

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

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.

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 rule⁶ 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).

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

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

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-

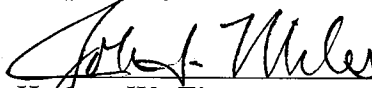
35. Because none of these three factors — irreparable harm, injury to party, and public interest — have been relevant and before the Commission until now, it is most appropriate and indeed, anticipated by Commission Rule 3.56(b) that relevant information concerning the consequences of the stay being 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 un rebutted.

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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March 10, 2010

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,)
a corporation, and)
))
JAMES FEIJO,)
individually, and as an officer of)
Daniel Chapter One.)
_____))

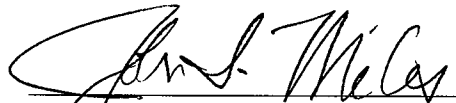
DOCKET NO. 9329

PUBLIC DOCUMENT

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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BEFORE THE FEDERAL TRADE COMMISSION**

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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)	
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_____)	

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