UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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

In the Matter of	)	
DANIEL CHAPTER ONE,	)	**DOCKET NO. 9329**
a corporation, and	)	
	)	
JAMES FEIJO,	)	**PUBLIC DOCUMENT**
individually, and as an officer of	)	
Daniel Chapter One.	)	

RESPONDENTS' APPLICATION FOR STAY OF MODIFIED FINAL ORDER PENDING JUDICIAL REVIEW

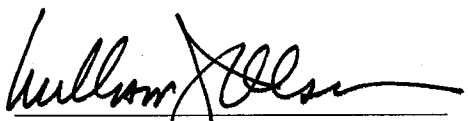
The Respondents, pursuant to 15 U.S.C. section 45(g)(2)(A) and section 3.56(b) of the Rules of Practice of the Federal Trade Commission ("FTC"), 16 C.F.R. section 3.56(b), respectfully apply to the Commission for a stay of the Modified Final Order ("Order") issued on January 25, 2010 and served on January 29, 2009, in the above-entitled matter, pending judicial review by a United States court of appeals in an appropriate federal judicial circuit.

For reasons therefor, Respondents submit: (i) that their arguments for overturning the Order on appeal are likely to succeed on the merits or, alternatively, are substantially meritorious; (ii) that the injuries to Respondents if enforcement of the Order were not stayed would be irreparable; (iii) that no party or the public would be injured by the granting of the requested stay; and (iv) that a stay of the Order would be in the public interest, all as more fully set forth in the attached Memorandum of Law in support of this Application, together

with the Declarations of James Fieijo, Patricia Feijo, Deane Mink, D.C., Karen S. Orr, D.C., Charles Sizemore, D.D.S., and Jerry Hughes.

WHEREFORE, Respondents pray that their Application be granted, and that the Commission enter an Order staying enforcement of the Modified Final Order herein until the later of the following — the expiration of the time for filing a petition for review of the Modified Final Order in a United States court of appeals, the issuance of a final order regarding Respondents' petition for review, the denial of a petition for panel rehearing, the denial of a petition for rehearing *en banc*, or the expiration of the time for filing such petitions for rehearing, the denial of a petition for certiorari in the United States Supreme Court, or the expiration of time to file such petition.

Respectfully submitted,



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February 25, 2010

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MEMORANDUM IN SUPPORT OF RESPONDENTS' APPLICATION FOR STAY OF MODIFIED FINAL ORDER PENDING PETITION FOR REVIEW

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INTRODUCTION

This Memorandum is submitted, pursuant to 16 C.F.R. section 3.56(b) and 15 U.S.C. section 45(g)(2)(A), in support of Respondents' Application for Stay of the Modified Final Order ("Order") of the Federal Trade Commission ("FTC") issued on January 25, 2010.

The Order should be stayed pending judicial review because:

(I) Respondents' legal and constitutional challenges are substantial;

(II) if a stay is not granted, Respondents will suffer irreparable harm;

(III) if the stay is granted, no party will be injured and if the stay is granted, the public interest would be benefitted.

See Washington Metropolitan Area Transit Co. v. Holiday Tours, Inc., 559 F.2d 841, 843 (D.C. Cir. 1977); FTC Rule 3.56(c).

ARGUMENT

I. RESPONDENTS' LEGAL AND CONSTITUTIONAL CHALLENGES TO THE ORDER ARE SUBSTANTIAL.

In assessing the likelihood of Respondents' success on the merits on appeal, the Commission need not "harbor doubt about its decision in order to grant the stay." In re California Dental Ass'n., 1996 FTC LEXIS 277, at *9 (May 22, 1996). Respondents satisfy the "merits" factor if their argument on at least one claim is "substantial" — so long as the other three factors weigh in their favor. *See* Deu Thapa v. Gonzales, 460 F.3d 323, 335-36 (2d Cir. 2006). *See also* WMAT v. Holiday Tours, 559 F.2d at 844-45; Michigan Coalition of Radioactive Material Users, Inc. v. Griepentrog, 945 F.2d 150 (6th Cir. 1991); Rum Creek Coal Sales, Inc. v. Caperton, 926 F.2d 353, 359 (4th Cir. 1991). Because the balance of the equities weighs in favor of Respondents, as shown in Parts II and III below, it is enough that

Respondents raise questions sufficiently serious and substantial to constitute "'fair ground for litigation.'" Safety-Kleen, Inc. v. Wyche, 274 F.3d 846, 859 (4th Cir. 2001). *See also* United States v. Baylor University Medical Center, 711 F.2d 38, 39-40 (5th Cir. 1983).

A. The FTC Failed to Apply the Statutory Requirements Governing FTC Jurisdiction over Respondents' Nonprofit Religious Ministry.

The FTC complaint charged that, beginning in 2005 and continuing to the present, Respondents engaged in the allegedly-deceptive practices specified therein. *See* Complaint, ¶ 5. During this entire period, Daniel Chapter One ("DCO") was operating as a "corporation sole," having been so organized in 2002 under the laws of the State of Washington. Opinion of the Commission ("Op."), p. 4. Under Washington law, only **churches or religious societies** may "become a corporation sole." RCW 24.12.010. A corporation sole is permitted to engage in commerce (RCW 24.12.020), but its "overseer" is required to hold all property gained from such commerce "**in trust** for the use, purpose, benefit, and behoof of his religious ... society or church." RCW 24.12.030 (emphasis added).

The FTC stated that DCO's Articles of Incorporation failed to "specifically declare that DCO was organized exclusively for charitable or other clearly nonprofit purposes." Op., p. 4. To the contrary, the Articles clearly state that DCO is a "church" dedicated to "promote the Kingdom of God."[1] *See* DCO Articles of Incorporation. Indeed, by definition, a Washington corporation sole is dedicated to engage in "religious" activities. *See* RCW 24.12.030.

The FTC found fault, however, with DCO's Articles for not expressly stating that, "upon dissolution," none of DCO's assets or earnings may distributed to "any individual or

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[1] Luke 4:43 ("[Jesus] said ... I must preach the kingdom of God.").

for-profit corporation." Op., p. 4. But Article 4 of DCO's Articles ensures the same result — having created an express trust whereby all assets, are held in trust for DCO's overarching religious purpose. *See* In re Catholic Bishop of Spokane, 329 Bankr. Rep. 304, 325-26 (E.D. Wash. 2005).

The FTC also incorrectly presumed that, by engaging in money-generating sales of products, DCO must necessarily be engaged in such activities for a commercial, profit-making purpose. *See* Op., pp. 4-8. Under Washington law, however, a corporation sole is authorized to "transact[] business" without negating the corporation's charitable purpose. *See* Catholic Bishop, 329 Bankr. Rep. at 327-28. Indeed, the history and modern use of the corporation sole form strongly establish their essential "ecclesiastical" nature and purpose. *See* J. O'Hara, "The Modern Corporation Sole," 93 *Dickinson L. Rev.* 23 (1988).

The FTC compounded its misunderstanding of state law by its misapplication of the federal law that circumscribes FTC jurisdiction over nonprofit corporations. Purporting to apply the rule in Community Blood Bank of the Kansas City Area, Inc. v. FTC, 504 F.2d 1011, 1015 (8th Cir. 1969), the FTC erroneously ruled that DCO was subject to FTC jurisdiction because "**by engaging in commercial activities**, DCO operates a commercial enterprise and thereby is not ... organized or engaged in only charitable purposes." Op., p. 7 (emphasis added). By this statement, the FTC repeated the same error that it made in Community Blood Bank when it claimed jurisdiction over "any corporation engaged in business only for charitable purposes ... that receives income in excess of expenses." *See id.*, 405 F.2d at 1016.

However, the court in Community Blood Bank expressly rejected that argument, ruling that "even though a corporation's income exceeds its disbursements its nonprofit character is not necessarily destroyed." *Id.,* 405 F.2d at 1017. Instead, the court adopted the rule that an entity's nonprofit character is lost **only if it can be shown that** either the entity or its members "derived a profit **over and above** the ability to **perpetuate or maintain** [its] existence." *Id.*, 405 F.2d at 1019 (emphasis added).

Applying this rule here, the FTC must prove that the income from DCO's marketed products was **not** being "used exclusively for the purposes authorized by law and their articles of incorporation." *See id.*, 405 F.2d at 1020. As pointed out above, the FTC erroneously presumed that simply "by engaging in commercial activities, DCO operates a commercial enterprise and thereby is not a business organized or engaged in only charitable purposes." Op., p. 7. But DCO is fully authorized by Washington state law governing corporation soles to engage in commercial activities for the benefit of its religious purpose of advancing the Kingdom of God. The mere fact that it "engages in commercial activities" does not transform the organization into a "commercial enterprise." Indeed, if the FTC's reasoning were adopted, it would extend FTC jurisdiction to cover **any** nonprofit organization that engages in **any** commercial activity, no matter what the purpose and use of the income.

In the alternative, the FTC determined that it had jurisdiction over DCO because Mr. Feijo, as overseer, "distributed [DCO] funds to himself and his wife for their benefit." Op., p. 8. In support of this finding, the FTC observed that the Feijos lived in two homes and used two cars, each of which was owned by "DCO or its affiliate," and DCO "was the source of all of [the Feijos'] living expenses." *Id.* But the legal test whether the FTC has jurisdiction over

DCO as a nonprofit organization is not whether the Feijos utilized DCO's assets, or even benefitted from DCO's payment of their expenses. Rather, the question is whether Mr. Feijo "derived a profit" for his personal "pecuniary gain," that is, whether DCO was "merely [a] vehicle through which a pecuniary profit could be realized for [himself and his wife]." *See* Community Blood Bank, 405 F.2d at 1017.

Notably absent from the Commission's ruling was any finding about the specific use to which the two homes and the two cars were put, and the reason for payment of certain expenses reimbursed to the Feijos'. *See* Op., p. 8. Under the rule of Community Blood Bank, it is incumbent upon the FTC to prove that such use and payments were for the Feijos' "personal profit, benefit, or advantage[,]" and not for the purpose of perpetuating and maintaining DCO's religious services and programs. *See id.*, 405 F.2d at 1021. The record shows that the Feijos, as the sole officers of DCO, are engaged full-time in the DCO "house ministry" — including, "spiritual counseling," health education, marketing DCO products, producing its publications, maintaining its website, and hosting its radio program. *See* Op., pp. 2, 4-6. As the court pointed out in Community Blood Bank, the **FTC has the burden** to show that the Feijos' use of DCO properties and receipt of payment for certain expenses were "infected with commercial intent," not with the intent of "promoting [DCO's] program in the public interest." *See id.*, 405 F.2d at 1022. **The FTC never met this burden.**

B. As Applied Here, the FTC's "Reasonable Basis Theory" Is Unauthorized by Statute and Violative of Respondents' First Amendment Rights.

The FTC has characterized its ruling as one in which it "found" DCO's representations with respect to BioShark, 7 Herb Formula, GDU, and BioMixx (hereinafter "the four Challenged Products") to be "deceptive because they were not substantiated by competent and reliable scientific evidence." *See* Order, Attachment A. Throughout the administrative proceedings, the FTC made **no effort** to demonstrate that Respondents' representations were, in fact, **untruthful** or **misleading**. *See* ALJ Initial Decision ("ALJ Dec."), p. 99 n.4; Op., pp. 11-12. Instead, utilizing its "reasonable basis theory," the FTC foisted upon Respondents the burden to "substantiate" their representations by what the FTC deemed to be "competent and reliable scientific evidence." ALJ Dec., pp. 99-100; Op., p. 20. The FTC's "**reasonable basis theory**" **presumes** that, if Respondents' representations are "**unsubstantiated,**" they are inherently **deceptive**. *See* Op., pp. 11-12. Such a presumption violates both sections 5 and 12 of the FTC Act, as well as the First Amendment commercial speech doctrine.

1. The FTC's " Reasonable Basis Theory" Is a Not a Rule of Law, but Only a Policy Guide Wholly Inapplicable to this Case.

The FTC claims that its "reasonable basis theory" is established by "Commission and federal case law." *Id.*, p. 11. However, neither of the two cases cited by the FTC demonstrates how the language of either section 5 or 12 of the FTC Act could possibly be construed to require marketing representations to meet an FTC-contrived standard of "reasonableness." Rather, it appears that the courts in the two cited cases simply assumed that the FTC's construct is authorized by law. *See* F.T.C. v. Pantron I, 33 F.3d. 1088 (9th Cir. 1994); Thompson Medical Co., Inc. v. FTC, 791 F.2d 189 (D.C. Cir. 1986). While the parties in these (and other) cases have "concede[d] the validity of the reasonable basis theory,"

along with its "competent-and-reliable-scientific-evidence" offspring,[2] Respondents vigorously contest them both.

The FTC standard of "competent and reliable scientific evidence" is not derived from the statutory language, but from the "reasonable basis theory," itself. *See* FTC v. National Urological Group, Inc., 2008 U.S. Dist. LEXIS 44145, *45-*44 (N.D. Ga. 2008). And the "reasonable basis theory" appears to have been created "because it does not require the FTC to prove that [a] message was false in order to prevail." *See* FTC v. Garvey, 383 F.3d 891, 901 (9th Cir. 2004). If the FTC is **not required** to shoulder its statutory burden of having to prove an advertisement to be, in fact, "false" or "deceptive," as it chose not to do in this case,[3] "it is difficult to imagine **how the Commission could fail to prevail** on a reasonable basis theory." Pantron I, 33 F.3d at 1096 (emphasis added). According to that theory, the advertiser has the burden to substantiate by "competent and reliable scientific evidence" any health-benefit claim, and the FTC is free to set the bar as high or as low as it wants. *See, e.g.,* Thompson Medical, 791 F.2d at 193-96.

The reasonable basis/scientific evidence standard is **not** a rule enacted pursuant to the Administrative Procedure Act's ("APA") rulemaking procedures. Rather, as FTC Commissioner J. Thomas Rosch has explained, the FTC aborted its effort to adopt a regulation

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

[3] *See* ALJ Dec., p. 99, n.4.

because "there did not appear to be a way to develop workable rules."[4] Instead, the FTC resorted to the promulgation of an Industry Guide to establish its policy governing health claims about dietary supplements. FTC Guide, *Dietary Supplements: An Advertising Guide for Industry* (hereinafter "DSG") (Apr. 2001).[5] Industry Guides are "administrative interpretations of the law intended to help advertisers comply with the [FTC] Act; [but] they are **not binding law themselves."** *See* "FTC Publishes Final Guides Governing Endorsements, Testimonials," ("Testimony Guide") p. 2 (Oct. 5, 2009) (emphasis added).

As an Industry Guide, the "require[ment] [that] claims about the efficacy or safety of dietary supplements ... be supported with 'competent and reliable scientific evidence'" is **not a fixed legal standard**, but is "'**flexible.**'" *See* Op., p. 16 (emphasis added). As the court noted in the American Home Products, "the Commission has chosen not to bind itself in advance to rules as to the interpretation of the phrase 'reasonable basis,'" and therefore any order issued by the FTC is deliberately "imprecise." *Id.*, 695 F.2d at 710. Thus, the Guide states that the standard is only "**typically** require[d] [of] claims about the efficacy and safety of dietary supplements." DSG, p. 9 (emphasis added). Further, the evidentiary standard is "sufficiently flexible" so that it may be raised or lowered depending upon the FTC's assessment of the type of product or claim, the cost/feasibility of developing substantiation of the claim, the risk of harm, and the opinions of experts. *Id.*, pp. 8-9, 25.

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

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

In this case, however, the FTC has presented the reasonable basis theory, with its companion "competent and reliable scientific evidence" standard, as if it were a fixed rule of law governing every FTC enforcement action against allegedly misleading health claims concerning dietary supplements:

> [W]here ... Respondents represented that the four Challenged Products would treat or cure cancer, prevent or shrink tumors, and/or ameliorate the destructive side effects of radiation or chemotherapy, the competent and reliable scientific standard **applies** under the Guide. [Op., p. 16 (emphasis added).]

The use of such flexible standard in an enforcement case is the rule of man masquerading as the rule of law. Not only does the Guide fail to provide any fixed rule of application, it does not purport to set the "competent and reliable scientific evidence" as the rule governing FTC enforcement actions. Rather, the Guide is "intended to help advertisers comply with the [FTC] Act." DSG, p. 2. As a "help to comply," the Guide serves the practical goal of ensuring an advertiser that — if he affirmatively substantiates "each interpretation" of every express and implied claim by competent and reliable scientific evidence — then the ad would be in "compliance with FTC law." DSG, p. 25. By imposing upon the advertiser this affirmative burden, the Guide is designed to provide a kind of "safe harbor" from a subsequent FTC enforcement action, **not** to impose upon the advertiser in that enforcement action the affirmative — and extra-statutory — burden of substantiating his health-benefit claims by what the FTC deems to be competent and reliable scientific evidence. Yet that is what happened in this case.

2. The Reasonable Basis Theory Erroneously Shifted the Burden of Proof to Respondents.

Both the ALJ and the Commission asserted that "**Respondents have the burden** of establishing what substantiation they relied on for their product claims." *See* ALJ Dec., p. 99; Op., p. 12 (emphasis added). This ruling is not derived from sections 5 and 12 of the FTC Act, but from the DSG, which states that "advertising for ... dietary supplements ... must be truthful, not misleading, **and substantiated."** DSG, p. 1 (emphasis added). Further, "supplement marketers are cautioned that the FTC will require **both** [i] strong scientific support **and** [ii] careful presentation for [health] claims." *Id.*, p. 2 (emphasis added). These two statements demonstrate why an Industry Guide is ill-suited to provide a legal standard governing an FTC enforcement action. It makes sense to advise an advertiser who is seeking a wide berth from an FTC enforcement action to assume the burden of affirmatively substantiating his product claims **before** he makes them. It does not make sense, however, to impose upon an advertiser **after** he has run an ad to affirmatively substantiate his claims in an enforcement proceeding in which the FTC has the statutory burden of proving that the claims are false or deceptive. But that is exactly what has occurred here.

While the FTC claims that "Complaint Counsel had borne the burden of proving that Respondents' representations were not substantiated" by competent and reliable scientific evidence (Op., p. 22), that is quite different from the burden imposed on the FTC under a fair construction of the language of the FTC Act. Section 5 declares that "false" advertisements are unlawful; section 12 declares "deceptive" ones to be so. It naturally follows from such language that the burden is upon the FTC to prove falsity or deceptiveness. *See* ALJ Dec., p. 99 n.4.

In this case, however, the Commission finds fault with Respondents for "hav[ing] not produced anything to show that they possessed and relied on any competent and reliable scientific evidence to support the overall net impressions conveyed by the advertisements at issue." Op., p. 18. If the FTC's theory is that an advertising claim is false or deceptive because there is no "competent and reliable scientific evidence" to support the claim, then the FTC should be required to "produce" such evidence showing that the "overall net impression" of Respondents' claims was demonstrably **false or deceptive**. Instead, the FTC has the burden only to show that the advertiser does **not** have sufficient scientific evidence acceptable to the FTC that his claim is demonstrably **true or nonmisleading**. *See* Op., p. 20. Thus, the Commission has characterized its ruling against Respondents as one in which the FTC "found [DCO's] claims for the [four Challenged Products] to be deceptive because they were **not substantiated** by competent and reliable scientific evidence." *See* Order, Attachment A (emphasis added).

As the court of appeals observed in Pantron I, "it is difficult to imagine how the Commission could fail to prevail ... on a reasonable basis theory,"[6] whereby the FTC has complete discretion to impose whatever evidentiary standard of reasonableness that it chooses and then, to require the advertiser to prove affirmatively that his claims meet that standard.

3. The Reasonable Basis Theory Is *Ultra Vires*, an FTC Add-On that Prejudiced Respondents.

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[6] Pantron I, 33 F.3d at 1096 n.23.

The DSG insists not merely that "that advertising for any product — including dietary supplements — must be truthful, not misleading, **and substantiated**." DSG, p. 1 (underlining original; bold added). To be substantiated, an advertisement for a dietary supplement must "typically" rest upon "competent and reliable scientific evidence." *Id.* at 3. But the DSG cites neither statutory provision nor agency regulation that imposes an affirmative duty upon any advertiser that "before disseminating an ad, [he] must have adequate substantiation for all objective product claims." *Id.* at 3. Rather, it is based on **yet another** FTC "policy" statement, purportedly resting upon "the FTC's deception authority." *Id.* n.6. In fact, it is an FTC add-on, a usurpation of authority never conferred by Congress.

Paragraphs II and III of the Order mandate not only that each of Respondents' representations concerning their products be "true" and "nonmisleading," but that "at the time it is made, Respondents **possess and rely** upon competent and reliable scientific evidence that substantiates the representation." (Emphasis added.) Further, the Commission affirmed the ALJ's decision not because it found DCO's claims "false" and "misleading," but because Respondents had failed to substantiate its claims "by 'competent and reliable scientific evidence.'" Op., p. 20.

Although the DSG claims that the FTC's "role" is "to ensure that consumers get **accurate** information about dietary supplements so that they can make an **informed decision** about these products" (DSG, p. 1 (emphasis added)), **the FTC makes the decision** for the consumer under the Guide's "reasonable basis theory." For example, the Guide states that "[i]t is not enough that a testimonial represents the honest opinion of the endorser. Advertisers **must also** have **appropriate scientific evidence** to back up the underlying claim." *Id.*, p. 18

(emphasis added). Thus, no matter how truthful and nonmisleading an advertising representation based upon an individual testimony may be, "**anecdotal evidence** of a product's effect, based solely on the experiences of individual consumers, is **generally insufficient** to substantiate a claim." *Id.*, p. 18 (emphasis added). In like manner, the Guide states that in "**some situations** ... **traditional use evidence** alone will be inadequate to substantiate a claim, even if that claim is carefully qualified to convey the limited nature of the support." *Id.*, p. 21 (emphasis added). In both instances, the Guide substitutes its standard of "competent and relevant scientific evidence" (*id.*, pp. 19-21), as the Commission did in this case. *See* Op., pp. 19-22.

In short, the FTC has presumptuously assumed a paternalistic role, selectively usurping the part of American consumers to choose, instead of enforcing the Congressional mandate to police false and deceptive ads so that **consumers can make an informed decision for themselves.** This is not only contrary to statute, but contrary to the First Amendment commercial speech doctrine.

4. The FTC's "Reasonable Basis Theory" Collided with Respondents' Rights under the First Amendment Commercial Speech Doctrine.

Throughout this proceeding, the FTC has rejected Respondents' claim that the FTC action against them violated the Supreme Court's First Amendment commercial speech doctrine. The Commission ruled that because the ALJ found "Respondents' commercial speech deceptive[,] no further analysis is necessary." *See* Op., p. 14. But the ALJ did **not** find that Respondents' representations were **actually** misleading or deceptive; rather, he presumed, and the Commission agreed, that they were misleading **solely** because they were not

supported by "competent and reliable scientific evidence." *See* ALJ Dec., pp. 99-106; Op., pp. 18-22. Such bootstrapping is constitutionally impermissible.

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

Unquestionably, the FTC case against Respondents is on all fours with Pearson. The FTC's predetermined standard of "competent and reliable scientific evidence" played the same role in this case as did the FDA's "signficant scientific agreement" standard — establishing that DCO's advertising claims were *per se* misleading. In a futile effort to show that "*Pearson* bears no resemblance to this case," the Commission asserted that "[t]his case involves a purely **adjudicatory challenge to specific representations** made in [DCO's] advertisements." Op., p. 21 (emphasis added). But, from beginning to end, the FTC's case has been exclusively based upon the asserted lack of "competent and reliable scientific evidence" for DCO's claims. And the standard by which those claims were measured to be "misleading" was pre-set in an

Industry Guide, which, in turn, was not even subjected to the APA rulemaking procedure, much less to the adversarial process characteristic of an adjudication.

C. Paragraphs II and III of the Final Order Unconstitutionally Deny Respondents Free Exercise of Religion and Freedom of Speech.

The FTC also misapplied Bolger v. Young Drugs Prods. Corp, 463 U.S. 60 (1983), to cut off Respondents' broader First Amendment claim that DCO's product claims must be considered in the context of its active engagement in the national debate on health care. *See* Op., p. 13. While the Bolger Court found that the ads in that case were "properly characterized as commercial speech," it warned that "an **economic motivation** ... would clearly be **insufficient** by itself to turn the materials into commercial speech." *See* Bolger, 463 U.S. at 66. (emphasis added). The FTC, however, did not heed that warning, having already erroneously and summarily concluded that "the **primary purpose and effect** of Respondents' representations concerning the four Challenged Products was to **sell** those products." Op., p. 13 (emphasis added).

In remarks delivered just five days after the FTC announced its Cancer Cure Sweep, FTC Commissioner Rosch acknowledged that the First Amendment raised a higher barrier to FTC regulation where an entity was engaged in an activity that "blend[ed] commercial speech [with] noncommercial speech and debate on an issue of public importance." Rosch, p. 5. Citing Nike, Inc. v. Kasky, 539 U.S. 654 (2003), Commissioner Rosch acknowledged that such blending of speech "pose[s] difficult constitutional issues." *Id.* Yet, despite Justice Stevens' strong suggestion in Nike that the New York Times rule of knowing falsity or

reckless disregard of such falsity,[7] would apply when "commercial speech, noncommercial speech and debate on an issue of public importance" converge,[8] Commissioner Rosch found the Supreme Court's New York Times rule totally inapplicable. *See* Op., p. 13. Commissioner Rosch was equally dismissive of the Schaumburg test[9] that requires proof of actual fraud or deception in the regulation of money solicitations by nonprofit organizations. *Id.* In short, the FTC decided that neither New York Times nor Schaumburg applied because Respondents were engaged in a commercial activity.

The First Amendment cannot be divorced from the money that is required to participate fully in the marketplace of ideas, whether it be the ongoing debate over healthcare, or the solicitation of money by nonprofit organizations, or the election of candidates for public office. Just a few weeks ago, the U.S. Supreme Court ruled that the government cannot deprive the people of vital "information, knowledge and opinion" by erecting economic barriers of entry into the electioneering marketplace. *See* Citizens United v. FEC, __ U.S. __, Majority Slip Opinion, p. 38 (Jan. 21, 2010). Nor does the First Amendment permit "[p]rolix laws [that] chill speech," as the Federal Election Commission ("FEC") is wont to do by "amorphous regulatory interpretation." *Id.*, Slip Op., p. 7. Neither can the FTC censor Respondents' overall healthcare speech by its overly complex "scientific" evidentiary standard.

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[7] New York Times v. Sullivan, 376 U.S. 254, 279-80 (1964).

[8] Nike, 539 U.S. at 664 (Stevens, J., concurring).

[9] *See* Illinois *ex rel* Madigan v. Telemarketing Associates, Inc., 538 U.S. 600, 612, 619-20 (2003).