ORIGINAL

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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

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

RESPONDENTS' REPLY TO COMPLAINT COUNSEL'S OPPOSITION TO RESPONDENTS' APPLICATION FOR STAY OF MODIFIED FINAL ORDER PENDING PETITION FOR REVIEW

INTRODUCTION

In his zeal to defeat Respondents' Application for a Stay of the Modified Final Order herein ("Opp."), Complaint Counsel makes assertions apparently based on personal predilection that are supported neither by case law, nor by the record, nor by sworn declaration. However, Complaint Counsel's unsupported opinions about the Daniel Chapter One ("DCO") ministry do not constitute record evidence, and his dismissive tone cannot change the fact that Respondents' legal claims on appeal are substantial, and that Respondents would suffer irreparable harm if their requested stay is not granted. Moreover, Complaint Counsel has not overcome Respondents' showing that, if the stay were granted, there would be no significant danger to the public health.

ARGUMENT

1. The Record Does Not Support Complaint Counsel's Claim That the Grant of a Stay "Threatens Public Health."

Without providing any page citation to the Commission's Opinion ("Opinion"), Complaint Counsel claims the Commission has already determined that granting a stay would endanger the public because:

- "the Commission found [that] permitting Respondents to continue to make [cancer treatment] claims **threatens the public health**" (Opp., p. 2 (emphasis added)); and
- "the Commission ruled [that] Respondents' deceptive marketing ... places especially vulnerable consumers — those suffering from cancer — at **grave risk of injury**" (Opp., p. 3 (emphasis added)).

These free-floating claims by Complaint Counsel are unfounded. Later, purportedly relying on pages 18 and 20 of the Commission Opinion, Complaint Counsel claims that "the injunctive relief ordered by the Commission ... underscores Respondents' **callous indifference** to the **grave public health risks** caused by their deceptive advertising for untested cancer cures." Opp., p. 8 (emphasis added). This is a gross exaggeration of what the Commission stated, and is wholly unsupported by the Administrative Law Judge's ("ALJ") findings of fact 356-61 upon which Complaint Counsel's statement allegedly rests. In fact, in the course of its review of the expert testimony before the ALJ, the Commission observed that the FTC's expert "testified that harm **potentially may** occur from **remedies** that are alternatives to those that have undergone clinical studies on humans." Opinion, p. 18 (emphasis added). Two pages later, the Commission observed that the ALJ's conclusion that "Respondents' representations needed to be substantiated by 'competent and reliable scientific evidence,'" in part, because

"their products **could be** harmful if used with the other products or therapies." *See* Opinion, p. 20 (emphasis added).

The Commission's cautious statements of possible or theoretical harm are a far cry from Complaint Counsel's assertion that the Commission's cease and desist order was based on "Respondents' callous indifference to ... **grave public health risks.**" Opp., p. 8 (emphasis added). To the contrary, the Commission has expressly stated that its Order is based on the **sole** ground that "(c)ompetent and reliable scientific evidence does not demonstrate that any of the ingredients in BioShark, 7 Herb Formula, GDU, or BioMixx, are **effective** when used for prevention, treatment or cure of cancer." *See* Modified Final Order ("Order") (emphasis added).

Indeed, the Government's expert testimony (upon which the Commission, and the ALJ before it, relied), viewed in a light most favorable to the Government, demonstrates only that certain ingredients in one or more of Respondents' four Challenged Products — not even the products themselves — could only potentially cause harm. *See* Opinion, pp. 18, 20 and ALJ, Findings of Fact 356-61. Yet, Complaint Counsel takes that evidence of "potential harm," and magnifies it into a finding by the Commission that "the Respondents' **products** pose a **significant health risk.**" *See* Opp., p. 11 (emphasis added). But there is no such finding in the Commission Opinion.

Complaint Counsel claims that he "**represents** the public interest in effective law enforcement" (*see* Opp., p. 2 (emphasis added)) which makes it sound like he embodies the public interest — but he misquotes the FTC which only said that he "**is responsible for representing** the public interest...." *See* In the Matter of California Dental Association, 1996

FTC LEXIS 277 AT *8 (May 22, 1996) (emphasis added). Indeed, Complaint Counsel is a lawyer working for a government agency, who not only must prove his case and argue from the record, but should perform his duties dedicated "to the spirit of fair play and decency...."[1] Complaint Counsel has no inherent competence to know what medical therapies are superior, except for himself.[2] Even the Commission is careful not to claim special expertise to represent the public interest in health and well-being, asserting only to have "the common sense and expertise to determine," without any direct evidence from consumers, "'what claims, including implied ones, are conveyed in a challenged advertisement'" (Opinion, pp. 10-11).

In this case Complaint Counsel is acting untethered to flesh-and-blood complainants — as he presented not even one witness who was injured by, or even had a complaint against, Respondents' products. Complaint Counsel never even alleged a "significant" or "grave" health risk in his complaint. *See* Complaint. Nor did Complaint Counsel present any evidence of complaints against DCO by any vulnerable consumer whose conventional cancer treatment might have theoretically been impaired by any of Respondents' four Challenged Products. Indeed, the sum total of evidence regarding alleged harm came from the testimony of a single

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[1] Attorney General Robert H. Jackson, The Federal Prosecutor, April 1, 1940.

[2] Although Complaint Counsel personally today may believe whatever he is told by oncologists and may not care about access to alternatives, DCO is fighting for his right to make health care decisions for himself only — not decisions for others. To deny this stay for the reasons advanced by Complaint Counsel would hold the FTC up to disrespect by a citizenry that is increasingly fed up with a government run by lawyers that is perceived to misuse their money, usurp their liberties, and intrude upon their lives.

expert witness[3] — Dr. Denis Miller — a physician who admitted that he makes his living designing and conducting studies to show the efficacy of chemotherapy, not engaging in the practice of medicine serving actual cancer patients. *See* Tr. 1/47-48. At the hearing, Dr. Miller exhibited no understanding of herbs — not even knowing whether herbs were plants. When asked by the ALJ: "I just want to know, is an herb a plant, is a plant an herb. How do you define it?" Dr. Miller replied: "I think a botanist could that question better than I. I just know where some of these agents come from, but I'm not that person to answer that question." Tr. 1/168-69.

There is no record evidence of danger to the public from DCO products, or that a stay pending judicial review would do anything more than preserve the status quo. Complaint Counsel urges reliance only on "competent and reliable" scientific evidence (*e.g.*, Opp., pp. 2, 12), but a continuous flow of medical developments reveals that placing faith in so-called scientific studies is like unto building a house on sand. Just in the last few weeks it has been revealed that "scientific studies" published in "peer-reviewed journals" had been faked.

> Pfizer had given some $74,000 to [Dr. Scott] Reuben for a **placebo-controlled study** of celecoxib (Celebrex) as part of a "multimodal" painkiller regimen for outpatient knee ligament surgery. The study was to enroll 100 patients. Reuben subsequently reported to Pfizer and in the journal article that 200 patients entered the trial and that the celecoxib regimen was effective. "In fact, **Dr. Reuben had not enrolled any patients into that study**, and the results reported both to Pfizer and to *Anesthesia & Analgesia* and, in turn, to the public were wholly made up by Dr. Reuben and therefore false...." [John Grever, "Research Fraud Probe Leads to Criminal Charge," MedPage

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[3] The Holy Bible teaches that facts are to be established by the testimony of two or more witnesses. II Corinthians 13:1. *See also* Deuteronomy 17:6.

Today (Jan 15, 2010) (emphasis added).]
http://www.medpagetoday.com/PublicHealthPolicy/Ethics/17985

Moreover, while it had been long believed cancer cells that leave the primary tumor metastasize and spread cancer elsewhere in the body, traveling away from the primary tumor, a new study at Memorial Sloan-Kettering Cancer Center demonstrates that circulating cancer cells show a proclivity to re-seed the site of the original cancer, calling into question the theory by which surgeons announce to patients "we got it all." *See* Mi-Young Kim, Thordur Oskarsson, Swarnali Acharyya, "Tumor Self-Seeding by Circulating Cancer Cells," *Cell* 139, 1315, 1323 (Dec. 24, 2009). Increasingly, medical oncologists are more candid about the limitations of their craft.[4]

In an area of increasing medical uncertainty, a stay would allow people to continue to access DCO products as they have in the past.

2. Respondents' Challenge to the Legality and Constitutionality of the FTC's "Substantiation Doctrine" is Substantial.

Acknowledging Respondents are waging an attack on "the FTC's substantiation doctrine," Complaint Counsel has finally conceded that, under that doctrine, the burden of proof is shifted to Respondents. How else could one explain Complaint Counsel's statement that "Respondents made no effort to produce competent evidence to substantiate their cancer

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[4] In a book published in the last few weeks describes a "pioneer overview study, 'The Contribution of Cytotoxic Chemotherapy to 5-year Survival in Adult Malignancies,' by Drs. Graeme Morgan, Robyn Ward, and Michael Barton in *Clinical Oncology* reports that 'The overall contribution of curative and adjuvant cytoxic chemotherapy to a 5-year survival in adults was estimated to be ... 2.1% in the USA.'" Gary Null, Ph.D., Martin Feldman, M.D., Debora Rasio, M.D., and Carloyn Dean, M.D., N.D. Death by Medicine, Praktikos Books, (2010), pp. 95-96.

cure claims"? Opp., p. 5. Indeed, how else could one justify Complaint Counsel's statement that "[t]he substantiation doctrine ... require[s] advertising touting the effectiveness of a product to have competent and reliable evidence that the claim is true"? *Id.* After all, if the FTC had to shoulder the burden to prove that Respondents' claims were misleading or false, it would not matter whether Respondents could "substantiate" their claims — unless and until the FTC produced evidence affirmatively substantiating that Respondents' claims were deceptive or false, as the language of sections 5 and 12 of the FTC Act clearly requires.[5]

Nor is this contest over the meaning of sections 5 and 12 of the FTC Act resolved by Complaint Counsel's claim that for "more than twenty-five years" the FTC has relied on its "substantiation doctrine." *Id.* As Oliver Wendell Holmes once said, "It is revolting to have no better reason for a rule of law than that ... it was laid down in the time of Henry IV." O.W. Holmes, "The Path of the Law," 10 *Harv. Law Rev.* 457, 469 (1897). Complaint Counsel purports to undergird the practice with "an unbroken string of judicial decisions **approving** the doctrine." Opp., p. 5 (emphasis added). But the string cite contains only cases wherein courts have **applied** the doctrine without **approving** it.

FTC v. Pantron I Corp., 33 F.3d 1088 (9th Cir. 1994) and Thompson Medical Co., Inc. v. FTC, 791 F.2d 189 (D.C. Cir. 1986) — two of the cases cited by Complaint Counsel as having "approved" the substantiation doctrine — were also relied upon by both the ALJ and the Commission. *See* Opinion, p. 11. As noted in Respondents' Memorandum in Support of

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[5] By implying at every turn that Respondents' advertisements have been proven "deceptive" in some direct and nefarious sense (*see* Opp., pp. 3, 7, 8, 9,and 11), Complaint Counsel seeks to avoid addressing the merits of the Respondents' demonstration that the balance of the factors weigh in favor of a stay pending judicial review.

Respondents' Application for Stay of the Modified Final Order ("Resp."), "it appears that the courts [in these two cases] simply assumed that the FTC's [substantiation doctrine] is authorized by law." *Id.*, p. 6. In fact, the court in Pantron I did not even apply the doctrine, the FTC having "abandoned" it on appeal so that the court only "discuss[ed] the falsity theory." Pantron I, 33 F.3d at 1096. In a footnote, the court recognized the existence of the FTC's "reasonable basis theory," but did not approve it. *See id.*, 33 F.3d at 1096 n.23. *See also* Resp., pp. 7, 11. While the propriety of a particular "reasonable basis standard" — one that required the establishment of an efficacy claim by "two clinical studies" before a specific claim could be made — was challenged in Thompson Medical, the legitimacy of the "reasonable basis theory," itself, was not. *Id.*, 791 F.2d at 192-94. Thus, the court in Thompson Medical **only applied** the FTC substantiation doctrine. *Id.*, 791 F.2d at 194-96.

In like manner, the courts of appeals in Sterling Drug, Inc. v. FTC, 741 F.2d 1146 (9th Cir. 1984), Removatron International Corp. v. FTC, 884 F.2d 1489 (1st Cir. 1989), and FTC v. QT, Inc., 512 F.3d 858 (7th Cir. 2008), only addressed issues of application of the substantiation doctrine. In Sterling Drug, the advertiser raised a number of issues addressing the nature and scope of the claims that the FTC claimed that it was making about a number of products, and whether there was sufficient evidence that such claims had not been substantiated. *Id.*, 741 F.2d 1150-54. In Removatron, the advertiser contested "various evidentiary rulings," the "sufficiency of the evidence," and a "requirement" that it "possess one well-controlled study" before making certain claims about its product. *Id.*, 884 F.2d at 1493. In QT, the advertiser "maintain[ed] that the magistrate judge subjected their statements to an excessively rigorous **standard** of proof," namely, "placebo-controlled, double-blind

stud[ies]." *Id.*, 512 F.3d at 861 (emphasis added). Thus, none of these cases supports Complaint Counsel's claim that these courts approved the FTC's substantiation doctrine.

The district court opinions in FTC v. Sabal, 32 F. Supp. 2d 1004 (N.D. Ill. 1998), FTC v. Bronson Partners, LLC, 564 F. Supp. 2d 119 (D. CT. 2008), and FTC v. Natural Solution, Inc., 2007 U.S. Dist. LEXIS 60783 (C.D. Calif. 2007) demonstrate Complaint Counsel's seeming confusion about the difference between a case that **applies** the FTC substantiation doctrine and one that **approves** it. In Sabal, the court simply assumes that the "reasonable basis theory" applies and proceeds "to ascertain the appropriate level of substantiation for the disputed claims and then determine whether it was met." *Id.*, 32 F. Supp. 2d at 1007. In Bronson Partners, the court accepted without question the reasonable basis theory, embarking only upon a discussion and analysis of whether the advertising claims have been substantiated. *Id.*, 564 F. Supp. 2d at 123-37. Similarly, in Natural Solution, the court recognized that case was based upon the "reasonable basis theory," and simply reviewed the record to ascertain whether the advertiser carried the substantiation burden. *See id.*, 2007 U.S. Dist. LEXIS at *13-*17.

Finally, the district court opinions in FTC v. National Urological Group, Inc., 645 F. Supp. 2d 1167 (N.D. Ga. 2008) and FTC v. Direct Marketing Concepts, Inc., 569 F. Supp. 2d 285 (D. Mass. 2008), clearly demonstrate the difference between the uncontested application of a rule and a contested one. In National Urological, the court assumes the FTC's "promulgated regulations require advertisements ... to be supported by adequate substantiation" (*id.*, 645 F. Supp. 2d at 1177), erroneously relying upon the FTC's

Advertising Guide for the Industry to supply the rule[6] by which the sufficiency of the substantiation is to be measured. *Id.*, 645 F. Supp. 2d at 1190. In Direct Marketing, the court applies the "reasonable basis" theory, even though it recognizes that "the FTC could also proceed under a more stringent 'falsity' theory," on the ground that "[e]ither approach suffices." *Id.*, 569 F. Supp. 2d at 298 n.6. In neither of the two cases is the substantiation doctrine contested, nor is the court's use of the Industry Guide in National Urological disputed. Respondents contest both issues here. *See* Resp., pp. 6-13.

In sum, Complaint Counsel has been unable to identify any case where the "reasonable basis" theory and its "substantiation doctrine" have been upheld against a frontal challenge, such as the one that Respondents have advanced here.

3. The First Amendment Commercial Speech Doctrine Applies.

Complaint Counsel dismisses Respondents' claim that the First Amendment's commercial speech doctrine applies on the sole ground that the doctrine "does not extend to speech that is **deceptive**," citing Central Hudson Gas & Electric Corp. v. Public Service Commission, 447 U.S. 557 (1980). Opp., p. 7 (emphasis added). As the district court in Direct Marketing points out, however, under the commercial speech doctrine as "refine[d]" by the Supreme Court, only "commercial speech that 'is ***actually* misleading**' may be prohibited entirely." *Id.*, 569 F. Supp. 2d at 306 (italics original, bold added).

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[6] The court mistakenly assumed that by issuing an Industry Guide, the FTC promulgated a rule. This is not true. *See* Resp. pp. 7-8. The two are governed by wholly different processes. *Compare* 16 CFR §§1.1 - 1.6 *with* §§1.7 - 1.18.

Having chosen to proceed against Respondents under the FTC's "reasonable basis" theory, the FTC did not even attempt to prove actual deception. *See* ALJ Decision, pp. 90-91. Thus, as the Commission itself has acknowledged, it has found Respondents' "advertising claims ... to be deceptive," not because they are actually untrue or misleading, but "because they were not substantiated by competent and reliable scientific evidence." *See* Order, Attachment A. Thus, as the district court concluded in Direct Marketing, under the reasonable basis theory, all that the FTC may claim here is that Respondents' representations respecting the four Challenged Products are "*likely* to mislead consumers." *See id.*, 569 F. Supp. 2d at 307 (italics original). Thus, the First Amendment commercial speech doctrine protects Respondents. *Id.*

In short, Complaint Counsel cannot have it both ways. It cannot take advantage of its "reasonable basis theory" to lower the bar of proof from "actual" deception to "failure to substantiate," and then make a 180-degree turn to block the door to Respondents' First Amendment commercial speech claim. *See* Pearson v. Shalala, 164 F.3d 650, 655 (D.C. Cir. 1999). *See also* Direct Marketing, 569 F. Supp.2d at 307 n.11.

4. Daniel Chapter One is Not a Commercial Enterprise.

Complaint Counsel insists that "DCO operates as a commercial enterprise" and, as such, is not only subject to the jurisdiction of the FTC (Opp. pp. 4-5), but outside the protection of the free exercise of religion and freedom of speech guarantees of the First Amendment. Opp., pp. 6-7.

In its "legal analysis" addressing the question whether the FTC had jurisdiction over DCO, the Commission purported to apply California Dental Ass'n. v. FTC, 526 U.S. 756

(1999) and Community Blood Bank v. FTC, 405 F.2d 1011 (8th Cir. 1969) as the "controlling authorities respecting [Respondents'] challenge to the FTC's jurisdiction." Opinion, p. 7. Again, Complaint Counsel cannot have it both ways. As the Commission has acknowledged, both precedents relate to FTC jurisdiction over nonprofit entities, not commercial enterprises. *Id.*, pp. 7-8. If DCO "operates as a commercial enterprise," as Complaint Counsel contends, then neither case would be applicable. But the Commission did not find that DCO was a sham. Rather, it found that "DCO is currently a 'corporation sole,'" and thus, a non-profit entity, even though "prior" to its incorporation as a corporation sole, "DCO was a for-profit corporation organized under the laws of Rhode Island." Opinion, p. 4. The jurisdictional question, then, is not one of the sufficiency of the evidence to support a finding that DCO operates as a for-profit commercial enterprise, as Complaint Counsel has contended (Opp., 4-5.), but whether the Commission misapplied the rule of Community Blood Bank governing FTC jurisdiction over a nonprofit entity. *See* Resp., pp. 2-5. Thus, the jurisdictional issue that would be before a court of appeals on a petition for review would **not** be subject to the rule of deference set forth in 15 U.S.C. section 45(c) and FTC v. International Federation of Dentists, 476 U.S. 447, 454 (1986), as contended by Complaint Counsel. *See* Opp., p. 4 n.3.

According to Complaint Counsel, "DCO sells cancer cures as part of a commercial enterprise," not as a religious ministry. Opp., p. 5. In Complaint Counsel's eyes, DCO is no different than Youngs Drug Products Corp., a for-profit company "engaged in the manufacture, sale, and distribution of contraceptives." *See* Opp., p. 7. Thus, Complaint Counsel dismisses Respondents' First Amendment free exercise and free speech claims as

"fiction," unworthy of serious consideration. Opp., p. 6. Complaint Counsel's argument, however, is based upon a totally erroneous understanding of the nature of a Christian ministry.

Complaint Counsel mistakenly believes that "the hallmarks of a religious endeavor" would require DCO to operate in a cocoon, limiting the use of its products to "religious services," and selling those products only "to DCO religious adherents." Opp., p. 5. Indeed, in Complaint Counsel's world view, the "free exercise of religion" guarantee of the First Amendment extends only to the use of products in "religious rites" participated in by only true believers (Opp., p. 7):

> Respondents' advertisements are disseminated broadly on the Internet, their products are sold to consumers regardless of religious affiliation, their products are not used as part of a religious service or ritual, and the advertisements are essentially devoid of religious content. [Opp., p. 8.]

By these statements Complaint Counsel demonstrates unfamiliarity with both the free exercise of religion guarantee and the Christian faith.

As the Supreme Court observed in Employment Division, Dept. Of Human Resources v. Smith (Smith II), 494 U.S. 872 (1990), the Free Exercise Clause of the First Amendment "involves not only belief and profession but the performance of (or abstention from) **physical acts**[,] [including] **proselytizing** ...." *Id.*, 494 U.S. at 877. The very meaning of "proselytizing" comprehends engaging in actions designed to convert persons who are of different, or of no, "religious affiliation." Webster's Third International Dictionary, p. 1821 (1964). Indeed, Jesus Christ began His ministry with a proselytizing message urging a small band, including fishermen, to "come follow me ... and I will make you fishers of men." *Matthew* 4:19. And from the beginning Christ's proselytizing effort included acts of "healing

every disease and sickness among the people" (*Matthew* 4:23), as a sign that He was the Messiah promised in the Hebrew scriptures. *Matthew* 8:16-17.

As a Christian ministry, DCO is organized to share the Good News of Jesus Christ, teaching the whole counsel of God — body, mind and spirit (*Luke* 4:18-19) — and to exercise all of the gifts of the Holy Spirit, including the healing of the human body. *See I Corinthians* 12:1-11. DCO's ministry is to the world, and is not limited to operating within the box that Complaint Counsel would care to put it. DCO understands the Word of God to teach the use of natural products, not to use artificial drugs.[7] As the Smith II Court observed, the free exercise of religion includes "abstaining from certain foods." *Id.*, 494 U.S. at 877.

Complaint Counsel has not cited a single case where the FTC has ever previously successfully asserted jurisdiction over a nonprofit organization other than a trade association, and certainly no cases where it successfully asserted jurisdiction over a religious organization like DCO. Yet, according to Complaint Counsel's rigid and narrow understanding of the nature of religion and of the free exercise thereof, FTC jurisdiction would be extended to any Christian healing ministry that sells or distributes literature making representations about human health and well-being that cannot be substantiated by what the FTC deems to be

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[7] In the Holy Bible, the Greek word translated as "sorceries" (*Revelation* 9:21) or "witchcraft" (*Galatians* 5:20) is "pharmacopeia" (*see* Abingdons Strong's Exhaustive Concordance of the Bible, pp. 958, 1176 (1984)), from which we get the English words, pharmacy and pharmaceuticals.

competent and reliable scientific evidence. Such action would not only violate the free exercise clause, but the freedom of speech guarantee as well.[8] *See* Smith II, 494 U.S. at 881-82.

5. Respondents' Due Process Claim is Not an *Ad Hominem* Attack.

Complaint Counsel pejoratively labels Respondents' due process argument as "*ad hominem*" attacks against certain Commissioners, which Complaint Counsel would "not dignify" by any further response. Opp. at 3 n.2. By choosing to make no response on the merits of Respondents' claim, Complaint did the Commission no favor. Respondents' contention, *inter alia*, about the importance of the appearance of impropriety with respect to administrative proceedings has strong support in the case law.[9] Moreover, Respondents' Due Process argument is not directed at the person of any Commissioner. Rather, it targets the impropriety of specific actions and words that strongly indicate bias or prejudice — actions and words that compromise the integrity of the administrative process. Surely, Complaint Counsel would agree that partiality has no place in the administration of the FTC Act, but if he truly believed that there had been no breach of the impartiality principle, he should have given support for his view.

6. Respondents' Claims Are Substantial.

Complaint Counsel has guaranteed the Commission that "Respondents will not prevail on appeal." Opp., p. 2. Respondents' counsel, on the other hand, do not purport to know

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[8] Complaint Counsel's claim that Respondents' First Amendment rights would be overridden by a "compelling government interest" in "protecting the health of cancer patients" (Opp., p. 10) has no factual support in the record. *See* Part 1, *supra*.

[9] *See, e.g.*, Cinderella Career and Finishing Schools, Inc. v. FTC, 425 F.2d 583 (1970).

what will be the outcome of the appeal — but they know that Respondents are not required to allege or prove they will prevail. As recognized in the cases, an argument before a tribunal that just ruled against Respondents that it is wrong on the merits normally would be unavailing. It is, therefore, enough for Respondents to have raised a substantial legal issue on at least one legal or constitutional claim, if the other factors considered by the Commission under Rule 3.56 — the irreparable harm that will be suffered if a stay is not granted, and the absence of injury to other parties if the stay is granted — weigh in their favor. *See* Resp., pp.1-2.

7. Respondents Will Suffer Irreparable Harm.

Complaint Counsel asserts that Respondents' argument that they will suffer irreparable harm is "unpersuasive given the **fact** that there are hundreds of other supplemental retailers that manage to thrive without making unsubstantiated disease claims." Opp., p. 9. Thus, he argues, the only thing that Respondents will lose if a stay is not granted is "the competitive advantage that their deceptive advertising previously provided them over their competitors." *Id.* Neither claim is supported by any citation to the record or by any appended declaration regarding the marketing of dietary supplements. Without such support, Respondents have been afforded no opportunity to evaluate or even understand the basis for Complaint Counsel's claims, aside from repeating the facts and arguments already submitted in support of Respondent's Application for a Stay.

Further, such unsupported statements are also belied by Complaint Counsel's understanding of the breadth of the cease and desist order in this case. While he states that the "Order **only** applies to the manufacturing, labeling, advertising, promotion, offering for sale,

sale, or distribution of products," Complaint Counsel would except from that mandate only "non-promotional discussions." Opp., p. 8 (emphasis added). Additionally, while Complaint Counsel, on the one hand, declares that "Respondents are free to say what they wish," he admits, on the other, that Respondents "**just** cannot make unsubstantiated claims while trying to sell their products." *Id.* (emphasis added).

In truth, even Complaint Counsel does not know what Respondents may say and do. And he only purports to know what they may not say and do. Indeed, at oral argument three times the ALJ asked Complaint Counsel "What could they say?" about their products, and he was unable to provide a clear response, except to say "They can say the truth." Tr. Closing Arguments, July 9, 2009, pp. 77-78. In a world where the government defines truth, and threatens draconian penalties if one is unable to satisfy the FTC "substantiation" requirements, the Order would have a chilling effect, leading Respondents to say virtually nothing about their products.

8. Respondents' Declarations Support a Stay.

Complaint Counsel argues that the declarations submitted in support of Respondents' application for stay "should be stricken," treating them as if they were submitted by Respondents to reopen the record in this case in an effort to substantiate the safety and efficacy of DCO's many products, including the four products challenged in this case. *See* Opp., pp. 11-12. To the contrary, as clearly indicated in Respondents' supporting memorandum, the Declarations were submitted in support of Respondents' claims that (a) the denial of a stay would cause irreparable harm to Respondents, whereas (b) the granting of the requested stay would harm no one, but instead, would actually be in the public interest. *See* Resp., pp. 24-

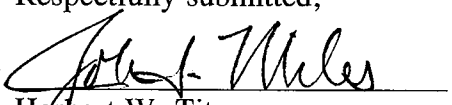
35. Because none of these three factors — irreparable harm, injury to party, and public interest — have been relevant and before the Commission until now, it is most appropriate and indeed, anticipated by Commission Rule 3.56(b) that relevant information concerning the consequences of the stay being granted or not be submitted in the form of sworn declarations. It is submitted that Complaint Counsel's call for the several declarations to be stricken is utterly without merit.

Apparently, Complaint Counsel has no response to the declarations of three licensed healthcare practitioners (two chiropractors and a general dentist) who speak to the importance to their patients to have continued access to DCO products. Complaint Counsel could have submitted declarations to respond to those of DCO, but he chose not to. As such, the declarations submitted in support of Respondents' Application for Stay stand unrebutted.

CONCLUSION

For the foregoing reasons, as well as those set forth in the Respondents' Application for Stay and accompanying documents, the FTC should stay its Order pending judicial review.

Respectfully submitted,



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DANIEL CHAPTER ONE,	)	**DOCKET NO. 9329**
a corporation, and	)	
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JAMES FEIJO,	)	**PUBLIC DOCUMENT**
individually, and as an officer of	)	
Daniel Chapter One.	)	
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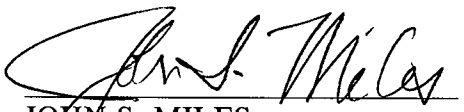
RESPONDENTS' CERTIFICATE OF COMPLIANCE

IT IS HEREBY CERTIFIED that, in compliance with Rule 3.22(c) of the FTC Rules of Practice, this Respondents' Reply to Complaint Counsel's Opposition to Respondents' Application for Stay of Modified Final Order Pending Petition for Review contains 4968 words, excluding the parts of the document that are exempted by Rule 3.22(c).

I declare under penalty of perjury that the foregoing is true and correct.



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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	)	
	)	

CERTIFICATE OF SERVICE

I hereby certify that on March 10, 2010, I served or caused to be served the attached Respondents' Reply to Complaint Counsel's Opposition to Respondents' Application for Stay of Modified Final Order Pending Judicial Review, and Respondents' Certificate of Compliance, on the following individuals by the means indicated:

By hand delivery and e-mail:

Office of the Secretary
Federal Trade Commission
600 Pennsylvania Avenue, NW, Room H-159
Washington, DC 20580