged representation that it possessed a reasonable basis for its cancer-cure claims necessitated a contextual determination of

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[13] Indeed, in describing Bio*Shark, DCO's Cancer Newsletter, expressly compared the product to a drug, stating:

> Scientists recognize the benefits of starving a tumor to limit its growth. They have been looking for a drug to patent that can do the same thing as shark cartilage.

JA50.

what level of substantiation consumers would reasonably expect. *See In re Thompson Medical Co.*, 104 F.T.C. at 821-22. Here, the Commission reasonably concluded that the requisite level is competent and reliable scientific evidence. JA101-04; JA319-20. The Commission thus treated DCO no differently than any other company making similar claims for a product it was marketing.

The Commission considered the testimony of six witnesses to determine whether DCO possessed competent and reliable scientific evidence to support its cancer-cure representations for the challenged products. Complaint counsel presented one of these witnesses, and DCO presented five. Complaint counsel's expert, Dr. Miller, was the only medical doctor among the witnesses, was the only witness with training regarding cancer or cancer treatment, and was the only witness who had conducted clinical studies regarding cancer treatments. JA316.

To form his opinion as to whether there was competent and reliable scientific evidence to support DCO's cancer-cure claims, Dr. Miller considered the challenged products and their labels, DCO's advertising claims, and the materials (including testimonials and articles) that DCO contended provided support for its claims. JA74-76. Dr. Miller also conducted an extensive literature search, and reviewed many cancer journals. JA74. He concluded that competent and reliable scientific evidence to support DCO's cancer-cure claims must consist of controlled clinical studies on

humans, but that there were no such studies to support the claims that DCO made. JA76.

As a part of his analysis of DCO's representations regarding Bio*Shark, *see* JA81-86, Dr. Miller explained that, although DCO attempted to rely, *inter alia*, on the work of Dr. William Lane, who wrote the popular book, *Sharks Don't Get Cancer*, careful research has debunked the work of Dr. Lane because sharks do get cancer, JA85. His analysis of the substantiation for the claims regarding 7 Herb Formula, *see* JA86-91, concluded that there were no clinical, or nonclinical (*i.e.*, *in vitro* or animal), trials that showed that the product, or any of its ingredients, would be effective to treat or cure cancer, JA87. In fact, studies showed that at least one of the ingredients may interfere with other forms of cancer treatment. *See* JA89 (cat's claw may interfere with chemotherapy). Similarly, there were no clinical trials of GDU or of any of its components. JA91-96. Some preliminary studies indicate that, although one of its seven ingredients, curcumin, might have some benefit for treating cancer, that ingredient might also inhibit the anticancer activity of other approved cancer treatments and exacerbate iron deficiency. JA96. The label for GDU contains no warning of these risks. JA93.

Dr. Miller considered DCO's substantiation for BioMixx, *see* JA96-99, and concluded that there were "absolutely no data" to support its claim that the product

could either assist the body in fighting cancer, or heal the destructive effects of radiation or chemotherapy. JA98. In fact, like 7 Herb Formula, BioMixx contains cat's claw, which may interfere with chemotherapy. JA89, 97. Finally, Dr. Miller considered the 30 testimonials proffered by DCO. He observed that two-thirds of the testimonialists had received not just the challenged products but also conventional anticancer therapy (such as surgery, chemotherapy, or radiation) making it impossible to assess any benefit from DCO's products. JA99. Although several of the testimonialists claimed that they benefitted solely from DCO's products, Dr. Miller concluded that further clinical testing would be necessary to demonstrate whether those results were a result of DCO's products.[14] JA99-100.

The Commission also considered the evidence presented by DCO's experts, and found that none of it constituted a reasonable basis for DCO's representations. Although Dr. Duke, who is a botanist, claimed there was a reasonable basis for DCO's cancer-cure representations, he did not base this conclusion on any scientific evidence. He did not know the quantities of the specific ingredients in DCO's products. JA317. Dr. Lamont, who is a naturopathic doctor, also concluded that there was a reasonable basis for the claims, but like Dr. Duke, her conclusions were not based on the actual

[14] DCO complains the Dr. Miller could not explain the distinction between a plant and an herb. *See* Br. 40 n.35. But Dr. Miller was not qualified as an expert botanist, and, in any event, the distinction has no relevance to this case.

composition of DCO's products. *Id.* Moreover, she recognized that, because the challenged products had not been tested, their effectiveness in the prevention, treatment, or cure of cancer is not known. IDF364, JA224. DCO's third expert, Rustum Roy, did not have any formal training in medicine, and had no idea of the ingredients in DCO's products or of the representations that DCO made. JA230-231. Finally, although DCO offered Jay Dew and Jim Lehr as experts, neither offered any evidence whatsoever regarding the efficacy of any of the challenged products.[15] JA231-32.

Given the nature of the expert evidence offered by DCO, the Commission's reliance on the testimony of Dr. Miller was not arbitrary or capricious. Thus, the Commission correctly determined that DCO lacked a reasonable basis (consisting of competent, reliable scientific evidence) to support its cancer-cure claims for the

[15] DCO contends that the Commission "disregarded" the opinions of its experts. *See* Br. 29. In fact, the Commission did not disregard those opinions – it considered, and then rejected, them.

challenged products.[16] Accordingly, its implied representations that it had such support were false.

C. A Finding of Deception Based on Lack of a Reasonable Basis Is Consistent with the Commission's Authority to Prohibit Deception

DCO attacks decades of established deception law under the FTC Act by arguing that the Commission's "reasonable basis theory" is somehow not supported by the Act. *See* Br. 32-35. DCO is, however, flatly mistaken. The existence or lack of a reasonable basis for advertising claims lies at the core of deception analysis under the FTC Act. In its advertising for the challenged products, DCO represented (and concedes that it represented) that it possessed a reasonable basis for its cancer-cure claims. Like any other material representation in an advertisement, whether express or implicit, if the substantiation representation that DCO made is false, then DCO has violated the FTC Act. *See FTC v. Pantron I Corp.*, 33 F.3d 1088, 1095 (9th Cir. 1994); *Thompson Medical v. FTC*, 791 F.2d at 193 ("Thompson correctly

[16] DCO contends that the Commission somehow required it to meet the standard that the FDA imposes on those seeking to market new drugs. *See* Br. 31-32. There is no such requirement in the Commission's Order. Instead, the Order requires DCO to substantiate its cancer-cure claims with competent and reliable evidence, defined as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." JA334. This allows DCO much more flexibility than it would have if it were required to comply with the FDA's new drug standard of "adequate and well-controlled studies." *See* 21 C.F.R. § 314.126.

acknowledges that in general an advertisement is considered deceptive if the advertiser lacks a 'reasonable basis' to support the claims made in it."). The Commission determined that, in fact, DCO did not possess the reasonable basis that it claimed it possessed. Accordingly, DCO's representation was false.[17] It is well-settled, and DCO does not dispute, that an advertiser's false representations with respect to a food or drug product violate the FTC Act. *See* 15 U.S.C. § 52. That is exactly what happened in this case.

Thus, DCO is mistaken when it contends that, by using the reasonable basis theory, the Commission attempts to circumvent the requirement that it prove that any representation is false. *See* Br. 33. Quite the contrary. If, as here, the Commission focuses on the lack of a reasonable basis for advertising claims, the Commission has the burden of proving that the advertiser lacks a reasonable basis for the claims it makes. That is exactly what the Commission did: it met its burden of proving the falsity of DCO's implicit representation that it possessed a reasonable basis for its

[17] Although courts and the Commission have sometimes referred to falsity and reasonable basis claims as separate categories, *see, e.g., Pantron*, 333 F.3d at 1096, where, as here, the Commission has alleged that DCO represented it possessed or relied upon a reasonable basis for its cancer-cure claims, and then determined that this representation was false, there is no meaningful distinction between the two categories.

cancer-cure claims. The burden in this case never shifted to DCO.[18] *See* Br. 26-27 (incorrectly suggesting otherwise).

DCO's argument that the Commission cannot challenge its lack of a reasonable basis for the cancer-cure claims because the Commission never promulgated a rule to implement the reasonable basis theory is a strawman. *See* Br. 34. As explained above, false material representations in advertising, including false representations regarding the level of substantiation the advertiser possesses, violate the FTC Act. The Commission need not promulgate a rule to prohibit what the FTC Act already forbids. Moreover, the Commission's guide, *Dietary Supplements: An Advertising Guide for Industry*, is not, as DCO suggests, an abortive attempt at rulemaking, *see* Br. 34, but is instead exactly what it purports to be: guidance to advertisers helping them to ensure (as DCO failed to do) that they possess adequate substantiation for their advertising. *See* http://www.ftc.gov/bcp/edu/pubs/business/ adv/bus09.shtm.[19]

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[18] The only burden that fell on DCO was the burden to respond to the Commission's requests, made during discovery, that DCO supply the substantiation upon which it relied to support its cancer-cure claims. As the Commission noted, *see* JA319, DCO failed entirely to meet this burden.

[19] DCO quotes a speech given by FTC Commissioner Thomas Rosch in support of its contention that the Commission was somehow unable to develop rules to implement the reasonable basis theory. *See* Br. 34. In fact, Commissioner Rosch's speech had nothing to do with DCO's reasonable basis argument. Instead, that speech described the Commission's attempt in the late 1970s to promulgate a rule that placed a limit on television advertising directed to very young children, the "KidVid" (continued...)

Thus, inquiry into the existence or lack of a reasonable basis for advertising claims is flexible not because the Commission is "exercis[ing] powers completely outside its statutory authority," *see* Br. 35, but because the Commission's case-by-case adjudication of deception cases must accommodate the wide variety of representations that advertisers make in their advertising. Here, the Commission engaged in a fact-intensive inquiry regarding the claims at issue, and carefully determined the type of substantiation that would provide a reasonable basis for the specific challenged advertisements, in light of the nature of the claims made, consumers' reasonable expectations, and other pertinent factors.[20] The FTC found DCO liable under the FTC Act because there was no truth to its implied claim that it possessed or relied upon a reasonable basis to substantiate its advertisements that the challenged products could prevent, treat, or cure cancer. Because DCO engaged in false advertising, it was properly held liable under the FTC Act.

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[19](...continued)
rulemaking. *See* http://www.ftc.gov/ speeches/rosch/080923Rosch-NADSpeech.pdf.

[20] *See* JA269-72 (ALJ's extensive analysis of the pertinent factual considerations, as originally set forth in *In re Pfizer, Inc.*, 81 F.T.C. 23, 64 (1972), and reiterated in *Thompson Medical*, 104 F.T.C. at 821-22); *see also* JA318 (Commission opinion, confirming that analysis).

D. The Dietary Supplement Health and Education Act Is Irrelevant to This Case

There is no conflict between the Commission's Order in this case and the Dietary Supplement Health and Education Act of 1995, Pub. L. 103-417 (1994) ("DSHEA"). *See* Br. 36-38. DSHEA amends the Food, Drug, and Cosmetic Act to provide that, for purposes of that act, dietary supplements are to be treated as food, not as drugs. *See* 21 U.S.C. § 321(ff). As a result, so long as the marketer of a dietary supplement does not claim that its product can treat, cure, or prevent any disease, that marketer may sell the dietary supplement without first obtaining FDA approval that the product is safe and effective. *See* 21 U.S.C. § 343(r)(6). Nothing in DSHEA, however, restricts the Commission's traditional authority to prohibit unfair or deceptive advertising. Similarly, nothing in the FTC Act, or in the order that the Commission entered in this case, requires DCO to establish the safety or efficacy of its products as a condition of selling them.

The requirements that the Commission's order imposes on DCO are not a result of DCO's sale of the challenged products, but of its deceptive advertising. Nothing in DSHEA countenances the sorts of false advertising claims that DCO has made.

Thus, the Commission has not taken on any "enhanced role" in this case, *see* Br. 38, but has simply exercised its traditional role of putting a halt to deceptive advertising.[21]

III. THE COMMISSION'S ORDER DOES NOT IMPINGE ON DCO'S FREEDOM OF SPEECH OR RELIGIOUS FREEDOM

DCO attempts to avoid the application of established law to its deceptive advertisements for "cancer cures," by contentions that it has a First Amendment right to engage in such speech, or that any prohibition on such deception tramples its religious freedom. On the contrary, although truthful commercial speech enjoys a level of First Amendment protection, deceptive speech does not. And nothing in the Commission's Order precludes DCO and Feijo from freely exercising their religious freedom; let alone "establishes" a scientific "religion."

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[21] DCO suggests something sinister in the fact that the Commission sometimes collaborates with other regulatory agencies, and that, in this case, the FDA sent DCO a warning letter. *See* Br. 37. In fact, as this Court has recognized, "ours is an age of overlapping and concurring regulatory jurisdiction." *Thompson Medical v. FTC*, 791 F.2d at 192. The mere fact that the FDA has not taken any further action in no way undermines the Commission's case, and if anything, the FDA's warning letter, sent in August 2008, put DCO on notice that its advertisements were problematic, and that its products were potentially subject to FDA regulations as new drugs, in light of the "therapeutic claims" that the websites made for their products. *See* www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048176.htm.

A. DCO's Deceptive Advertisements Enjoy No First Amendment Protection

As the Commission correctly recognized, the First Amendment provides no shield to the sort of deceptive advertising in which DCO has engaged. As the Supreme Court explained in *Central Hudson,* 447 U.S. at 563, deceptive advertising is entitled to no First Amendment protection. DCO attempts to avoid this bedrock principle by insisting that the Commission never alleged, or proved, that its advertisements for the challenged products were deceptive. *See* Br. 49. As detailed above, however, that is exactly what the Commission alleged and proved. DCO apparently believes that the present case falls outside of the established general rule because the Commission's finding of deception was based on "the 'reasonable basis' theory." *Id*. As explained above, however, that "theory" is simply one mode of analysis in a consumer deception case, based on the same underlying standard. When an advertiser puts forth claims for consumer products that imply the existence of reasonable substantiation, but it in fact has no such substantiation, it has deceived consumers.[22] DCO provides no support for the novel notion that some forms of deceptive commercial speech are protected by the First Amendment, while others are

[22] Nor can DCO escape liability on the strength of its desultory and obscure "disclaimers." As the Commission properly found after a close review of the disclaimers as they appeared in DCO's advertisements, they did nothing to dispel the overall net impression of those advertisements. JA308.

not. Its speech was properly adjudicated to have been deceptive, so it can claim no First Amendment protection.

Accordingly, DCO's heavy reliance upon this Court's decision in *Pearson v. Shalala*, 164 F.3d 650, *see* Br. 50-51, is misplaced. That case involved a challenge to an FDA regulation that imposed a blanket prohibition on making health claims for dietary supplements, regardless of how such claims were presented, unless the FDA had pre-approved the claims based on a finding that there was significant scientific agreement among experts regarding the accuracy of the claim. *Id.* at 651. In *Pearson*, the principal issue before this Court was whether a claim lacking scientific agreement could be barred by a regulation on the ground that it was "potentially misleading." *Id.* at 655. That is, the FDA argued that its rule should be free from First Amendment scrutiny because some of the health claims to which the regulation applied might be deceptive, even though others would not be. This Court rejected that argument and therefore conducted a First Amendment analysis of the rule's restrictions under the three-part test set forth in *Central Hudson*. *Id.* at 655-56. The situation with regard to DCO is different. Here the Commission found, on the basis of a full evidentiary record involving specific advertisements that had already run, that those advertisements were actually (not potentially) deceptive. Thus, DCO's advertisements for the challenged products were entitled to no First Amendment protection.

B. The Remedial Order Does Not Violate DCO's First Amendment Free Speech Rights

Nor is there any merit to DCO's contention that the remedial provisions in the Commission's Order violate the First Amendment. *See* Br. 53. In particular, DCO argues that, instead of suppressing its advertising, the Commission should have permitted it to include disclaimers. *See id.* The premise of this argument is faulty because the Commission's Order does not suppress DCO's advertising. Instead, it provides that, if DCO makes a cancer-cure claim for any of the challenged products, or any similar product or service, that claim must be true, and DCO must possess competent and reliable scientific evidence substantiating the claim. JA325.

In any event, even assuming that the Commission's remedy will preclude some speech that might otherwise and independently be entitled to First Amendment protection, this is by no means unusual or improper. In this case, the Commission has already determined that DCO violated the law, and the restrictions have been imposed to prevent future law violations. It is well settled that, "[h]aving been caught violating the [FTC] Act, respondents 'must expect some fencing in.'" *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 395 (1965) (*quoting FTC v. National Lead Co.*, 352 U.S. 419, 431 (1957)). The substantiation requirement imposed by the Commission is appropriate fencing in. Moreover, DCO is simply mistaken when it argues that "there was no 'reason' for the FTC to dismiss outright DCO's disclaimer efforts." *See* Br. 53.

DCO's past disclaimers were in tiny type, hidden among copyright statements, and were confusing. *See, e.g.*, JA308. The Commission had no obligation to assume that DCO would so improve its disclaimers in future advertising as to cure any misimpressions, and acted well within its remedial discretion in rejecting that approach.

To the extent that Commission remedial orders are subject to First Amendment scrutiny, it is under the *Central Hudson* standard. *See Novartis Corp. v. FTC*, 223 F.3d 783, 788-89 (D.C. Cir. 2000). Under that test, nondeceptive commercial speech may be regulated, consistent with the First Amendment "if the government satisfies a test consisting of three related prongs: First, the government must assert a substantial interest in support of its regulation; second, the government must demonstrate that the restriction on commercial speech directly and materially advances that interest; and third, the regulation must be 'narrowly drawn.'" *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 623-24 (1995) (describing the three-part test first set forth in *Central Hudson*).

The Commission's order easily passes this test. First, the Commission has a substantial interest – prohibiting deceptive advertising.[23] Second, the Order directly

[23] DCO contends that the Commission's interest is limited to protecting consumers from deceptive efficacy claims. *See* Br. 52. In fact, the Commission's interest is broader – prohibiting any deception in advertising. DCO's false representation was (continued...)

and materially advances that interest because it prohibits DCO from representing that it can substantiate its cancer-cure claims unless that representation is true. Third, the restriction is narrowly drawn because it requires DCO to possess substantiation for its cancer-cure claims. The failure to possess such substantiation was the reason DCO's advertising was deceptive in the first place. Even assuming, as DCO argues, that disclaimers might be a less restrictive alternative, they would not provide as reliable protection against future consumer deception, as explained above. The Supreme Court has explained that the final part of the *Central Hudson* test does not require the government to employ the least restrictive means of advancing its interests; it is sufficient that there is a "reasonable fit" between means and ends – "a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is in proportion to the interest served." *Bd. of Trustees of State Univ. of New York v. Fox*, 492 U.S. 469, 480 (1989)(internal quotation marks omitted). The provision in the Commission Order requiring substantiation for cancer cure claims easily passes muster under that standard.

Finally, DCO states, without any elaboration, that Part V of the Commission's Order violates its First Amendment rights. *See* Br. 55. That part of the Order requires DCO to send a letter to past purchasers of the challenged products explaining that

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[23](...continued)
that it possessed substantiation to support its cancer-cure claims.

DCO lacked substantiation for its cancer-cure claims. *See* JA340 (text of letter). Grounded in the findings below regarding potential adverse health risks that might result from using DCO's products, *see, e.g.* IDF355-61, JA223, the letter also tells consumers that "[i]t 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." JA340. The letter requirement clearly satisfied the three-part test. *See Novartis Corp. v. FTC*, 223 F.3d at 788-89 (applying the three-part test to a corrective advertising requirement imposed in a Commission order). The Commission has a substantial interest: correcting the misimpression created by DCO's past advertising. The letter directly and materially advances that requirement because it is to be sent to past purchasers, and it will inform them of the deception in DCO's advertising. As to the third part of the test, it is hard to imagine how the Commission could have crafted a remedy that is more narrowly tailored to its interest – the letter is directed only to those who purchased the challenged products in response to DCO's deceptive advertising, and it carefully explains DCO's deception.[24]

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[24] DCO argues that the letter requirement violates the "well-established First Amendment principle of speaker autonomy." *See* Br. 61-62. But this principle has no application here. As the Supreme Court has made clear, in the context of a commercial transaction, "an advertiser's rights are adequately protected as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers." *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626, 651 (1985). As explained above, the letter requirement (continued...)

C. The Commission Has Not Established the "Religion of Scientism"

DCO contends that, because the Commission relied on the testimony of Dr. Miller, and because Dr. Miller testified that controlled clinical studies are necessary to support DCO's cancer-cure representations, the Commission has somehow established the religion of scientism. *See* Br. 38-48. This argument is entirely unhinged from the facts of this case. One sentence crystallizes DCO's ten-page argument: "By adopting Dr. Miller's standard for its own, the FTC has, in effect, ruled out any cancer or tumor treatment approach that did not conform to 'conventional anticancer therapy,' leaving **absolutely no** room for 'alternative medicine.'" Br. 42-43 (footnote omitted; emphasis and quotation marks in original). This sentence completely mischaracterizes the Commission's actions. First, the Commission did not "adopt[] Dr. Miller's standard for its own." The Commission relied on Dr. Miller's testimony that DCO's substantiation did not constitute a reasonable basis for its cancer-cure claims.[25]

Second, the Commission has in no way ruled out "alternative medicine." All that the Commission did in this case was to hold that, when an advertiser represents,

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[24](...continued)
is reasonably related to the Commission's interest in preventing deception.

[25] Indeed, the standard to which DCO so objects, controlled clinical studies, is nowhere mentioned in the Order the Commission entered. *See* JA334 (defining "competent and reliable scientific evidence").

whether implicitly or explicitly, that it has a reasonable basis to support its objective claims that its products can cure cancer, without any further explanation, consumers assume that the advertiser possesses competent and reliable scientific evidence. Nothing that the Commission has done restricts the marketing of alternative medicines. Instead, it was DCO's actions that caused it to run afoul of the FTC Act. DCO chose to advertise that the challenged products could cure cancer, and chose to create the false impression in its advertising that it possessed competent and reliable scientific evidence to support its cancer-cure claims. It was those actions, not any standard adopted by the Commission, that led to DCO's violations of the FTC Act. DCO could have marketed its products honestly. It could have made prominent that the context of its claims were not objective, but rather subjective statements of belief and healing, and that nothing it claimed about its products was based on science. But DCO failed to do so, and in fact did not shy from science-based advertisements.[26] Thus, far from establishing any religion of scientism, this case is merely one in a long line of cases brought by the Commission combating deceptive advertising.

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[26] Indeed, DCO's advertisements included many references to science. For example, in describing DCO's approach, BioMolecular Nutrition, the BioGuide states that "[t]he principles of BioMolecular Nutrition were those missing principles needed to bind together those of the nutritionists and the biochemists." IDF96-87, JA180.

D. DCO's Religious Freedom Restoration Act Defense Fails

There is no merit to DCO's contention that the Commission's Order substantially burdens its exercise of religion. *See* Br. 54-62. The Religious Freedom Restoration Act ("RFRA"), 42 U.S.C. § 2000bb, *et seq.*, provides a defense if a government action substantially burdens a person's exercise of religion. It is for the entity asserting the defense to establish the substantial burden, *Diaz v. Collins*, 114 F.3d 69, 71-72 (5th Cir. 1997), and DCO has failed to do so. To establish the substantial burden triggering RFRA, DCO would have to show that the Commission's Order "forces [it] to engage in conduct that [its] religion forbids or that [the order] prevents [it] from engaging in conduct [its] religion requires." *Henderson v. Kennedy*, 253 F.3d 12, 16 (D.C. Cir. 2001), *on pet. for rehearing*, 265 F.3d 1072 (D.C. Cir. 2001). This understanding of the "substantial burden" element of RFRA is underscored by its background: RFRA was enacted chiefly to overturn the less protective Free Exercise Clause analysis of *Employment Division, Dep't of Human Resources of Oregon v. Smith*, 494 U.S. 872 (1990); Congress sought to restore pre-*Smith* standards, which included a required showing of "substantial burden," in the sense that "individuals are forced to choose between following the tenets of their religion and receiving a government benefit * * * or coerced to act contrary to their religious beliefs by the threat of civil or criminal sanctions * * * ." *Navajo Nation v. United*

States Forest Service, 535 F.3d 1058, 1069-70 (9th Cir. 2008) (en banc); *see also Henderson*, 265 F.3d at 1073-74 (specifically holding that amendment to RFRA definition of "exercise of religion," 42 U.S.C. § 2000cc-5, did not alter this analysis).

Under this standard, the Commission reasonably concluded that restrictions on DCO's "commercial advertising" contained in Parts II and III of the Order imposed no substantial burden on its religious exercise.[27] JA322. Despite general assertions of its goal of propagating its "perspectives on the **integration of spiritual and physical well being,**" Br. 57 (emphasis in original), DCO has made no proffer that its religious principles require it to engage in the commercial sale of dietary supplements, much less that it is required to make "cancer-cure" and other health claims for such products in the absence of substantiation as recognized by conventional medical science. Even accepting all of DCO's assertions regarding its religious mission, it still has "a multitude of means" of pursuing that mission." *See Henderson*, 253 F.3d at 17. DCO is free, for example, to sell dietary supplements and promote their use as consistent with its view of God and the Bible, as long as it refrains from making claims about their efficacy that cannot be supported in accordance with the Order. Alternatively, if DCO wishes to proselytize for Biblically-inspired alternative

[27] Those parts of the Order require that, if DCO makes any claim regarding the efficacy of any product, it must have competent and reliable scientific evidence to support that claim.

medicine and dispute scientific orthodoxy, it is entirely free to do so as long as it refrains from the sale in commerce of dietary supplements for which it is making efficacy claims. Accordingly, there is no truth to DCO's contention that compliance with Parts II and III of the Order "would require DCO to change its allegiance from God and the Bible to 'the expertise of professionals in the relevant area.'" *See* Br. 58 (quoting JA324).

Nor is any substantial burden on DCO's religious exercise imposed by Part V.B of the Order, which is aimed at correcting misimpressions that DCO customers are likely to have, as a result of its prior deception, about the efficacy of its products or the existence of substantiation for DCO's claims. As noted above, this Court has upheld such requirements against constitutional challenge. *See Novartis*, *supra*. In the present case, the required notice serves the further purpose of "ensur[ing] that all aspects of [purchasers'] medical treatment work together," JA340, in light of the findings below that use of DCO products could prove injurious to consumers' health, *see, e.g.* IDF355-61, JA223. Furthermore, the Commission carefully tailored such relief to ensure that DCO is *not* required to repudiate any of its beliefs or "embrace the FTC's **secular belief**." Br. 60 (emphasis in original). Part V.B (JA336) simply requires DCO to send a letter to past customers in which it must recite that *the FTC* has found its past advertising claims to be deceptive, and that "the FTC requires that

we send you the following information *from the FTC* about scientific evidence on these products * * * ." JA340 (emphasis added). Thus, although DCO is being required to deliver the message (to ensure that it actually gets to the consumers in question) the message is unambiguously that of the FTC. In other words, DCO is not really complaining of being forced to take actions in conflict with its religious principles, but is essentially making religious objection to governmental initiatives. RFRA's "substantial burden" requirement is not so easily met. *See Kaemmerling v. Lappin*, 553 F.3d 669, 678-80 (D.C. Cir. 2008). Thus, DCO has identified nothing in the letter that in any way burdens its exercise of religion, and it has therefore failed to mount a defense based on the RFRA.

CONCLUSION

For the foregoing reasons, the Commission's Order should be affirmed.

Respectfully submitted,

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September 17, 2010

CERTIFICATE OF SERVICE

I hereby certify that on September 17, 2010, I electronically filed the Brief of Respondent Federal Trade Commission on the Clerk of this Court. I certify that counsel for petitioners, who are named below, are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system and I also served counsel for petitioners by express overnight delivery. On that same day, I also filed eight copies of the same document on the Clerk.

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I certify that this brief complies with Fed. R. App. P. 32(a)(7)(B). It is proportionally spaced and contains 13,962 words, as counted by the WordPerfect word processing program.

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