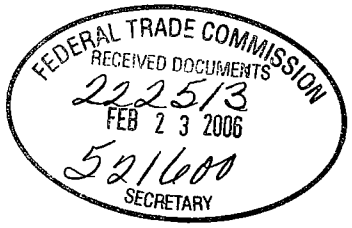
ORIGINAL

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of	)	
BASIC RESEARCH, L.L.C.,	)	
A.G. WATERHOUSE, L.L.C.,	)	
KLEIN-BECKER USA, L.L.C.,	)	
NUTRASPORT, L.L.C.,	)	
SOVAGE DERMALOGIC	)	**Docket No. 9318**
LABORATORIES, L.L.C.,	)	
BAN, L.L.C.,	)	**PUBLIC VERSION**
DENNIS GAY,	)	
DANIEL B. MOWREY, and	)	
MITCHELL K. FRIEDLANDER,	)	
Respondents.	)	



CORPORATE RESPONDENTS' PRETRIAL BRIEF

BASIC RESEARCH, L.L.C.
A.G. WATERHOUSE, L.L.C.
KLEIN-BECKER USA, L.L.C.
NUTRASPORT, L.L.C.
SOVAGE DERMALOGICS LABORATORIES, L.L.C.
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TABLE OF CONTENTS

Table of Authorities

Cases

U.S. Supreme Court

Federal Circuit Courts

Federal District Courts

Administrative Proceedings

U.S. Constitution

Federal Statutes and Regulations

Scientific Publications

Andrews, JC, Netemeyer, RG, Burton S. Consumer Generalization of Nutrient Content Claims in Advertising. Journal of Marketing 62:62-75, Oct 1998

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Brownell, et al. *The Double-Blind in Danger: Untoward Consequences of Informed Consent.* 139:11 Am. J Psychiatry 1487.....15, 64

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Everitt BS, Pickles A. Statistical aspects of the design and analysis of clinical trials (London: Imperial College Press 1999).....59

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Meinert CL. Clinical trials: design, conduct, and analysis. (New York: Oxford 1986) 59

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Miscellaneous

"A Brief History of the Federal Trade Commission," FTC 90th Anniversary Symposium Brochure, *available at* http://www.ftc.gov/ftc/history/docs/90thAnniv_Program.pdf

"Annual Report of the Federal Trade Commission for the Fiscal Year ended June 30, 1939," *available at* http://www.ftc.gov/os/annualreports/ar1939.pdf.....12

Clinical Guidelines on the Identification, Evaluation and Treatment of

I. SUMMARY

The Federal Trade Commission (hereinafter FTC or the Commission) has charged the limited liability companies Basic Research L.L.C., A.G. Waterhouse, L.L.C., Klein-Becker USA, L.L.C., Nutrasport, L.L.C., and Sovage Dermalogic Laboratories,L.L.C. (hereinafter collectively "Respondents") with making certain representations in commerce the implications of which are said to be "false and misleading."[1] The FTC has not charged Respondents with making any literally false claims. The FTC has not charged Respondents with "unfairness" or "unfair methods of competition." The FTC argues, rather, that the claims it alleges are implied by Respondents' advertising lack a reasonable basis in scientific support.[2] FTC seeks a draft order from the Chief Administrative Law Judge that Respondents "shall not represent...that [their] product[s] cause[] weight or fat loss, unless, at the time of the representation is made, Respondents possess and rely upon 'competent and reliable scientific evidence.'" CX 001 at 19-20.

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[1] The Commission has also named as Respondents the individuals Dennis Gay, Dr. Daniel Mowrey, and Mitchell Friedlander. The individual Respondents are separately filing their own pretrial briefs.

[2] The allegedly implied claims are that: (1) Leptoprin and Anorex "cause[] weight loss of more than 20 pounds, including as much as 50, 60, or 147 pounds, in significantly overweight users." CX 001 at ¶28, 33; (2) Leptoprin and Anorex "cause[] loss of substantial, excess fat in significantly overweight users." CX 001 at ¶28, 33; (3) "clinical testing" proves that Leptoprin "cause[s] weight loss of more than 20 pounds, including as much as 50, 60, or 147 pounds, in significantly overweight users." CX 001 at ¶ 31; (4) "clinical testing" proves that Leptoprin "causes loss of substantial excess fat in significantly overweight users." CX 001 at ¶ 31; (5) Dermalin-APg ("Dermalin"), Cutting Gel, and Tummy Flattening Gel cause "rapid and visibly obvious fat loss in the areas of the body to which [they are] applied." CX 001 at ¶ 14, 17, 20; (6) "published, clinical testing proves" that Dermalin, Cutting Gel and Tummy Flattening Gel cause "rapid and visibly obvious fat loss in the areas of the body to which [they are] applied." CX 001 at ¶ 24-26; (7) PediaLean "causes substantial weight loss in overweight or obese children." CX 001 at ¶37; and (8) "clinical testing proves that PediaLean causes substantial weight loss in overweight or obese children." CX 001 at § 40.

FTC Counsel have failed to satisfy their burden of proof to justify the speech restrictions they seek. The products in issue perform as advertised. The totality of publicly available scientific evidence confirms that performance, indeed even to the extent of achieving the performance results alleged by FTC Counsel to be implied by the advertising. FTC Counsel have not a shred of empirical evidence (surveys or copy tests) to support its charge that consumers perceive the ads to carry the implications they allege. FTC market expert Mazis never performed such tests. Indeed, Mazis never evaluated the actual target audiences for the claims. He never took into account actual empirical evidence contrary to his assessment that reveals a high degree of consumer skepticism about weight loss advertising. He bases his "facial analysis" on a fiction detached from any real world evidence concerning the effect of the ads on their target audience, empirical evidence about weight loss consumers, the specific channels of communication used in advertising, or the effect of disclaimers contained in the ad on consumer perception. His assessment is incompetent or, at the very least, contradicted by empirical evidence that confirms high consumer skepticism concerning weight loss advertising. In the presence of such skepticism, the performance of the products establishes that far from falling beneath consumer expectations, the products exceed them. They actually do cause weight and fat loss, as the totality of publicly available evidence confirms. Thus, this case is no *Telebrands* clone, as FTC Counsel endeavors to cast it. In *Telebrands*, there was no scientific evidence to support the claims made; here, the evidence comes in the form of thousands of peer-reviewed scientific journal articles based on original research that is well-accepted, oft-cited, and highly corroborative of the actual physiological impact of the products on users. In *Telebrands*, the challenged claims included literal falsehoods; here FTC Counsel's entire case hinges on alleged implications. The only common chord struck in *Telebrands* and in this case is the presence of

Mazis, but there, as his Honor knows, Mazis at least endeavored to perform some empirical testing. Here he has none to present. That absence of empirical support in the presence of solely implied claims and in the presence of contrary empirical evidence of high consumer skepticism makes the admonition in *Kraft* an imperative here: To condemn advertising claims, FTC Counsel needed (but never obtained) empirical proof. There is on the facts here no substitute for that evidence. The academic suppositions of Mazis are not a replacement for the needed empirical data.

Under the Federal Trade Commission Act (FTCA)[3] and under the First and Fifth Amendments, government speech regulators must start with a presumption that those whom they accuse of misleading speech are innocent until proven guilty. Thus, the burden of proof lies with FTC to establish that the speech in issue in this case is inherently misleading (i.e., incapable of being rendered nonmisleading through the addition of a qualification or disclaimer) before that speech may be suppressed, or FTC must establish the speech in issue to be potentially misleading before that speech may be restricted; and then the speech may be restricted.[4] But even in the latter, potentially misleading context, the speech may be restricted only if there are no obvious, less speech restrictive alternatives, such as claim qualifications or disclaimers that can eliminate perceived misleadingness.

The Commission bears the burden of proof to show that Respondents lacked a reasonable basis for their advertising claims.[5] Under the "reasonable basis theory," the Commission "must first determine what level of substantiation the advertiser is required to have for [the] advertising

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[3] See, e.g., *FTC v. Garvey*, 383 F.3d 891, 901 (9th Cir. 2004); *FTC v. Publishing Clearinghouse Inc.*, 104 F3d 1168, 1170 (9th Cir. 1997)(citing *FTC v. American Standard Credit Sys.*, 874 F.Supp. 1080, 1087(C.D.Ca.1994))

[4] *See e.g., Bates v. State Bar of Arizona*, 433 U.S. 350 (1977).

[5] *Garvey*, 383 F.3d at 901 (*citing FTC v. Pantron I*, 33 F.3d 1088, 1096 (9th Cir. 1994); *FTC v. Enforma Natural Produs.*, Inc., 362 F.3d 1204, 1217 N. 14 (9th Cir. 2004)).

claims [and] then the Commission must determine whether the advertiser possessed that level of substantiation."[6] But here, neither the FTC by rulemaking or case-by-case has intelligibly defined what level, degree, quality, or quantity of scientific evidence a regulatee must have to be assured that advertising is in a safe harbor, free of the risk of recurrent prosecution. The absence of a comprehensible standard denies Respondents the ability to know what is expected of them and impugns the integrity if FTC Counsel's whole case because their prayer for relief, the order they seek from the Chief ALJ, is to require adherence to that unintelligible standard as a condition precedent for future speech.

[* * REDACTED * *]

[6] *Garvey*, 383 F.3d at 901 *citing Pantron I*, 33 F.3d at 1096.

Even were one to presume, on faith, that the implied claims are the ones the target audiences perceived from viewing the actual claims, those implied claims are so ambiguously worded, so subjective and imprecise, that it is undoubtedly the case that the physiological effects begot from the products are ones described by the implications alleged. **[* * REDACTED * *]**

Based on the scientific evidence, there is a reasonable basis for the actual claims made in Respondents' advertising (and for the claims FTC presumes are implied). If the Chief ALJ were to conclude otherwise, it is nevertheless legally impermissible to impose any restriction on Respondents' future advertising (such as the standard prohibition on future advertising of the same or similar claims unless and until Respondents possess "competent and reliable scientific evidence" requested in FTC Counsel's prayer for relief) because FTC has never explained with sufficient clarity to guide the regulated class (in a rulemaking, in this proceeding, or in any other case) the level, degree, quality or quantity of science necessary to support a health benefit advertising claim.

Neither the FTC nor the Chief ALJ has defined what science Respondents must possess to advertise secure in the knowledge that they will not be charged again with "implied" deception. There is, according to FTC counsel, no articulated standard of review for the evaluation of scientific evidence in support of the advertising claims. While the "competent and reliable scientific evidence" is the *de facto* standard (indeed, it is the very standard FTC Counsel's draft order seeks from the Chief ALJ), it was not adopted through notice and comment rulemaking, nor articulated with sufficient clarity in case by case adjudication to guide the regulated class. As explained *infra*, those defects render this proceeding a violation of Respondents' Fifth Amendment substantive, and administrative, Due Process rights and a violation of the Administrative Procedure Act (APA).

Under Supreme Court commercial speech precedent, all commercial speech is presumptively protected by the First Amendment until such time as the government proves it misleading. The burden of proof remains squarely on the state to prove not that the Respondents lack a desired level of evidentiary support but that the FTC possesses proof that the claims are false. Absent proof of falsity, the constitutional resort of this government is to provide a reasonable claim qualification and disclaimer, not an effective ban on speech under an undefined proof requirement. In this case, FTC Counsel have not alleged that the ads in question are literally false. Rather, FTC Counsel have argued that implications allegedly arising from the ads are false. The ads are thus, at worst, only potentially misleading within the meaning of First Amendment precedent.[7] Indeed, when speech is capable of at least two interpretations (one true, one false), the speech is at worst potentially misleading and our Supreme Court has held that such speech may not be banned but may be regulated to avoid misleadingness through the

[7] See *Central Hudson Gas & Electric Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 564 (1984); *see also, Pearson v. Shalala*, 164 F.3d. 650, 655 (D.C.Cir. 1999).

mandate of a qualification or disclaimer.[8] Potentially misleading speech is that speech which can avoid a misleading connotation through use of a qualification or disclaimer.[9]

To ensure that Respondents are given sufficient guidance to discern what constitutes illegal conduct consistent with the requirements of the Fifth Amendment Due Process clause, administrative due process, the APA, and the First Amendment, they are entitled to an assessment under the *Central Hudson* factors of the implied claims here in issue; they are entitled to know from the Chief ALJ in his decision a defined standard against which the science they supply is judged by this Commission; they are entitled to know what qualifications or disclaimers they may use to avoid any perceived misleadingness if the Chief ALJ finds such misleadingness arising from their ad content; and they are entitled to a clearly defined safe harbor (a knowledge of what level, degree, quality, or quantity of scientific evidence they must possess to advertise without fear of FTC prosecution). Nothing short of that clarity will suffice under the Constitution or the APA. Nothing short of that clarity avoids the extensive self-censorship that an order that restricts future speech (such as the order requested by FTC Counsel) otherwise causes (due to its inexactitude in areas that trench on protected speech).

For those reasons and the others explained in the following Findings and Conclusions, the Chief ALJ may not lawfully grant FTC Counsel's prayer for relief, should deny FTC Counsel the relief they seek, and should dismiss this action.

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[8] See *Bates v. State Bar of Arizona,* 433 U.S. 350, 376 (1977); *see also Peel v. Att'y Registration and Disciplinary Comm'n*, 496 U.S. 91, 110 (1990), *In re R.M.J*, 455 U.S.191, 206 n.20 (1982); *Shapero v. Kentucky Bar Ass'n*, 486 U.S. 466, 478 (1988); *Greater New Orleans Broadcasting Assn., Inc. v. United States*, 527 U.S. 173, 183, 144 L. Ed. 2d 161, 119 S. Ct. 1923 (1999)

[9] See *Bates*, 433 U.S. at 376; *see also Peel*, 496 U.S. at 110 ("A state may not ...completely ban statements that are not actually or inherently misleading..."); *cf. American Home Prods. Corp. v. FTC*, 695 F.2d 681, 684, 696-702 (3d Cir. 1983)(upholding FTC order requiring advertiser who wished to make an unsubstantiated scientific claim to include a disclaimer that the claim was open to substantial question).

II. PROPOSED FINDINGS OF FACT

A. THE COMMISSION HAS CHARGED RESPONDENTS WITH FALSE ADVERTISING UNDER THE FTCA

1. In its Complaint, the Commission has charged Respondents with making certain representations in commerce the implications of which are said to be "false or misleading." Complaint, CX 001 at ¶¶ 16, 19, 22, 24, 26, 30, 32, 34, 39, 41, 43. In its Complaint, the Commission has not charged Respondents with making any literally false claims. In its Complaint, the Commission has not charged Respondents with "unfairness" or "unfair acts or practices." *See* CX 001.

2. In its Complaint, the Commission asks the ALJ to issue an order that prohibits Respondents from advertising the claims here in issue unless Respondents then possess "competent and reliable scientific evidence." Compl. at 8-9, 15-17.

3. The Commission has confirmed that "[t]he issue for trial is whether Respondents engaged in false advertising." *FTC Counsel's Memorandum in Opposition to Respondents' Motion for Partial Summary Decision Adverse to Petitioner on Any Counsel for Unfair Acts or Practices and in Opposition to Respondent's Friedlander's Motion for Summary Decision for Lack of Subject Matter Jurisdiction* at 5; *see also* November 4, 2004 Order ("the issue to be litigated at the trial in this matter is whether Respondents violated the FTC Act's prohibition against false and misleading advertising."); January 23, 2005 Order at 2 (quoting same language from November 4, 2004 order); January 10, 2006 Order at 8 (quoting same language).

4. The Commission has invoked its authority to challenge the advertising at issue as a deceptive act under Section 5(a) of the FTC Act. *FTC Counsel's Memorandum in Opposition to Respondents' Motion for Partial Summary Decision Adverse to Petitioner on Any Counsel for Unfair Acts or Practices and in Opposition to Respondent's Friedlander's Motion for Summary Decision for Lack of Subject Matter Jurisdiction* at 7 ("[T]he Complaint does not challenge any practices under the FTC's independent unfairness jurisdiction, but challenges Respondents' advertising under the FTC's deception jurisdiction, as a subset of its unfairness jurisdiction").

5. The Commission does not claim that Respondents have engaged in non-deceptive, but unfair, advertising. *FTC Counsel's Memorandum in Opposition to Respondents' Motion for Partial Summary Decision Adverse to Petitioner on Any Counsel for Unfair Acts or Practices and in Opposition to Respondent's Friedlander's Motion for Summary Decision for Lack of Subject Matter Jurisdiction* at 2 ("FTC Counsel acknowledges that it intends to establish, at trial, that the Respondents violated Section 5(a) of the FTC Act, applying the Deception Standard first set forth in *Cliffdale Associates, Inc.*, 103 F.T.C. 110 (1984), and not the Unfairness Standard initially set forth in *International Harvester Co.*, 104 F.T.C. 949 (1984)" (attaching the Commission's December 17, 1980 policy statement on unfairness), and subsequently codified at Section 5(n) of the FTC Act).

6. The Commission's Complaint does not charge Respondents with violating Section 5(n) of the FTC Act, *i.e.*, that the challenged advertisements resulted in a substantial risk of injury to ordinary prudent consumers in the relevant market (*but for reasons other than a likelihood of confusion*) that could not be reasonably avoided under the circumstances (*although ordinary prudent consumers were not misled and were given a 100% money-back guarantee*), and that this risk of harm is not outweighed by other considerations (*such as the First Amendment rights of advertisers to promote freely their goods and services with truthful, non-misleading product information*). *See* CX 100; *see also* 15 U.S.C. § 45(n) (no act or practice can be declared "unfair" unless "the act or practice causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or competition").

B. THE COMMISSION CLAIMS THAT THE CHALLENGED ADS ARE IMPLIEDLY FALSE OR MISLEADING BECAUSE RESPONDENTS ALLEGEDLY DID NOT POSSESS ADEQUATE SUBSTANTIATION WHEN THE ADVERTISING COMMENCED.

7. The Commission claims that the challenged advertisements are false or misleading because: (a) the ads allegedly represented to ordinary prudent consumers in the relevant market that Respondents possessed *a reasonable basis that substantiated* the allegedly implied product claims when Respondents allegedly did not possess a reasonable basis substantiating those claims (Complaint CX 100 at ¶¶ 15, 16, 18, 19, 21, 22, 29, 30, 34, 35, 38, 39) and (b) the ads allegedly represented to ordinary prudent consumers in the relevant market that *clinical testing proved* some of the allegedly implied product claims when clinical tests allegedly did not substantiate those claims (Complaint CX 100 at ¶¶ 23, 24, 25, 26, 31, 32, 40, 41).

8. The Commission claims that in order (a) to have a reasonable basis that substantiates the allegedly implied product claims at issue in this proceeding, and (b) for the allegedly implied establishment claims to be truthful and non-misleading, Respondents needed "competent and reliable scientific evidence" substantiating those claims before they were made. *See* FTC Counsel's Response to Basic Research LLC's First Set of Requests for Admission, RX 147 at No. 42 ("Respondents needed competent and reliable scientific evidence to support the claims regarding the Challenged Products alleged in its Complaint."); FTC Counsel's Response to Basic Research LLC's First Set of Requests for Admission, RX 147 at No. 36 ("'Competent and reliable scientific evidence' is the standard the Commission requires for all claims relating to the safety or health benefits of a dietary supplement").

9. The Commission's Complaint does not charge Respondents with making expressly false or misleading claims. *See* Complaint, CX 001 at ¶¶ 14-16, 17-19, 20-22, 23-26, 28-32, 33-35, 37-41.

10. The Commission argues that Respondents' advertisements impliedly represent to consumers that:

    1. Each Epidril Product "causes rapid and visually obvious fat loss in areas of the body to which it is applied;"
    2. Each ECA Product "causes loss of substantial, excess fat in significantly overweight users;" and
    3. PediaLean™ "causes substantial weight loss in overweight or obese children."

C. "RULE" OR "GUIDANCE"

11. The Commission has stated that under Section 5(a) of the FTC Act advertisers are obligated to possess "competent and reliable scientific evidence" before making a weight loss claim. *See* RX 034 (November 30, 2000 denial of the Whitaker Rulemaking Petition, (Sections 5(a) and 12 of the FTC Act "impose two basic obligations: 1) advertising must be truthful and not misleading; and 2) before disseminating an ad, advertisers must have adequate substantiation for objective product claims." "'Competent and reliable scientific evidence' is the standard the Commission requires for all claims relating to the safety or health benefits of a dietary supplement")); RX 032(April 1, 2004 denial of the FAHFA Rulemaking Petition ("Advertisers are prohibited from making false or misleading claims for [products] and also must have adequate substantiation for objective product claims before the claims are disseminated")); RX 153 (FTC Counsel's Response to Basic Research LLC's First Set of Requests for Admission, RFA No. 36 ("'Competent and reliable scientific evidence' is the standard the Commission requires for all claims relating to the safety or health benefits of a dietary supplement")).

12. FTC has identified "competent and reliable scientific evidence" as a rule of decision in Congressional Testimony, in this case, in numerous other FTC proceedings, and in statements to the public. *See* RX 001, RX 002, RX 003, RX 005, RX 006, RX 009, RX 010, RX 011, RX 015, RX 017, RX 019.

13. Howard Beales testified before Congress on June 16, 2004 that the "competent and reliable scientific evidence" standard is the "rule of law" for parties advertising health benefit claims for their products. "Commission law requires that claims about the safety and efficacy of any health-related product, including dietary supplements, be substantiated by competent and reliable scientific evidence before the claims are made." Prepared Statement at 3; FTC 03841. "Over the past decade the Commission has filed or settled more than 100 *law enforcement* actions challenging allegedly false or unsubstantiated claims about the efficacy or safety of a wide variety of supplements." Prepared Statement at 3; FTC 03841 (emphasis added). RX 019 at 3.

14. FTC has an advertising guide for the dietary supplement industry that states that advertising substantiation must meet the competent and reliable scientific evidence standard. RX 015.[11] It mentions no other substantiation standard under the FTCA.[12]

15. FTC has a 1983 policy statement on substantiation for advertising. It discusses only the competent and reliable scientific evidence standard and mentions no other standard that can be met to prove advertising is not deceptive. RX 005.

16. FTC has never found advertising it holds not backed by competent and reliable scientific evidence to be non-deceptive under the FTCA. *See* CX 052; RX 147.

17. FTC did not engage in notice and comment rulemaking in adopting the "competent and reliable scientific evidence" standard after notice and comment rulemaking pursuant to 5 U.S.C.S. § 553(b). RX 110.

18. FTC has not defined the level, degree, quality, or quantity of scientific evidence it expects to support advertising claims of health benefits.

19. FTC holds advertising to be deceptive and illegal if the advertiser fails to possess documentary proof in the form of "competent and reliable scientific evidence" before the ad is published. RX 005, RX 015, RX 017, RX 018.

20. Despite the representations made by FTC, as noted in paragraphs numbered 10 through 18 above, the Commission denies that it has adopted a "rule" under Section 5(a) of the FTC Act requiring advertisers, including Respondents, to possess "competent and reliable scientific evidence" before making a weight or fat loss claim in dietary supplement advertising. *See Reply Memorandum in Support of the Federal Trade Commission's Motion to Dismiss*, filed in the action entitled, *The Carter-Reed Company, LLC v. FTC*, Case No. 2:04CV01142 DB, United States District Court, Central District of Utah (Commission's position is that its prior case law, policy statements and public comments about "competent and reliable scientific evidence" is non-binding "guidance" and would not qualify as a "rule under any analysis").

D. FACTS CONCERNING FTC

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[11] The advertising guidance states: "The FTC typically requires claims about the efficacy or safety of dietary supplements to be supported with 'competent and reliable scientific evidence,' defined in FTC cases as 'tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have 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.'" RX 005.

[12] The advertising guidance states, ambiguously: "There is no fixed formula for the number or type of studies required or for more specific parameters like sample size and study duration. There are, however, a number of considerations to guide an advertiser in assessing the adequacy of the scientific support for a specific advertising claim." RX 005.

21. Since 1938, the Commission has required advertisers to possess a reasonable basis before making an objective product claim. *See* "Annual Report of the Federal Trade Commission for the Fiscal Year ended June 30, 1939," 4-5 *available at* http://www.ftc.gov/os/annualreports/ar1939.pdf *as of* February 6, 2006. *See also* "A Brief History of the Federal Trade Commission," FTC 90th Anniversary Symposium Brochure *available at* http://www.ftc.gov/ftc/history/docs/90thAnniv_Program.pdf *as of* February 6, 2006.

22. The Commission has regulated weight loss claims in dietary supplement advertising for at least 80 years. *See* "Federal Trade Commission Advertising Cases Involving Weight Loss Products and Services" *available at* http://www.ftc.gov/opa/1997/03/dietcase.htm *as of* February 6, 2006.

23. FTC has engaged in a national public education campaign to inform consumers that advertising promoting dietary supplements for weight loss is false and misleading. RX 002. *See* "FTC Announces 'Operation Waistline'--A Law Enforcement and Consumer Education Effort Designed to Stop Misleading Weight Loss Claims" *available at* http://www.ftc.gov/opa/1997/03/waistlin.htm *as of* February 6, 2006. [13]

24. The Commission maintains the position that no weight loss is achievable through ingestion of dietary supplements. RX 006. [14]

25. FTC does not require testing on human subjects of a complete finished product in order to substantiate claims of effect. RX 015.[19]

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[13] Weight loss dietary supplement claims identified as false and misleading include: (1) the product will cause substantial weight loss for all users; (2) the product causes substantial weight loss without diet or exercise; (3) users of the product can eat all they want and still lose weight; (4) weight loss will be rapid; (5) weight loss will be long-lasting; (6) weight loss will occur only from specified parts of the body; (7) substantial weight loss will occur due to blockage or absorption of fat or calories; (8) significant weight loss in excess of three pounds per week for more than four weeks can be safely achieved; and (9) a product worn on the body or rubbed into the skin will cause substantial weight loss.

[19] "The FTC will consider all forms of competent and reliable scientific research when evaluating substantiation. [...] Results obtained in animal and in vitro studies will also be examined, particularly where they are widely considered to be acceptable substitutes for human research or where human research is infeasible." *Id.* at 10.

26. FTC has not informed the Respondents of what level, degree, quality, or quantity of scientific evidence the FTC would require to support their advertising claims despite repeated requests for same. RX 131, RX 134, RX 137, RX 138.

27. FTC has not informed the Respondents of what kind of scientific evidence the FTC would require to support their advertising despite repeated requests for same. RX 131, RX 123, 134, RX 137, RX 138, 141.

28. FTC has not given Respondents and does not give any in the regulated class advisory opinions at their request concerning whether science in support of a health benefit claim is adequate support for a claim. RX 010 and RX 032.[20]

E. FACTS CONCERNING FTC'S LACK OF FAIR NOTICE

29. The Commission argues that Respondents' advertisements impliedly represent to consumers that:

1. Each Epidril Product "causes rapid and visually obvious fat loss in areas of the body to which it is applied;"
2. Each ECA Product "causes loss of substantial, excess fat in significantly overweight users;" and
3. PediaLean™ "causes substantial weight loss in overweight or obese children."

See Complaint CX 001 at ¶¶ 14, 17, 20, 28, 33, 37.

30. The Commission has not defined what constitutes "rapid," "substantial" or "visually obvious" weight or fat loss. CX 001.

31. FTC Counsel did not objectively define the terms "rapid," "substantial," or "visually obvious" in its Complaint. CX 001.

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[20] "Petitioners' proposal that the agency implement a policy of pre-approving, through advisory opinions, advertising claims about the benefits of supplements does not conform to the Commission's Rules of Practice governing the appropriate use of advisory opinions. Moreover, the proposed policy would be unfeasible because of the large number of potential claims and the extensive resources that would be required to conduct a thorough analysis of the scientific literature relevant to each claim." RX 110 (Denial of Whitaker Petition).

[22] **[* * REDACTED * *]**

32. The Commission's experts have not given the terms "rapid," "substantial," or "visually obvious" any objective meaning in their Expert Reports or deposition testimony and have no empirical evidence or any other form of credible evidence to support their interpretations of those terms. RX 050, RX 054, RX 075, RX 077, RX 086, RX 064, RX 036, RX 037, RX 067, RX 044, RX 055, RX 813.

33. The Commission has not defined through rulemaking what constitutes "a reasonable basis" for the alleged efficacy claims at issue. RX 050, RX 044.

34. The Commission has determined that the definition of a reasonable basis for a health benefit advertising claim is "competent and reliable scientific evidence." *Bristol-Myers Co. v. FTC*, 102 F.T.C. 21, 321, aff'd, 738 F.2d 554 (2d Cir. 1984), cert. denied, 469 U.S. 1189, 105 S. Ct. 960, 83 L. Ed. 2d 966 (1985)

35. The Commission's experts have stated that "competent and reliable scientific evidence" is not a standard used in the medical community. RX 050, RX 044.

36. The Commission's experts have stated that reasonable minds can differ as to what constitutes "competent and reliable scientific evidence." RX 050, RX 044.

37. The Commission's experts have provided conflicting testimony as to what constitutes "competent and reliable scientific evidence." RX 050, RX 044.

38. The Commission has given Respondents no guidance concerning:

(a) What nature, degree, quality, and quantity of tests, analyses, research, studies, or other evidence (collectively, "scientific evidence") the FTC requires to support a claim. Must there be human clinical trials? Will one study suffice? Will studies on an active ingredient in a product be sufficient or must all ingredients of the product be evaluated? Will studies by independent individuals and entities on the same ingredient used in a product suffice or must the product itself be tested? When, if ever, must studies be published in peer-reviewed scientific journals to be competent and reliable? If a study is published in a peer-reviewed journal, does that confer the requisite "competent and reliable" attributes necessary under the Commission's standard?

(b) What level of expertise, credentials, experience or background a person possess in order to qualify as a "professional in the relevant area," or to qualify to conduct or evaluate claim substantiation.

(c) Upon the expertise of how many professionals in the relevant market must the scientific evidence be based? Will one suffice? Will two concurring professionals suffice? Will agreement among some minority of professionals in the field suffice or must a plurality of all experts in the field agree? What level of agreement among some professionals is necessary?

(d) What criteria does the FTC employ in determining whether a test, analysis, research, study or other evidence has been conducted and evaluated in an objective manner? What criteria does FTC employ in determining whether a test, analysis, research, study or other evidence is adequately designed? How many subjects are required? Is there a minimum duration for a study or test?

(e) What factors does the FTC take into account to determine whether scientific evidence is accurate and results are reliable? To what extent must a study otherwise acceptable to the FTC be repeated yielding the same or substantially the same results before it is deemed reliable? What level of opposing evidence is necessary to make a study otherwise acceptable to the FTC unreliable?

(f) How do practical realities of the market come into play? Are health related claims for dietary supplements and cosmetics required to meet the same standard of proof as pharmaceutical drugs, which yield substantially more revenue and justify the enormous, $1.6 billion cost of redundant double-blinded, placebo controlled, human trials?

F. WEIGHT LOSS GENERALLY

39. Not all FDA-accepted (for purposes of drug approval) studies of human subjects use placebo controls or are double-blinded. *See* FDA Regulations for Good Clinical Practice and Clinical Trials; 21 C.F.R. § 314.126; RX 828 at 71-72 (citing Fontaine, KR et. al., Results of soy-based meal replacement formula on weight, anthropometry, serum lipids & blood pressure during a 40 week clinical weight loss trial. 18;2(1) Nutr J Nov 14 (2003)(FTC witness Stephen Heymsfield named as co-author); Hrobjartsson, A and Gotzsch, PC, Is the Placebo Powerless? An Analysis of clinical trials comparing placebos with no treatment. 334(21) N Eng J Med 1594 (2001)); see also Brownell, et al. *The Double-Blind in Danger: Untoward Consequences of Informed Consent.* 139:11 Am. J Psychiatry 1487 (Nov. 1982)(describing side effects of medication in advance of treatment allowed for identification of assignments and may influence the integrity of double-blind studies).

40. FDA drug approval requirements are considered among the most rigorous in the world. Statement of John M. Taylor, Director, Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration; Before the Special Committee on Aging, United States Senate, Sep. 10, 2001. http://www.fda.gov/ola/2001/healthfraud0910.html.

41. FDA does not require that all clinical studies for approval of weight loss drugs be placebo-controlled. 21 C.F.R. § 314.126.

42. FDA does not require that all clinical studies for approval of weight loss drugs be double-blinded. *See* FDA Regulations for Good Clinical Practice and Clinical Trials; 21 C.F.R. § 314.126.

43. FDA has granted approval for Orlistat based on studies that were not double-blinded and were not placebo controlled. FDA also granted approval for Redux on the basis of clinical trials that had a duration of less than one year. *See* Orlistat Nonprescription Briefing Document Joint Nonprescription Drugs Advisory Committee and Endocrine and Metabolic Drugs Advisory Committee Meeting, January 23, 2006.

44. Weight loss is a measurement independent of a subject or study administrator's perceptions.[22]

45. The NIH publication on obesity in the United States reports that weight loss of 1-2 pounds per week is considered significant. RX 806 at 33 (Clinical Guidelines on the Identification, Evaluation and Treatment of Overweight and Obesity in Adults by the National Institutes of Health).

46. The NIH publication on obesity in the United States reports that in the morbidly obese (those with a BMI of greater than 35) weight loss in excess of 10% of total body weight within 6 months is considered a clinically beneficial result. RX 806 at 33.

47. The NIH publication on obesity does not recommend weight loss regimens that result in weight loss of more than 1 to 2 pounds per week. ("Weight should be lost at a rate of 1 to 2 pounds per week [...] A greater rate of weight loss does not yield a better result at the end of 1 year." RX 806 at 23.

H. ANOREX AND LEPTOPRIN

48. Of the six products at issue in this case, two are dietary supplements, tradenamed Anorex and Leptoprin. CX 001 at 3.

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[* * REDACTED * *]

H. DERMALIN, TUMMY FLATTENING GEL, AND CUTTING GEL

[* * REDACTED * *]

[* * REDACTED * *]

[* * REDACTED * *]

[* * REDACTED * *]

I. PEDIALEAN

157. The sixth product at issue in this case is a dietary supplement with the tradename PediaLean. RX-697, 698.

158. The PediaLean ads are attached to the Complaint as Exhibit K-L. CX 001 at 15.

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J. FACTS CONCERNING DR. DANIEL MOWREY AS THE CONSULTING SCIENTIST TO CORPORATE RESPONDENTS

214. Dr. Daniel Mowrey is the consulting scientist to Corporate Respondents. RX 051 at 303-311.

215. Dr. Daniel Mowrey has a Ph.D. in Experimental Psychology from Brigham Young University with an emphasis in psychopharmacology, which is the study of the relationship between drugs and behavior and involved an understanding of physiology and biochemistry. Psychopharmacology also involves the study of the experimental analysis of behavior and emphasizing the design, conduct, and evaluation of experimental studies. RX 828 at 79, RX 051 Mowrey Depo. at 66-68.

216. Dr. Daniel Mowrey is trained in the scientific method, statistics, and the evaluation of scientific evidence. RX 828 at 79, RX 051 at 67-68.

217. Dr. Mowrey's Ph.D. dissertation concerned the effects of ginger root on motion sickness. RX 828 at 79. Dr. Mowrey's study and dissertation were published in the Lancet Medical Journal. RX-828 at 79.

218. While a graduate student at BYU, Dr. Mowrey taught courses in statistics, experimental psychology, psychopharmacology, and experimental design. RX 051 at 24.

219. Dr. Daniel Mowrey evaluated over 100 different experimental designs presented by his students at BYU, including the appropriateness of the statistical analysis, whether the design suited the testing of the hypothesis and the overall execution of the studies. Anticipated testimony.

220. Dr. Daniel Mowrey has spent 30 years studying published research concerning the effects of medicinal plants, nutrients and other substances at specified dose levels on physiological response and processes. RX 828 at 78.

221. Dr. Daniel Mowrey shares the generally accepted scientific view that one must assess the totality of all publicly available scientific evidence and opinion pertaining to a specific nutrient and potential physiological effects to determine whether that nutrient likely produces those effects on the body. RX 051.

222. Dr. Daniel Mowrey has published several books in the area of herbal medicine: "Scientific Validation of Herbal Medicine" (1986); "Guaranteed Potency of Herbs: Next Generation Herbal Medicine" (1989); "Herbal Tonics and Therapies" (1993); "Fat Management: The Thermogenic Factor" (1996). RX 051 at 33-34; RX 828 at 79-81, 84.

223. Dr. Daniel Mowrey has spent approximately 20 years formulating products based on published research concerning the effects of nutrients and other substances at specified dose levels on physiological response and processes. RX 828 at 88.

224. Since approximately 1986, Dr. Daniel Mowrey has acted as a consultant to several companies in the area of herbal medicine by aiding in the development of scientific substantiation for their products. RX 051.

225. Dr. Daniel Mowrey is a research scientist and has studied the effects of nutritional formulas he has designed on test subjects in original research and on consumers in the market. RX 828 at 78-89.

226. Dr. Daniel Mowrey wore a white lab coat in an advertisement for Leptoprin and was referred to as a Doctor. Nothing in the ad conveys the impression that he is a physician as opposed to a research scientist. In his work at American Phytotherapy Research Laboratires (APRL), Dr. Mowrey wears a white lab coat when in the lab and is ubiquitously referred to as "Doctor Mowrey" in light of his Ph.D. in experimental psychology. RX 051 at 489-492.

K. FACTS CONCERNING CORPORATE RESPONDENTS' DEVELOPMENT OF PRODUCTS AND ADVERTISING

[* * REDACTED * *]

[* * REDACTED * *]

L. RESPONDENTS' REFUND POLICY

227. For all of their products Respondents offer a 30 day no questions asked refund guarantee. Complaint CX 002.

[* * REDACTED * *]

M. FACTS CONCERNING FTC'S LACK OF PROOF IN SUPPORT OF ITS COMPLAINT

244. Dr. Stephen B. Heymsfield is not an expert in statistics, and admits that he is not a statistician. Heymsfield Jan. Depo. at 227. RX 050.

245. Heymsfield is not an expert in biostatistics, and admits that he is not a biostatistician. Heymsfield Jan. Depo at 462. RX 050.

246. Heymsfield is not an expert in conducting power calculations or determining the number of study participants needed for a "valid" study. Heymsfield Aug. Depo at 537-538. RX 813.

247. Heymsfield admitted that he did not seek commentary or review from a qualified biostatistician to assess the validity of the data contained in the Daly study. Heymsfield Aug. Depo at 540-541. RX 813.

248. Heymsfield admitted that he did not seek commentary or review from a qualified biostatistician to assess the validity of the data contained in any of the additional substantiation studies he reviewed that pertain to active ingredients in the challenged products. Heymsfield Aug. Depo at 551. RX 813.

249. Heymsfield admitted that he is not an expert on advertising or promotion of products. Heymsfield Jan. Depo at 166-167. RX 050.

250. Heymsfield admitted that he is not an expert on meaning of the language used in the ads. Heymsfield Jan. Depo at 166-167. RX 050.

251. Heymsfield could not identify experts in the field of dietary supplement and weight loss research. Heymsfield Aug. Depo at 653-654. RX 813.

252. Heymsfield testified that he is never privileged to review the raw data of any of the studies that he reviews. Heymsfield Feb. Depo at 420. RX 054.

253. Heymsfield testified that he has not researched the published literature to determine if there were written criticisms of the studies that he cited in his expert report. Heymsfield Aug. Depo. at 551-552. RX 813.

254. Heymsfield testified that he did not distinguish between a drug and a dietary supplement in his analysis of the challenged products. Heymsfield Aug. Depo. at 546. RX 813.

[* * REDACTED * *]

258. Heymsfield testified that he is unable to define overweight because it has "no scientific definition." Heymsfield Feb. Depo. at 349-350. RX 054.

259. Heymsfield testified that there is no qualitative definition of the terms "significantly overweight," and he was unable to answer any questions pertaining to that term. Heymsfield Feb. Depo. at 360. RX 054.

260. Heymsfield testified that the word "substantial" is not a scientific quantitative term, and he was unable to define it. Heymsfield Feb. Depo. at 365. RX 054.

261. Heymsfield is unable to define or identify a source that can provide the definition of "competent and reliable scientific evidence." Heymsfield Aug. Depo at 526. RX 813.

262. Heysmfield could not explain or define placebo effect, and stated that he was not an expert on it. Heymsfield Aug. Depo at 492-495. RX 813.

263. Heymsfield admits that he did not consult the entire record of substantiation. Heymsfield Feb. Depo at 468-469. RX 054.

264. Heymsfield, by contrast, states unequivocally that he does not give credence to any study that lacks placebo controls, has drop-outs in excess of 20%, and has a duration of two months or less. Heymsfield Feb. Depo. at 381, RX 054; Heymsfield Expert Report at 13-25, RX 086.

265. Heymsfield admits that he rejects all scientific evidence on the subject except that which comes in the form of prospective, large scale, randomized, double-blind, placebo controlled clinical trials of over 2 months duration. Heymsfield Feb. Depo. at 381, RX 054; Heymsfield Expert Report at 13-25, RX 086.

266. Heymsfield lacks education, experience, and training in the area of statistics and is not adept at evaluating statistical significance. Heymsfield Feb. Depo. at 461. RX 054.

267. A study's sample size does not determine its power; yet Dr. Heymsfield makes that fundamental error. See Heymsfield Feb. Dep. at 464, RX 054; *see also* Daniel Mowrey's Expert Report, RX-828.

268. Heymsfield has admitted that he neglects to review entire articles in which he is listed as co-author and, oftentimes, has but a small part in the work leading to the ultimate published study. *See* Heymsfield Aug. Depo. at 455-459. RX 813.

269. Heymsfield served as co-author in studies that were later found to be fabricated. Dr. Heymsfield does not contest the fabrication; he admits it. *See* Heymsfield Aug. Depo. at 465-490. RX 813.

270. Heymsfield's position is that he was unaware of the source data for the articles that bore his name and was, indeed, largely, if not completely, unaware of the content of those articles. RX 813.

271. Heymsfield admits no detailed knowledge of studies bearing his name as co-author unless he is the lead co-author. RX 813.

272. In the publication *The Scientist*, Heymsfield stated: "The response was that Emory asked me to leave; my grants dried up. I was tenured, so they couldn't fire me. But they definitely considered me an eyesore. I was set aside – taken off the ladder to the sky. It was obvious that there would be no promotions or opportunities."[29] Heymsfield, while testifying, stated that he could neither admit nor deny having said the quoted lines. Heymsfield Aug. Depo. at 631-634. RX 813.

273. Michael Mazis, Ph.D. did not perform any survey or other qualitative or quantitative analysis to determine consumer perception of the Respondents' advertising. Mazis Nov. Depo. at 25-26. RX 036.

274. Mazis bases his "facial analysis" of the meaning of the ads in question solely upon his opinion of their meaning without any foundation in empirical evidence whatsoever. Mazis Nov. Depo. at 25-26. RX 036.

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[29] Dalton, Rex. "Fraudulent Papers Stain Co-Authors." *The Scientist*, Vol. 1, issue 13, p. 1: May 18, 1987.

275. The approach taken by Mazis separately discusses each particular alleged claim. Mazis does not explore interactions among other constituent elements of the ads that might serve to moderate or alter their impacts on reasonable consumers. RX 064.

276. Mazis states that he has relied upon the psychological literature on "pragmatic implications" in his analysis. "Pragmatic implications" "occur when statements in an advertisement strongly suggest something that is not explicitly asserted." He includes several articles on this topic in his materials. In these articles such inferences occur because of *an interaction between a consumer's prior knowledge about the world and the stimuli from the ad itself.*[30] RX 064.

277. The "facial analysis" presented by Mazis in the present case does not contain any differentiations among consumers, yielding no information as to what percentage of the target audience – if any – is deemed to have the same view of the meaning of ads that Mazis purports to have. RX 064.

278. The Mazis report also fails to acknowledge other constituent elements of the ads that should contribute to the "net impression" taken away by readers.[31]

279. Mazis testified that he did not have any documents pertaining to work that he performed for the Federal Trade Commission, the FDA, or any other federal agency in the role of an expert, a consultant, or any other capacity relating to obesity, weight loss, fat loss, clinical trial protocols or procedures, FTC advertising rules or regulations, the definition or meaning of competent and reliable, evidence of dietary supplements or weight-loss or fat loss advertising. Mazis Nov. 2004 Depo. at 18. RX 036.

280. Mazis also testified that he did not have any documents that support his definition of the terms "rapid," "substantial," "visibly obvious," and "causes." Mazis Nov. 2004 Depo. at 19. RX 036.

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[30] (e.g., Searleman and Carter in *Applied Cognitive Psychology (1988 – CX-239, p. 50 of 85)* say: "... This presumably occurs because of an interaction between the actual content of the message and the person's knowledge of the world." Harris, in discussing deception through implied claims, says: "Most often such "leading" comes through the interaction of the linguistic input and the hearer's stored knowledge." (CX-239, p44 of 85, from the Journal of Applied Psychology, 1977).

[31] As described in detail in Footnote 3, Mazis' own research supports the fact that disclosures have impacts on what consumers take away from an ad, suggesting that he had especially good reason to incorporate these in to his facial analysis here, and (2) Mazis is well aware that consumer expectations (which reflect past knowledge and experience) can be important in determining what is taken away from an ad. In the present case, the fact that these are highly segmented and targeted products means that the audience will be persons with special levels of interest, experience, and/or knowledge, thereby likely to bring particular expectations to the reading of these ads.

281. Mazis admitted that he did not have any documents "relating to consumer tests, copy tests, penetration studies, focus groups," and, moreover, that he had no similar research that he conducted, directed, supervised or assisted in connection with the challenged products. Mazis Nov. 2004 Depo. at 20. RX 036.

282. Mazis also stated that he had not conducted any empirical research concerning the challenged products at issue and had not planned on doing any research in relation to this proceeding. Mazis Nov. 2004 Depo. at 25-26. RX 036.

283. In a paper co-authored by Mazis, he emphasizes the importance of survey research by stating: "When the alleged violation involves consumer perception or consumer behavior issues, survey research can provide government agencies with the needed objective data." Hastak, Manoj, Michael B. Mazis, and Louis A. Morris (2001), "The Role of Consumer Surveys in Public Policy Decision Making," *Journal of Public Policy & Marketing*, 20 (2), 170-185, at 174-175. RX 036.

284. In a previously published article, Mazis concluded that consumers are very skeptical of advertisements for health claims. Mazis, Michael B. and Mary Anne Raymond (1997), "Consumer Perceptions of Health Claims in Advertisements and on Food Labels," *Journal of Consumer Affairs*, 31, 10-26. RX 036.

285. Mazis concluded that consumer beliefs for health claims may not be as strong when those claims are made in the form of advertisements instead of in the form of labels and standardized nutritional information. Mazis, Michael B. and Mary Anne Raymond (1997), "Consumer Perceptions of Health Claims in Advertisements and on Food Labels," *Journal of Consumer Affairs*, 31, 10-26. RX 036.

286. Mazis worked for the FTC from 1977 to 1979. RX 064, RX 036.

287. Mazis has testified as an expert for FTC in 12 proceedings between 1979 and the present. RX 064.

288. Mazis conducted no survey of consumer perception of, or copy test of, the Respondents' advertising and product labels. RX 064 at 4, 18.

289. Mazis cannot quantify precisely what percentage of consumers have the perception of Respondents' ads he attributes to consumers in his expert report. RX 064 at 4-6.

290. Mazis did not cite to or rely upon a peer-reviewed publication that includes the results of a survey, or test of consumer perception of, weight loss or fat loss advertising. Mazis Nov. Depo. 25-26. RX 036.

291. Mazis has done no empirical research in this case. RX 036.

292. Mazis did not include any of the marketing research documenting consumer skepticism of advertising and of weight loss advertising in particular, in his Expert Report. RX 036.

293. Mazis has cited Calfee and Ringold, "Consumer Skepticism and Advertising Regulation: What Do the Polls Show?" 15 Advances in Consumer Research 244-248 (1988) in his own published work: Mazis and Mary Anne Raymond "Consumer Perceptions of Health Claims in Advertisements and on Food Labels," 31 The Journal of Consumer Affairs 10, 11 (Summer 1997). He did not cite Calfee and Ringold in his expert report. RX 064.

294. Mazis has written in the article with Raymond cited in paragraph 290, *supra*, the following:

> Public opinion poll data collected over two decades by the Roper Organization consistently report that consumers are skeptical of advertising claims. For example, about half of consumers claim they are "not at all confident" that they "can depend on getting the truth in most advertising." Also, about 60 percent of the public believes that business fulfills its responsibilities of "advertising honestly" either "not too well" or "not at all well." Finally, over 75 percent of the population concludes that "advertising hoodwinks consumers" (Calfee and Ringold 1988). RX 064.
>
> Consumers reported that mistrust of advertising claims has carried over into their perceptions about the veracity of health claims. For example, a *Washington Post* poll found that "only three percent of Americans believe that food manufacturers never make misleading claims about the health benefits of their products, while a third believe they make them 'a lot'" (Sugarman and Morin 1992, E1). Also, only 15 percent of the public thinks that advertised helath claims are accurate "most of the time." About 30 percent of those interviewed believed that health claims are "almost never true" (Mueller 1991). RX 064.

295. In his expert report, Mazis did not define the target audiences to which he understood the specific advertisements were directed. RX 064.

296. In his expert report, Mazis did not take into account the demographics and degree of ad skepticism present in each target audience in his "facial" assessment of consumer perception of Respondents' advertising. RX 064.

297. In his expert report, Mazis did not identify overweight consumers as the target audience for Leptoprin and Anorex. RX 064.

298. In his expert report, Mazis did not identify women with excess fat on their stomachs and thighs as the target audience for Tummy Flattening Gel and Dermalin. RX 064.

299. In his expert report, Mazis did not identify parents of overweight children and adolescents as the target audience for PediaLean. RX 064.

300. In his expert report, Mazis did not identify body builders as the target audience for Cutting Gel. RX 064.

301. Mazis has not conducted any empirical research to determine how overweight consumers and parents of overweight children perceive weight loss product advertising. RX 064.

302. Mazis has not conducted any empirical research to determine how women who have excess fat on their stomachs and thighs perceive fat loss product advertising. RX 064.

303. Mazis has not conducted any empirical research to determine how parents of overweight children perceive weight loss product advertising. RX 064.

304. Mazis has not conducted any empirical research to determine how body builders perceive fat loss product advertising. RX 064.

305. Mazis has stated that FTC "could benefit greatly from increased use of survey evidence in cases involving consumer perception" (Mazis, Michael B. and Mary Anne Raymond (1997), "Consumer Perceptions of Health Claims in Advertisements and on Food Labels," *Journal of Consumer Affairs*, 31, 10-26), but relies on no survey evidence for the opinions he expresses in his expert report. RX 064.

306. In his expert report Mazis did not evaluate the significance of any disclaimer or qualifications appearing in Respondents' ads such as "So What's the Catch" and "'The Fine Print.'" RX 064.

307. Geoffrey Nunberg, Ph.D. bases his assessment of the meaning of the ads in question solely on his opinion of their meaning without any foundation in empirical evidence whatsoever. RX 067.

308. Nunberg alleges that the term "significant" can only be interpreted as having the sense "of a noticeably or measurably large amount," in the context of the challenged advertisements. In his expert report, Nunberg does not take into account any variable interpretations of the meaning of the terms herewith. RX 067 at 3.

309. Nunberg's conclusion that the Advertisements indicate that the results of the PediaLean (Livieri) clinical trial will be an effective obesity treatment for the reader's children, but does not acknowledge that "a meaningful amount" may reflect a moderate and limited amount of weight loss as implied by the following excerpted quote:

> "Does PediaLean work? You bet it does! In a well-controlled double-blind clinical trial, each and every child who used PediaLean as directed lost a

significant amount of excess body weight...a success rate of 100% (Complaint Exhibit K, 5050054, 5050066). RX 067.

310. Nunberg used lexical analysis to attempt to determine what consumers might think about advertisements for PediaLean, and examined the word "significant" by conducting searches of newspaper articles for its meaning, rather than conducting consumer survey research to ascertain what consumers actually thought about terms contained in advertisements. RX 067.

311. Nunberg did not examine how the word "significant" was used in advertisements, but instead analyzed how it was used in general newspaper articles. In his expert report, Nunberg did not take into account the likely effects of consumer skepticism of advertisements for PediaLean. RX 067.

312. Nunberg used Webster's dictionary for some definitions, while using the American Heritage Dictionary for others, giving rise to the appearance that he was "shopping" for definitions that portrayed the terms in a more egregious or extreme light. RX 067.

313. Nunberg did not perform any empirical or survey research studies involving actual consumers and consumer perception. RX 067 at 3.

314. Research published in academic, peer reviewed journals recite the need to collect survey data to determine what consumers perceive about advertisements. Andrews, J. Craig, and Thomas J. Maronick (1995), "Advertising Research Issues from FTC versus Stouffer Foods Corporation," Journal of Public Policy & Marketing, 14 (2), 301-309. RX 067.

315. Survey research, unlike lexical analysis, is a well-accepted technique among marketing academics, as it provides the type of objective information that is needed to test a hypothesis. Hastak, Manoj, Michael B. Nunberg, and Louis A. Morris (2001), "The Role in Consumer Surveys in Public Policy Decision Making," Journal of Public Policy & Marketing, 20 (2), 170-185. RX 067.

316. The FTC frequently relies on advertising copy tests in deceptive advertising cases, because that type of information is far less subjective than other types of analyses, such as lexical analysis. Andrews, J. Craig, and Thomas J. Maronick (1995), "Advertising Research Issues from FTC versus Stouffer Foods Corporation," Journal of Public Policy & Marketing, 14 (2), 301-309. RX 067.

317. Lawrence Solan, Ph.D. disagrees with Nunberg's characterization and assessment of the terms "significant" and "substantial." Solan Dec. Depo. at 43, RX 049.

318. Solan focused his expert report on the meanings of certain words in the context of expressions such as "substantial reduction," "significant reduction," and "considerable reduction." RX 089.

319. In forming his opinion, Solan relied on his knowledge of linguistic literature, and consulted various dictionaries, database searches of relevant expressions, and conducted term searches within the databases. RX 049 at 74.

320. In his report, Solan concluded that the meanings of the terms "rapid reduction," "rapid decrease," and "rapid increase," "depend upon prior expectations about how much of a reduction, decrease or increase, must occur within a time period for it to be considered rapid. Absent additional information, these expressions are not subject to precise quantification in everyday speech." RX 049 at 103.

321. The FTC has adduced no scientific evidence either on its own or from its experts that the products in question do not function as advertised. RX 086.

322. The FTC does not contend that scientific evidence exists that refutes the claims. RX 086.

323. The FTC has presented no consumer survey evidence or other empirical evidence that consumers understand the advertisements to imply the claims it alleges and no such evidence that consumers were deceived by any of the actual claims in the ads or those it says are implied. RX 064.

324. FTC has presented no evidence that ordinary prudent consumers in the relevant market expected any particular nature or level of support greater than the nature and amount of support obtained by Respondents for the challenged advertisements. RX 064.

325. FTC has presented no evidence that ordinary prudent consumers in the relevant market would likely be confused by the nature or level of support held by Respondents for the challenged advertisements. RX 064.

326. FTC has presented no evidence that any alleged difference between the nature and amount of support FTC speculates consumers allegedly believed Respondents possessed, and the nature and amounts Respondents actually possessed for their claims, was material to the purchasing decisions of ordinary prudent consumers in the relevant market. RX 064.

327. FTC has presented no evidence concerning (a) the likelihood and degree of harm to ordinary prudent consumers in the relevant market if the alleged product claims are untrue; (b) the degree of reliance on the alleged product claims by ordinary prudent consumers in the relevant market acting reasonably under the circumstances; and (c) the accessibility and cost of substantiating the alleged product claims to the FTC's satisfaction. RX 064.

328. FTC has presented no evidence that it is impossible to define with specificity what constitutes "rapid," "visibly obvious," and "substantial" weight or fat loss through rulemaking. RX 064, RX 067.

329. FTC has presented no evidence that it is impossible to define with specificity, through rulemaking, what constitutes a "reasonable basis" or "competent and reliable scientific evidence" for a weight or fat loss claim. RX 064, RX 067.

330. FTC has not informed Respondents of the level, degree, quality, or quantity of scientific evidence it would accept or qualification or disclaimer FTC would accept as adequate support for a claim and has thus created no "safe harbor" from the threat of recurrent prosecution for deceptive advertising. RX 064, RX 067.

331. In the near 20-year span from 1984 to July 2003, the Commission has reported that it has prosecuted approximately 130 cases based on advertisements for dietary supplement and weight-loss products; an average of about 6½ cases per year. The number of cases the Commission has brought in this industry increased after *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999). In the first 5 years after *Pearson* was decided, the Commission reported that it has prosecuted over 60 cases based on advertisements for dietary supplement and weight-loss products: an average of over 12 cases per year. *See* Federal Trade Commission, Dietary Supplement Advertising Cases, 1984—July 2003, available at http://www.ftc.gov/bcp/reports/dietadvertisingcases.htm.

332. In 2004, the Commission reported that it had filed over two dozen cases concerning claims for dietary supplements, weight-loss, and fat-loss products—which is double the Commission's five-year trailing average for such cases (*see* www.ftc.gov/os/adjpro).

333. In November 2002, the Commission held a "Weight Loss Workshop" at which its staff conceded that the existing regulatory approach was not working. *See* FTC Weight Loss Advertising Workshop, Tuesday, November 19, 2002, available at http://www.ftc.gov/bcp/workshops/weightloss/index.html ("The Federal Trade Commission will hold a workshop to explore alternate approaches to reducing deceptive claims in advertising for weight-loss products. Following up on the issuance of the FTC staff report, *Weight-Loss Advertising: An Analysis of Current Trends*, the workshop will give the FTC staff and interested parties an opportunity to discuss new strategies for fighting weight-loss fraud"). RX 002.

N. FACTS CONCERNING CORPORATE RESPONDENTS

334. The Respondents corresponded with FTC on November 11, 2003, December 3, 2003, and June 10, 2004. The Respondents requested guidance from Bureau staff on what the Competent and Reliable Scientific Evidence standard means, on what scientific evidence they would have to have in order to satisfy the Bureau's concerns that the claims were not adequately corroborated, and on what disclaimers the Bureau would accept as obvious less speech restrictive alternatives to prosecution. RX-132, RX-135, RX-142.

335. In response to Basic Research's inquiries, Bureau staff refused to define the standard in a way that would give the Respondents sufficient information to know how to avoid violation of it. RX-099. Bureau staff refused to explain what level, degree, quality,

and quantity of science the Respondents need to support the Respondents' advertising claims. RX-099, RX-100. Bureau staff refused to advise the Respondents of what disclaimers they might use as less speech restrictive alternatives to prosecution. RX-099, RX-100.

336. FTC has never informed the Respondents precisely what content within their ads FTC deems deceptive and what content FTC accepts as non-deceptive.

337. This Complaint was filed on June 16, 2004, the same date that Howard Beales testified before Congress on the Federal Trade Commission's position on deceptive advertising. RX-019.

338. FTC first contacted Respondents regarding their advertising substantiation on April 12, 2002. RX-107.

339. Prior to the filing of the Complaint, FTC last communicated with Respondents on June 9, 2004. RX-141.

340. None of the challenged claims to which the FTC objects in its Complaint is an express claim made in the Respondents' advertisements. Complaint at 8, 14, 17. Each is one FTC Counsel have stated is implied by the ad. *Id*; *see also,* FTC Counsel's First Supplemental Response to Respondent's First Set of Interrogatories, Respondent's Interrogatory No. 1a, b, and c ("Based upon the evidence presently available to FTC Counsel, the representations made by Respondents in promotional materials for the challenged products are strongly implied claims"). No copy test or survey exists to support FTC Counsel's conclusion that to ordinary consumers the claims are implied by the advertisements. RX 064.

III. PROPOSED CONCLUSIONS OF LAW

A. RESPONDENTS' PRODUCTS PERFORM AS ADVERTISED

The products in question are of three essential kinds.

[* * REDACTED * *]

Ephedra, Caffeine, and Aspirin. Ephedra combined with caffeine is effective in producing statistically significant weight loss in overweight individuals.

[* * REDACTED * *]

[* * REDACTED * *]

Weight loss in excess of 4 pounds per month is considered significant by the Food and Drug Administration. *See* http://www.fda.gov/medwatch/safety/ 2005/jul_PI/Meridia_PI.pdf, July 28, 2005. A greater rate of weight loss (more than the 1 to 2 pounds a week recommended by NIH) does not yield a better result at the end of 1 year." RX 806 at 23.

FTC Counsel contend that the claims made in Respondents' advertising for Leptoprin imply that "clinical testing proves that Leptoprin causes weight loss of more than 20 pounds, including as much as 50, 60, or 147 pounds, in significantly overweight users." Complaint at 14. FTC Counsel contend that the claims made in Respondents' advertising for Leptoprin imply that "clinical testing proves that Leptoprin causes loss of substantial, excess fat in significantly overweight users." Complaint at 14. FTC Counsel contend that both representations are deceptive without ever defining the terms "significant overweight," and "substantial loss." Complaint at 14. The claims alleged are not in fact stated in the ads. The claims alleged have not been shown by empirical evidence to be implied by the ads. Even were the claims implied they would not be false and misleading given the scientific evidence. That evidence reveals that subjects who carry 30 or more pounds of excess weight do indeed experience disproportionately

higher weight loss in the scientific studies. Consider the following chart showing evidence of weight loss:

[* * REDACTED * *]

[* * REDACTED * *]

[* * REDACTED * *]

[* * REDACTED * *]

[* * REDACTED * *]

[* * REDACTED * *]

[* * REDACTED * *]

FTC relies on no empirical evidence to support its view that the ads in question create in the mind of a reasonable consumer under extant circumstances the implications alleged. FTC relies on no empirical evidence that ECA does not produce weight loss and does not produce weight loss of more than twenty pounds in subjects who are 30 or more pounds overweight. Moreover, empirical evidence of record (and for which judicial notice is proper[33]) reveal that far from expecting large amounts of weight loss from dietary supplements, consumers of weight loss dietary supplements are highly skeptical of claims of product effectiveness. Trottier, K, Polivy,

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1. [33] Rule 3.43(d) of the Commission's Rules of Practice provides that the Administrative Law Judge and the Commission may take official notice of material facts that do not appear in evidence of the record, as long as the other party is given the opportunity to disprove such noticed facts upon a timely motion. 16 C.F.R. § 3.43(d). The standard of official notice is parallel to that of judicial notice, provided for under Rule 201 of the Federal Rules of Evidence, and courts have consistently recognized that administrative agencies' ability to take official notice is even broader than the court's ability to take judicial notice. *See generally* Kenneth C. Davis and Richard J. Pierce, Jr., II *Administrative Law Treatise* (3d ed. 1994) §§ 10.5 & 10.6 (discussing cases and observing that administrative agencies operating under the Administrative Procedures Act enjoy broader discretion to take notice of contested material facts than do courts operating under the Federal Rules of Evidence).

J, Herman, P. Effects of Exposure to Unrealistic Promises about Dieting: Are Unrealistic Expectations about Dieting Inspirational? Int J Eat Disord 2005; 37:142-149, RX 828..[34] Far from deriving implications from weight loss advertising that weight loss is achievable in every case, weight loss product consumers are highly skeptical that weight loss is achievable. RX 828.[35] Thus, FTC's speculation that significantly overweight consumers understand that they will experience weight loss of over 20 pounds, including as much as 50, 60, or 147 pounds, not only lacks support from empirical evidence of consumer perception[36] but is in fact contradicted by empirical evidence of consumer skepticism of weight loss advertising.

There is no evidence of actual deception in this case. The only empirical evidence of consumer perception reveals that it is exceedingly unlikely that any consumer was deceived.[37] In light of pervasive consumer skepticism, and a marketplace replete with numerous cautions and warnings about the credibility of weight loss advertising in general,[38] statements alleged to be material may in fact have no materiality at all—may not be ones responsible for a purchasing

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[34] *See* Calfee, J, Ringold, D. Consumer Skepticism and Advertising Regulation: What do the Polls Show? Adv. In Cons. Res. V.15, 1988: p. 244-248; Trottier, K, Polivy, J, Herman, P. Effects of Exposure to Unrealistic Promises about Dieting: Are Unrealistic Expectations about Dieting Inspirational? Int J Eat Disord 2005; 37:142-149.

[35] *Id.*

[36] In *Kraft*, the Seventh Circuit (in a case dealing with nondisclosure of material information about calcium content) found for the agency after expert witness's testimony found "solid evidence" that consumers placed great importance on calcium consumption. See *Kraft* at 970 F.2d 311 (7th Cir. 1992).

[37] We may add to this the salient observation that the products in question carry with them a complete money back guarantee. Thus, if a consumer perceived him or herself to be misled, there is an automatic remedy—a simple request for return of the purchase price. Note well that the alleged misleadingness is one of degree of weight loss perceived, not one of whether weight loss would be achievable at all. As explained herein, there is no serious question whatsoever about the effectiveness of ephedra and caffeine in producing weight loss.

[38] See United States, Mexico, Canada (MUCH) Combat Weight Loss Fraud; http://www.ftc.gov/opa/2005/10/much.htm, October 24, 2005; "FTC Announces 'Operation Waistline' – a Law Enforcement and Consumer Education Effort Designed to Stop Misleading Weight Loss Claims" www.ftc.gov/opa/1997/03/waistlin.htm (last visited 2/6/2006).

decision. FTC's assumptions of materiality are likewise wholly uncorroborated. Here, the FTC has presented no empirical evidence to establish that purchasing decisions were made based on any specific representations in the ad that consumers viewed as material. The only empirical evidence of record confirms that weight loss advertising carries with it a stigma in the minds of consumers (who harbor a bias against the believability of the ads in question). In that environment, it is unreasonable and illogical to assume that a consumer who would not anticipate to lose any, let alone several pounds per week, would believe a product that actually causes weight loss on average of 6 to 10 pounds per month (and more for those who are 30 or more pounds overweight) to be one that was anything less than a substantial weight loss aid. Indeed, it is counterintuitive and illogical to view the ad outside the context of the market in which it appears. In that market, by comparison to other dietary supplement weight loss aids (and even by comparison to drugs such as those mentioned above), any reasonable calculation of the actual effects of the products in question would be that they do indeed yield substantial weight loss in significantly overweight individuals.

Reliance on *Kraft* is unavailing for FTC counsel. Unlike here, in that case the ad in question omitted material information necessary to comprehend its significance. Here the Aminophylline gel product ads carried an express, bold, and catchy disclaimer: "So What's the Catch?"[39] That case did not involve a challenge predicated solely on implied claims, as the instant challenge. Here, where FTC Counsel's whole case rests on implications (and not a shred of empirical evidence to support the implications, but empirical evidence contradicting the

[39] CX 001 at Exhibits B, C, D, K, and L "What does this mean in plain English? Children who used PediaLean along with a healthy, but not calorie-restricted diet and modest exercise lost an incredible 20% of their excess body weight" and "[at www.weightlossforchildren.com] you'll also get full access to a personalized, easy-to-follow eating and exercise plan for your child based on gender, height, weight, and age."

implications), the *Kraft* admonition that there be empirical evidence to support a charge becomes imperative. See *Kraft Foods v. FTC*, 970 F.2d 311 (7th Cir. 1992). In the absence of such evidence, and in the presence of contradictory empirical evidence (as explained supra), this Court should hold that the FTC has failed to satisfy its burden of proof and that, as a matter of fact and law, there is no adequate proof of deceptive advertising.

Moreover, from a read of the ad language itself in context and in its entirety, there is no reasonable basis for concluding that it deceives. In point of fact no claim appears in any of the advertisements questioned by the government that the typical user will experience weight loss of 50, 60, or 147 pounds, albeit those amounts are indeed achievable through use of the ephedra, caffeine, and aspirin combination in those who are significantly overweight. The examples given in the ad are of people with before weights of 203 lbs (in a woman who lost 50 pounds); 404 lbs (in a man who lost 147 pounds); and 235 lbs (in a woman who lost 60 pounds). Those before weights are exceptional and, in light of that fact, it would not be reasonable to presume that the typical consumer who weighs less would expect from the ad the same results as those overtly represented in the ads as having a starting weight that is atypically high. Nevertheless, for those who do weigh the same or more than those represented, consistent use of the product would, as the chart above demonstrates, cause weight loss comparable to or greater than the amounts of weight lost by those presented in the ad.. There is in this no deception.

The ads questioned by FTC Counsel do not convey to a reasonable consumer content that is deceptive. All of the content is backed by scientific evidence. That evidence is reliable because it is generally recognized as such in the scientific community that evaluates the effect of the combination of ephedra, caffeine, and aspirin on weight loss. Proof of its reliability and general acceptance comes in the form of peer-reviewed literature by competent scientists in the

field (ones with extensive publication histories involving their original research on weight loss effects[40]) who cite to and rely upon that same evidence in their own reviews of the literature and assessment of original research. *See* (among Respondents' substantiation composites, JX 003 and JX 007

[* * REDACTED * *]

The government's designated expert on weight loss, Dr. Stephen Heymsfield, takes a view that is not representative of those who study the combination of ephedra, caffeine and aspirin. Dr. Heymsfield's peers look to the totality of publicly available scientific evidence, as indeed the FDA and FTC require of themselves,[41] and give credence to weight loss studies that may lack placebo controls, experience variable drop out rates, and have a duration of 4 weeks or less. Those peers examine the totality of the evidence and derive their opinions from that totality.[42] Dr. Heymsfield, by contrast, states unequivocally that he does not give credence to any study that lacks placebo controls, has drop-outs in excess of 20%, and has a duration of two

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[40] Contrast that with FTC's expert, Heymsfield. He has but three publications bearing his name as a co-author that concern ephedra and weight loss. In two of these he is the principal co-author, yet by his own testimony he rarely, if ever, performed original research or even knew of the data in studies that show him as a co-author. *See* RX 054, RX 813, RX 086.

[41] 21 CFR § 101.14(c) (FDA will promulgate regulations authorizing a health claim...when...based on the totality of publicly available scientific evidence); *see also* RX 015 at 9 "Where there is an existing standard for substantiation developed by a government agency or other authoritative body, the FTC accords great deference to that standard"); *see also Whitaker v. Thompson*, 248 F.Supp. 2d 1, 27-28 (D.D.C. 2002)(when credible evidence supports a claim that claim may not be absolutely prohibited); Hulley, et al., *supra*, Designing Clinical Research, at 13.

[42] "Errors are an inherent part of all studies. The main issue is whether the errors will be large enough to change the conclusions in important ways." Hulley SB, Cummings SR, Browner WS, Grady D, Hearst N, Newman TB. Designing Clinical Research, at 13 (Lippincott Williams & Wilkins: New York 2001).

months or less. RX 054, Heymsfield Feb. Depo. at 381; RX 086, Heymsfield Expert Report at 13-25. He admits that he rejects all scientific evidence on the subject except that which comes in the form of prospective, large scale, randomized, double-blind, placebo controlled clinical trials of over 2 months duration. RX 054, Heymsfield Feb. Depo. at 381; RX 086, Heymsfield Expert Report at 13-25. By contrast, the federal Food and Drug Administration's rules permit approval of weight loss drugs based on studies that Dr. Heymsfield would have rejected, i.e., based on studies without double-blind, without randomization, and without placebo-controls. FDA has approved the weight loss drug Orlistat, for example, based on studies with drop out rates in excess of 20%.[43] It did so under the FDA's "substantial evidence" standard, considered the most rigorous standard of scientific review in the world. See Federal Register Vol. 63, No. 94: Guidance for Industry on Providing Clinical Evidence of Effectiveness for Human Drugs and Biological Products; Availability. http://www.fda.gov/cder/fdama/fedreg/2411noa.txt, May 15, 1998.

The persuasiveness of a study is in large measure determined by its statistical significance.[44] Dr. Heymsfield admits that he is not a statistician and not a biostatistician. See RX 054, Heymsfield Feb. Depo. at 460-463. He lacks education, experience, and training in the area of statistics and is not adept at evaluating statistical significance. See RX 054, Heymsfield Feb. Depo. at 461. A study's sample size does not determine its power; yet Dr. Heymsfield

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[43] The clinical trial for Orlistat was double-blind, randomized, placebo-controlled, and evaluated over a two year period. There were a total of 403 subjects out of 1187 enrolled subjects who completed the two years of the study. The drop out rate and the variable dosing would, based on Heymsfield's testimony, be unacceptable and would be grounds for perfunctory exclusion of the study from the analysis. *See* RX 086 at 24; *see also* RX 050, Heymsfield Jan. Depo. at 232; RX 813, Heymsfield Aug. Depo. at 611-612.

[44] U.S. Food and Drug Administration: Guidance for Institutional Review Boards and Clinical Investigators 1998 Update; http://www.fda.gov/oc/ohrt/irbs/default.htm. Dr. Mowrey's Ph.D. included classes in statistics. While a graduate student he taught statistics to undergraduates

makes that fundamental error. See Heymsfield Feb. Dep. at 464. *See also* Daniel Mowrey's Expert Report, RX-828 at 40.[45] A scientist who cannot, by his own admission, assess the statistical significance of the studies he has reviewed cannot weigh them either individually or collectively. In sum, Dr. Heymsfield is not capable of determining the significance of any single study or the combined weight of all studies. Moreover, Dr. Heymsfield's exclusive reliance on prospective, large scale, randomized, double-blind, placebo controlled clinical trials leaves him blind to the contributions all other studies make to a balanced assessment of the evidence and entirely at odds with the generally accepted view of the scientific community (that looks to the totality of available scientific evidence). Dr. Heymsfield's view is a position not in accord with the approach required by the FTC. See footnote 30, supra, see also Hulley SBet al., *supra*, Designing Clinical Research, at 13.

Under Dr. Heymsfield's narrow view of science, the evidence still supports weight loss, just not weight loss in the amounts he thinks necessary to support the implied claims. When one takes into account all of the evidence, as do Respondents, the conclusion reached by evaluation of the Colker, Daly, and Boozer studies, there can be no doubt that ephedra, caffeine, and aspirin

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[45] Determining the number of subjects needed in a study is not a random choice such as "a minimum of 100" as Dr. Heymsfield suggests. Instead it is based on established methods of probability for a number of characteristics of potential effects including the probability of a large effect with relatively little inherent random variability. Hulley SB, Cummings SR, Browner WS, Grady D, Hearst N, Newman TB. Designing Clinical Research. (Lippincott Williams & Wilkins: New York, 2001); Bowling A. Research methods in health. (New York: McGraw-Hill 2002); Toutenburg H. Statistical analysis of designed experiments (New York: Springer 2002); Rosner B. Fundamentals of biostatistics. (Belmont: Wadsworth 1995); Meinert CL. Clinical trials: design, conduct, and analysis. (New York: Oxford 1986); Everitt BS, Pickles A. Statistical aspects of the design and analysis of clinical trials. (London: Imperial College Press 1999). When the result is expected such as a large effect with relatively little inherent random variability, a small sample is sufficient for deriving meaningful population level inferences. There are equations for calculating sample size based on expected results. Rosner B. Fundamentals of biostatistics. (Belmont: Wadsworth 1995); Meinert CL. Clinical trials: design, conduct, and analysis. (New York: Oxford 1986).

produce an average of 6 to 10 pounds of weight loss per month and produce greater weight loss in those with more to lose. Through consistent ingestion of the substances in the dose amounts recommended on the Leptroprin and Anorex labels an overweight person will lose on average 6 to 10 pounds per month. Those who are in excess of thirty pounds overweight can experience greater weight loss. The results given in the ads are actual results but are said by the terms of the ads to be "not typical"[46] and the atypically high before weights of each person are given in each ad. Thus, consumers are on notice that those with the specific weights of the testimonial givers achieved the weight loss specified but that they were not representative of all consumers.

Dr. Heymsfield's assessment of the scientific literature should not be credited for additional reasons. Above we have explained Dr. Heymsfield's methodological and statistical knowledge shortcomings and the fact that his opinion is inconsistent with the opinions of peers who possess greater direct research experience and understanding of the science and of statistics. It is also the case that any searching review of Dr. Heymsfield's record reveals that he (1) generally lacks direct involvement in the studies that bear his name and (2) represents himself to have expertise in areas where he has none.

Under examination Dr. Heymsfield has admitted that he neglects to review entire articles in which he is listed as co-author and, oftentimes, has but a small part in the work leading to the ultimate published study. *See* RX 813, Heymsfield Aug. Depo. at 455-459. In confirmation of that observation we have his testimony concerning the ill-fated, so-called Darsee studies. In those six studies in which Dr. Heymsfield served as co-author, the empirical evidence supporting those studies was found to be fabricated. *See* RX 813, Heymsfield Aug. Depo. at 460-590. Dr. Heymsfield does not contest the fabrication; he admits it. His position is that he was unaware of

[46] CX 001 at Exhibit H.

the source data for the articles that bore his name and was, indeed, largely, if not completely, unaware of the content of those articles. *See* RX 813, Heymsfield Aug. Depo. at 460-590. He could not be a party in fact to the fraud, he argues, because he was oblivious to the content that made the articles fraudulent—that despite the fact that he is listed as co-author on each one. *See* RX 813, Heymsfield Aug. Depo. at 460-590. He buttresses that point by reciting it to be his general pattern (i.e., to be unaware of empirical data in studies that bear his name). *See* RX 813, Heymsfield Aug. Depo. at 455-459. Those admissions (combined with the fact that he is a named co-author on only three studies dealing with ephedra and weight loss) raise a serious question as to whether Dr. Heymsfield should be credited with specific scientific expertise in the study of the ephedra, caffeine, and aspirin combination in weight loss. We simply cannot know that he is directly knowledgeable of the works that bear his name. We likewise cannot know the extent of his involvement in research that resulted in the studies. The foregoing also helps explain why Dr. Heymsfield, unlike his colleagues who study the ephedra, caffeine and aspirin combination, places so little credence in any study other than ones that are large scale, prospective, randomized, double blind, placebo controlled clinical trials. He appears unaware of the scientific significance of work in the field that he professes he understands expertly.

Discredited experts carry a heavy burden to justify subsequent judicial reliance on their testimony. *Cf. CSX Transp. v. Board of Pub. Works*, 95 F.3d 318, 323 (4th Cir. 1996). To be sure, for one who has spent a majority of his career in academia, revelation that five studies he co-authored with Darsee were fraudulent affected Dr. Heymsfield greatly. In the publication *The Scientist*, he described the effect thusly: "The response was that Emory asked me to leave; my grants dried up. I was tenured, so they couldn't fire me. But they definitely considered me an eyesore. I was set aside – taken off the ladder to the sky. It was obvious that there would be

no promotions or opportunities."[47] Now, years hence, he says he can neither admit nor deny having said the quoted lines. Heymsfield Aug. Depo. at 631-634. For one who regarded the event, and rightly so, as devastating, Dr. Heymsfield cannot be believed when he says he can neither admit nor deny having said the words. When an expert witness lacks credibility, the proper resort is to discount or exclude his testimony. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 125 L. Ed. 2d 469, 113 S. Ct. 2786 (1993); *General Elec. Co. v. Joiner*, 522 U.S. 136, 118 S. Ct. 512, 517, 139 L. Ed. 2d 508 (1997). Giving that testimony any credence destroys the integrity of the truth-seeking process.

Finally, Dr. Heymsfield has no direct experience determining whether effects predicted in the science are borne out in the market. By contrast, Dr. Daniel B. Mowrey has 30 years of experience studying the scientific literature on the combination of ephedra, caffeine, and aspirin and experience observing the physiological effects in the population of consumers who have purchased the products. See RX 828 at 79.[48] He knows the experimental study predictions and has seen those predictions borne out in the market. Dr. Mowrey, in the course of his regular practice, contacted the authors of important studies to clarify study information, obtain additional data and statistical information, and to discuss their expert opinion on certain subjects. He also engaged in product research and development, relied on stringent scientific reviews, clinical trials, his own experience in the field of psychopharmacology, book authorship, and years of study. He reviewed all of the scientific data available to him, printed out studies, and compiled substantiation binders. Dr. Mowrey concludes that the products are effective as weight loss

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[47] See RX 812, Dalton, Rex. "Fraudulent Papers Stain Co-Authors." *The Scientist*, Vol. 1, issue 13, p. 1: May 18, 1987.

[48] Dr. Mowrey has taught statistics to undergraduates, among other courses. He has taught clinical study design to undergraduates. He has continually combed published available scientific literature during those 30 years and published four books that assess nutritive value and beneficial effect for a multitude of herbs and nutrients. Anticipated testimony.

agents and do in fact lead to a reduction of 12 to 13 pounds in a six week period on average in the user population. See RX 828 at 32. He reports that ECA is designed for long term use, becomes safer with long term use, and overcomes at least in part the body's plateauing effect of weight loss. RX 828 at 32-33. He further confirms that weight loss in excess of the average is achievable in people who have weights comparable to those given as examples in the advertisements. See RX 828 at 39.

Weight Loss and Fat Loss Are Objective Measurements. The FDA has recognized multiple study designs including study designs for drug approval that do not include placebo control. 21 C.F.R. § 314.126(b)(2)(iii).[49] FTC has previously recognized, in accordance with FDA regulations that when objective measurements of effectiveness are available and the placebo effect is negligible, comparison of treated and untreated subjects may be appropriate (without use of a placebo). *In re Thompson Medical Center, supra*, at 162. Moreover, "Objective measures are useful in a clinical trial because multiple measurements can corroborate one another." *Id.* Thus, objectively measuring weight loss by pounds and fat loss by circumference of a thigh are objective measures, easily documented, valuable proof even in the absence of a "placebo."

The value of placebo controls has been critically examined in the New England Journal of Medicine. Hrobjartsson, et al. *Is the Placebo Powerless? An analysis of Clinical Trials Comparing Placebo with No Treatment.* 344 N. Eng. J Med. 1594 (May 24, 2001)(corrected N. Engl. J. Med 2001:345:4). See RX 828 at 72. Moreover, the "double-blind" study design (where neither subjects nor administrators know who receives medication and who receives the

[49] FTC has recognized that the FDA standards for clinical testing are the standards accepted by the medical/scientific community as a whole. *In re Thompson Medical Center, supra*, at para. 223.

placebo) is not infallible because one cannot "blind" for long an overweight subject who experiences actual weight loss or who witnesses a reduction in thigh circumference. It has been recognized that patients and physicians correctly identify medication assignments such as in "double-blind" studies in 70% of the cases in the double-blinded trial of an appetite suppressant. Brownell, et al. *The Double-Blind in Danger: Untoward Consequences of Informed Consent.* 139:11 Am. J Psychiatry 1487 (Nov. 1982)(describing side effects of medication in advance of treatment allowed for identification of assignments and may influence the integrity of double-blind studies). Thus, Dr. Heymsfield's supposition that adherence to placebo is an essential element to any valid clinical trial (thus eliminating from analysis all trials conducted in the absence of placebo) is contrary to logic, FDA regulation, and recognized authorities.

For the foregoing reasons, the Chief Administrative Law Judge should conclude that FTC Counsel have not proven that Respondents lack a reasonable basis for the objective claims made in advertising for the challenged products. None of the claims is false and misleading within the meaning of Section 5 of the FTCA.[50] Accordingly, FTC Counsel's Complaint should be denied and dismissed.

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[50] Indeed, even if the ad copy were capable of at least one reasonable implication that could deceive, the speech in issue would be—at worst—only "potentially misleading" and not "inherently misleading." See *Central Hudson Gas & Electric Corp. v. Public Serv. Comm'n.*, 447 U.S. 557; 100 S. Ct. 2343; 65 L. Ed. 2d 341 (1980) (*quoting* "Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all. *Bates v. State Bar of Arizona, supra*, at 374).
Under apposite precedent, potentially misleading commercial speech is entitled to First Amendment protection under the commercial speech standard set forth in *Central Hudson Gas & Electric Corp. v. Public Serv. Comm'n.*, 447 U.S. 557; 100 S. Ct. 2343; 65 L. Ed. 2d 341 (1980), and its progeny. *Peel v. Attorney Registration & Disciplinary Comm'n of Ill.*, 496 U.S. 91 (1990), *see also In re R.M.J.*, 455 U.S. at 203.*Pearson,* 164 F.3d 650; *Bd. of Trs. v. Fox*, 492 U.S. 469 109 S. Ct. 3028; 106 L. Ed. 2d 388 (1989) ("Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all." *Bates v. State Bar of Arizona, supra*, at 374)

[* * REDACTED * *]

(*see, e.g., Central Hudson*, 447 U.S., at 566; *Metromedia, Inc. v. San Diego*, 453 U.S. 490, 507-508 (1981) (plurality opinion); *In re R. M. J.*, 455 U.S. 191, 203 (1982); *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 644 (1985); *Posadas de Puerto Rico Associates v. Tourism Company of Puerto Rico, supra*, at 343; *San Francisco Arts & Athletics, Inc. v. United States Olympic Committee*, 483 U.S. 522, 535 (1987); *Shapero v. Kentucky Bar Assn.*, 486 U.S. 466, 472 (1988). Under that precedent, as explained *infra*, government must employ obvious, less speech restrictive alternatives. In this case, that alternative would be a mandatory qualification or disclaimer, not resort to an order imposing any continuing jurisdiction over advertising for a term of years or any requirement that future advertising meet an undefined, "competent and reliable scientific evidence" standard. *See infra* at paragraphs 3-20 for analyses of these problems in FTC regulation.

[* * REDACTED * *]

FTC contends that the claims made in Respondents' advertising for PediaLean imply that "PediaLean causes substantial weight loss in overweight or obese children" and that "clinical testing proves that PediaLean causes substantial weight loss in overweight or obese children." FTC contends that both representations are deceptive. FTC relies on no empirical evidence to support its view that the ads in question create in the mind of a reasonable consumer under extant circumstances the implications alleged. Moreover, empirical evidence of record reveals that the average consumer of weight loss products is highly skeptical of all weight loss claims. Trottier, K, Polivy, J, Herman, P. Effects of Exposure to Unrealistic Promises about Dieting: Are Unrealistic Expectations about Dieting Inspirational? Int J Eat Disord 2005; 37:142-149. RX 828.[53] Far from deriving from weight loss advertising implications that "substantial" weight loss

[53] **[* * REDACTED * *]**
See also Calfee JE, Ringold, DJ. Consumer Skepticism and Advertising Regulation: What Do the Polls Show? Adv in Cons Res 15: 244-248, 1988; Ford, GT, Smith DB, Swasy, JL. Consumer Skepticism of Advertising Claims: Testing Hypotheses from Economics of Information. Journal of Cons Res 16: 433-441, 1990.

is achievable in every case, weight loss product consumers have been shown to be highly skeptical that weight loss is achievable at all. Thus, far from deriving from the ads implications of specific amounts of weight loss achievable, consumers likely question whether any loss of weight is achievable, yet the products perform and that performance likely exceeds their expectations. Indeed, the apparent response of the typical consumer of weight loss products to weight loss advertising is to question the truthfulness of the ad and to purchase the product in question on the off chance that some weight loss may result. Thus, there is no evidence of any parent of an overweight child expecting a specific amount of weight loss achievable. On this record there is no reasonable basis to conclude anyone has been deceived.[54] In light of pervasive consumer skepticism about weight loss advertising, an idea marketplace replete with numerous cautions and warnings about the credibility of weight loss advertising in general,[55] statements alleged to be material may in fact have no materiality at all—and are certainly not provably responsible for a purchasing decision. Here, the FTC has presented no empirical evidence to establish that purchasing decisions were made based on any implied claim alleged to be a material and false representation.

Moreover, from a read of the ad language itself, there is no reasonable basis for concluding that it deceives. In point of fact no claim appears in PediaLean advertising that the product produces "substantial weight loss" (whatever that means) or that clinical testing proves

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[54] We may add to this the salient observation that the products in question carry with them a complete money back guarantee. Thus, if a consumer perceived him or herself to be misled, there is an automatic remedy—a simple request for return of the purchase price. Note well that the alleged misleadingness is one of degree of weight loss perceived, not one of whether weight loss would be achievable at all.

[55] See United States, Mexico, Canada (MUCH) Combat Weight Loss Fraud; http://www.ftc.gov/opa/2005/10/much.htm, October 24, 2005; "FTC Announces 'Operation Waistline' – a Law Enforcement and Consumer Education Effort Designed to Stop Misleading Weight Loss Claims" www.ftc.gov/opa/1997/03/waistlin.htm (last visited 2/6/2006);

that the product produces "substantial weight loss." RX 647. Rather, the results of the clinical trial in question are plainly revealed to the consumer. The consumer is also informed that "individual results may vary." RX 647.

Dr. Heymsfield addresses the PediaLean product, contending that a clinical study cited is flawed because it has too few subjects (RX 813 at 12), lacks adequate controls, lacks adequate power, did not specifically evaluate the product component of PediaLean, failed to provide weight data and presented results as "excess weight," contained serious design and analysis flaws, was statistically flawed and fails to produce any efficacy inferences. *Id.* at 12. As explained above, Dr. Heymsfield lacks expertise in statistics and, so, cannot speak expertly to the significance of the study. Moreover, Dr. Heymsfield maintains a bias against all studies except ones that are large scale, prospective, randomized, double-blind, placebo controlled clinical trials that are impossibly perfect, model, not real world. He thus ignores completely the significance of the fact that the mechanistic evidence revealing the bulk producing property of glucomannan is confirmed in the Livieri clinical trial and in Dr. Mowrey's Expert Report. See RX 828. Dr. Heymsfield maintains an unscientific "all or nothing" view of the scientific evidence. He supposes the existence of a perfect study, knowing that in reality perfection is not possible, certainly not in any study in which he has been involved. He then faults all studies presented to him based on any imperfection found whether material or not to the study's outcome and significance, and he condemns the studies one and all without gleaning from them a single valuable finding. His position is unique among his peers and not representative of how scientists evaluate studies or of what is generally accepted in the scientific community as yielding accurate and reliable results. **[* * REDACTED * *]**

[* * REDACTED * *]

[* * REDACTED * *]

Based on the foregoing and the basic Heymsfield flaws identified above, Dr. Heymsfield's myopic analysis is neither representative of the scientific community nor reasonable in light of the evidence. Dr. Heymsfield lacks familiarity with the compound yet gives no credence whatsoever to those who have familiarity with it or to the mechanistic evidence confirming the fiber's bulk producing properties, its ability to create feelings of satiety, and the role of satiety as a proven catalyst to weight loss.

For the foregoing reasons, the Chief Administrative Law Judge should conclude that FTC Counsel have not proven that Respondents lack a reasonable basis for their advertising claims and that the charge of deceptive advertising within the meaning of Section 5 of the Federal Trade Commission Act is not supported by the evidence.[59] Accordingly, FTC Counsel's Complaint should be denied and dismissed.

Aminophylline Gels. Aminophylline is approved by the Food and Drug Administration as a weight loss agent. See Food and Drug Administration Statement: Thigh Creams, http://www.cfsan.fda.gov/~dms/cos-202.html, February 24, 2000. It is an uncontroversial point among scientists who study the compound that it causes adipose cells to excrete fatty acids or deflate, thereby reducing their size. It is an uncontroversial point among scientists who study the compound that it is effective in producing localized fat reduction. When fatty acids are excreted

[59] Indeed, even if the ad copy were capable of at least one reasonable implication that could deceive, the speech in issue would be—at worst—only "potentially misleading" and not "inherently misleading." *Greater New Orleans Broadcasting Assn., Inc. v. United States*, 527 U.S. 173, 183, 144 L. Ed. 2d 161, 119 S. Ct. 1923 (1999). Under apposite precedent, potentially misleading commercial speech is entitled to First Amendment protection under the commercial speech standard set forth in *Central Hudson Gas & Electric Corp. v. Public Serv. Comm'n.*, 447 U.S. 557; 100 S. Ct. 2343; 65 L. Ed. 2d 341 (1980), and its progeny. Under that precedent, as explained infra, government must employ obvious, less speech restrictive alternatives. In this case, that alternative would be a mandatory qualification or disclaimer, not resort to an order imposing any continuing jurisdiction over advertising for a term of years or any requirement that future advertising meet an undefined, "competent and reliable scientific evidence" standard. *See infra* at paragraphs 2 through 30 for analyses of these problems in FTC regulation.

from adipose tissue, the tissue itself reduces in size yielding an appearance and reality of fat reduction. See RX 317, 318, 319, United States Patent 4,588,724. Greenway, III et. al. Treatment for Selective Reduction of Regional Fat Deposits, filed January 11, 1985; patent granted May 13, 1986.

Dr. Robert Eckel, FTC's expert witness, does not dispute the effectiveness of aminophylline as a weight loss agent. See RX 055 at 12-13. Dr. Eckel frankly admits that he is not a dermatologist and, while aware of the scientific literature on the effectiveness of aminophylline as a weight loss agent, he is not versed in the science concerning the extent to which specific gels are effective delivery vehicles for the aminophylline. See RX 055 at 1.

[* * REDACTED * *]

[* * REDACTED * *]

[* * REDACTED * *]

For the foregoing reasons, the Chief Administrative Law Judge should conclude that FTC Counsel have not proven that Respondents lack a reasonable basis for the objective claims made. Accordingly, the Chief ALJ should dismiss and deny FTC Counsel's Complaint.

B. THE FTC HAS NOT SATISFIED ITS BURDEN OF PROOF; THE ADVERTISING IN QUESTION IS NOT DECEPTIVE UNDER SECTION 12 OF THE FTCA

Burden of Proof. Under the First Amendment to the United States Constitution (U.S. Const. Amend. I), and under the FTCA, 15 U.S.C. Sec. 45(a)(1), the Federal Trade Commission, like every government agency that regulate speech, has the burden of proving the speech inherently misleading before it may ban its utterance in the market and potentially misleading before it may restrict its utterances in the market.[61] *United States v. Playboy Entm't Group, Inc.*, 529 U.S. 803, 120 S. Ct. 1878, 146 L. Ed. 2d 865 (2000), *Greater New Orleans Broadcasting Assn., Inc. v. United States*, 527 U.S. 173, 183, 144 L. Ed. 2d 161, 119 S. Ct. 1923 (1999). The

[61] When potentially misleading, the speech restriction must rely on qualifications or disclaimers whenever possible, for they comply with the last *Central Hudson* prong that compels speech regulators to rely on obvious, less speech restrictive alternatives. See *Central Hudson Gas & Electric Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 564 (1984).

accused does not have the burden of proving that its advertising is non-deceptive, or otherwise protected speech. Rather, the burden remains squarely fixed from beginning to end on the government. *FTC v. Garvey*, 383 F.3d 891, 901 (9th Cir. 2004); *FTC v. Publishing Clearinghouse Inc.*, 104 F3d 1168, 1170 (9th Cir. 1997)(*citing FTC v. American Standard Credit Sys.*, 874 F.Supp. 1080, 1087(C.D.Ca.1994)); *See Thomas v. Chi. Park Dist.*, 534 U.S. 316, 122 S. Ct. 775, 151 L. Ed. 2d 783 (2002), *United States v. Playboy Entm't Group, Inc.*, 529 U.S. 803, 120 S. Ct. 1878, 146 L. Ed. 2d 865 (2000), *Greater New Orleans Broadcasting Assn., Inc. v. United States*, 527 U.S. 173, 183, 144 L. Ed. 2d 161, 119 S. Ct. 1923 (1999) ("The Government bears the burden of identifying a substantial interest and justifying the challenged restriction"); *Reno*, 521 U.S. at 879 ("The breadth of this content-based restriction of speech imposes an especially heavy burden on the Government to explain why a less restrictive provision would not be as effective [...]"); *Edenfield v. Fane*, 507 U.S. 761, 770-771, 123 L. Ed. 2d 543, 113 S. Ct. 1792 (1993) ("[A] governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree"); *Board of Trustees of State Univ. of N. Y. v. Fox*, 492 U.S. 469, 480, 106 L. Ed. 2d 388, 109 S. Ct. 3028 (1989) ("The State bears the burden of justifying its restrictions [...]").

The modern commercial speech standard was adopted in *Central Hudson Gas & Electric Co.*, 447 U.S. 557; 100 S. Ct. 2343; 65 L. Ed. 2d 341 (1980) in 1984. Commercial speech and FTC speech restriction cases pre-dating *Central Hudson* are not good law in so far as they fail to apply the four part burden of proof standard applicable to every government speech restriction. *Central Hudson* has been modified by its progeny to the present. To be sure, no speech regulation by this government, regardless of its source, can pass constitutional muster unless it

satisfies the burden of proof requirements prescribed in *Central Hudson* as modified by its progeny. In an unbroken line of precedent, applied from allegedly deceptive lawyer advertising to dietary supplement and compounded drug claims alike, the Supreme Court has consistently held it the government's burden to justify restrictions on commercial speech and the Central Hudson four part test the unavoidable standard for decision. *See Peel,* 496 U.S. at 109; *Western States,* 535 U.S. 357; *Pearson,* 164 F.3d 650; *Bd. of Trs. v. Fox*, 492 U.S. 469 109 S. Ct. 3028; 106 L. Ed. 2d 388 (1989); *see, e.g., Central Hudson*, 447 U.S., at 566; *Metromedia, Inc. v. San Diego*, 453 U.S. 490, 507-508 (1981) (plurality opinion); *In re R. M. J.*, 455 U.S. 191, 203 (1982); *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 644 (1985); *Posadas de Puerto Rico Associates v. Tourism Company of Puerto Rico, supra*, at 343; *San Francisco Arts & Athletics, Inc. v. United States Olympic Committee*, 483 U.S. 522, 535 (1987); *Shapero v. Kentucky Bar Assn.*, 486 U.S. 466, 472 (1988).

Moreover, the Supreme Court has demanded that speech regulation imposed after-the-fact avoid prohibiting the content in question if that speech can be rendered non-misleading through the addition of a qualification or disclaimer. *See Peel*, 496 U.S. at 110; *In re R.M.J.*, 455 U.S. at 206 n.20; *Shapero*, 406 U.S. at 478. This same burden has been imposed on government regulation of compounded drug advertising and dietary supplement claims. *See Thompson v. Western States Medical Center*, 535 U.S. 357 (2002); *Pearson*, 164 F.3d 650 (D.C. Cir. 1999).

A claim that can be rendered non-misleading through the addition of a disclaimer or qualification is speech protected by the First Amendment. *See In re R. M. J.*, 455 U.S. 191, 102 S. Ct. 929; 71 L. Ed. 2d 64 (1982), *44 Liquormart v. R.I.*, 517 U.S. 484, 116 S. Ct. 1495; 134 L. Ed. 2d 711 (1996); *Pearson*, 164 F.3d at 657 (*citing Peel*, 496 U.S. at 110 (citations omitted). Speech not provably false but, rather, containing incomplete truth is nevertheless protected by

the First Amendment. See *Central Hudson Gas & Electric Co.*, 447 U.S. 564; 100 S. Ct. 2343; 65 L. Ed. 2d 341 (1980) (quoting "Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all" *Bates v. State Bar of Arizona*, 433 U.S. 350, 374 (1977). It is correctable through qualification and disclaimer. *Id.*

FTC Counsel would have the Chief ALJ believe that he may perfunctorily declare any speech he reviews inherently misleading if at least one reasonable connotation arising from it is found to mislead.[62] Under the first prong of *Central Hudson*, inherently misleading speech may be condemned outright, *see Central Hudson Gas & Electric Co.*, 447 U.S. 564; 100 S. Ct. 2343; 65 L. Ed. 2d 341 (1980), but neither the Chief nor this Commission may satisfy the constitutional burden of proof to restrict commercial speech without discerning whether a reasonable disclaimer or qualification exists that would render the speech non-misleading. If so, then the claims are, at worst, only potentially misleading. Indeed, it is the government's burden to adduce empirical evidence of misleadingness; misleadingness sufficient to justify outright suppression may not be presumed but must be proved and proved by evidence grater than the speculation that is the FTC's expert's opinion (Mazis, Nunberg). *See Shapero v. Kentucky Bar Ass'n*, 486 U.S. 466, 108 S. Ct. 1916; 100 L. Ed. 2d 475 (1988), *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 85 L. Ed. 2d 652, 105 S. Ct. 2265 (1985). Accordingly, the Chief may not forbid or restrict Respondents from advertising in future

[62] Under the First Amendment speech that misleads through omission, that is true but for the absence of further information, is protected. *See Central Hudson Gas & Electric Co.*, 447 U.S. 564; 100 S. Ct. 2343; 65 L. Ed. 2d 341 (1980) (*quoting* "Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all" *Bates v. State Bar of Arizona*, 433 U.S. 350, 374 (1977). It is correctable through qualification and disclaimer. *Id.*

without first establishing the absence of any reasonable qualification or disclaimer capable of eliminating the connotation FTC Counsel argues is implied. Under *Central Hudson*'s direct advancement prong, failure to do so denies the regulated sufficient information to discern what speech in future can be safely communicated.[63] Under *Central Hudson's* final prong, failure to rely on disclaimers is a constitutionally invalid act ignoring obvious less speech restrictive alternatives.[64] See *Pearson*,164 F.3d. 650 (D.C.Cir. 1999); see also *Edenfield,* 507 U.S. 761, 770-771, 123 L. Ed. 2d 543, 113 S. Ct. 1792 (1993); *Bates*, 433 U.S. 350, 374 (1977).

FTC Counsel would argue that the Commission need not comply with this First Amendment requirement, arguing that it – unlike the Food and Drug Administration – erects no restraint on the right to advertise. Assuming, arguendo, the absence of an FTC prior restraint, it is nevertheless the case that government restrictions on advertising have been required to satisfy this standard even when the restraint was not imposed prior to the communication in issue. *See Bd. of Trs. v. Fox*, 492 U.S. 469 109 S. Ct. 3028; 106 L. Ed. 2d 388 (1989), *Central Hudson*, 447 U.S., at 566; *Metromedia, Inc. v. San Diego*, 453 U.S. 490, 507-508 (1981) (plurality opinion);

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[63] The "competent and reliable scientific evidence" rubric fails to apprise the regulate of what degree, quantity, quality or nature of evidence that will suffice to convince this Commission that an ad is adequately substantiated.

[64] While it is the government condemnor of speech who bears the burden of crafting a corrective qualification or disclaimer with no corresponding duty upon the accused, Respondents offer the following as examples of qualifications that would be acceptable to them and assure the FTC that, indeed, any reasonable qualification or disclaimer would be acceptable to them:

ECA Products:

* Users of this product may not experience substantial weight loss in amounts equal to 50, 60, or 147 pounds. See FTC Complaint at 14.

Aminophylline Gels:

* Users of this product may not experience fat loss that is rapid and localized.

PediaLean:

* Users of this product may not experience weight loss that is rapid and significant.

In re R. M. J., 455 U.S. 191, 203 (1982); *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 644 (1985); *Posadas de Puerto Rico Associates v. Tourism Company of Puerto Rico, supra*, at 343; *San Francisco Arts & Athletics, Inc. v. United States Olympic Committee*, 483 U.S. 522, 535 (1987); *Shapero v. Kentucky Bar Assn.*, 486 U.S. 466, 472 (1988). But, in fact, the FTC's rule on point is a restraint imposed prior to publication of the ads in question. FTC requires that before advertiser publishes his or her health benefit ad, he or she possess in hand at the time the ad enters the market, competent and reliable scientific evidence corroborating the ad claims.[65] That documentation requirement just as surely works a prior restraint on speech that is no less absolute than FDA's ban on nutrient-disease claims published without confirmation by FDA that the supportive science is credible. *See Whitaker v. Thompson*, 248 F. Supp.2d 1, 27-28 (D.D.C. 2002) (*citing Pearson*, 164 F.3d at 659). Presumably this equation of inadequate corroboration in hand equaling unlawful deception applies even if the speech, coincidentally, is true by virtue of proof in someone else's hands or by proof that subsequently comes to light.[66] Under the First Amendment at no time is truthful commercial speech constitutionally proscribable. The burden of proof to establish the speech suppressible because inherently misleading or regulable because potentially misleading is ineluctably the government's – the burden never shifts. *See Thomas v. Chi. Park Dist.*, 534 U.S. 316, 122 S. Ct. 775; 151 L. Ed. 2d 783 (2002), *United States v. Playboy Entm't Group, Inc.*, 529 U.S. 803, 120 S. Ct. 1878; 146 L. Ed. 2d 865 (2000), *Greater New Orleans Broadcasting Assn.,*

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[65] Competent and reliable scientific evidence is vaguely 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." See FTC Complaint at 19.

[66] This effects unequal justice, affording the poor no defense even if what they say is provably true but the proof exceeds their financial wherewithal to obtain and possess. It works to the great disadvantage of all new market entrants. It is anti-competitive.

Inc. v. United States, 527 U.S. 173, 183, 144 L. Ed. 2d 161, 119 S. Ct. 1923 (1999) ("The Government bears the burden of identifying a substantial interest and justifying the challenged restriction"); *Reno*, 521 U.S. at 879 ("The breadth of this content-based restriction of speech imposes an especially heavy burden on the Government to explain why a less restrictive provision would not be as effective [...]"); *Edenfield v. Fane*, 507 U.S. 761, 770-771, 123 L. Ed. 2d 543, 113 S. Ct. 1792 (1993) ("[A] governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree"); *Board of Trustees of State Univ. of N. Y. v. Fox*, 492 U.S. 469, 480, 106 L. Ed. 2d 388, 109 S. Ct. 3028 (1989) ("The State bears the burden of justifying its restrictions [...][...]").

When government presumes the power to regulate speech, it must establish procedural safeguards to guide regulatees in comprehending precisely how they may communicate in future to avoid prosecution. See *Clark v. Community for Creative Non-Violence*, 468 U.S. 288, 293 (1984); *see Heffron v. International Society for Krishna Consciousness, Inc.*, 452 U.S. 640, 648 (1981) (*quoting Virginia Pharmacy Bd. v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 771 (1976)). *Lakewood v. Plain Dealer Publishing Co.*, 486 U.S. 750, 769-772 (1988) (4-to-3 decision); *Heffron v. International Society for Krishna Consciousness, Inc., supra*, at 649; *Freedman v. Maryland*, 380 U.S. 51, 56 (1965); *Thornhill v. Alabama*, 310 U.S. 88, 97 (1940). Establishing a safe harbor in terms that are intelligible to guide regulatees in channeling their speech content is essential if the government is to avoid imposition of an unconstitutionally vague restraint that suppresses protected expression by drawing it within the same prosecutorial net as unprotected expression. Those in government who would regulate commercial speech cannot exercise unbridled discretion. They must define standards that make clear to the

regulated class what is expected of them, and they must set those bounds constitutionally. See *FTC v. Garvey*, 383 F.3d 891, 901 (9th Cir. 2004); *FTC v. Publishing Clearinghouse Inc.*, 104 F3d 1168, 1170 (9th Cir. 1997)(*citing FTC v. American Standard Credit Sys.*, 874 F.Supp. 1080, 1087(C.D.Ca.1994)); *See Thomas v. Chi. Park Dist.*, 534 U.S. 316, 122 S. Ct. 775, 151 L. Ed. 2d 783 (2002), *United States v. Playboy Entm't Group, Inc.*, 529 U.S. 803, 120 S. Ct. 1878, 146 L. Ed. 2d 865 (2000), *Greater New Orleans Broadcasting Assn., Inc. v. United States*, 527 U.S. 173, 183, 144 L. Ed. 2d 161, 119 S. Ct. 1923 (1999)

Despite this constitutional and statutory law, this agency, under its Rule 3.43(a), (16 C.F.R. § 3.43(a)), effectively shifts the First Amendment burden of proof immediately following its filing of a complaint from the government to the accused. In this case, for example, all evidence germane to the claims in issue upon which FTC relies is derived from the accused and from the FTC's experts' evaluation of that same evidence. None is developed through an independent search of the publicly available scientific evidence, a survey of the opinion of scientists who study the compounds in question, or any other objective and independent measure of validity. FTC Counsel depends on testimony from Heymsfield whose exclusive focus is upon the science possessed by Respondents, and he aims to poke holes in it as the predicate for a decision that the claims are deceptive. Heymsfield ignores the universe of scientific evidence and does not prove the presence of any evidence that would disprove product effectiveness or claims. Likewise FTC restricts Eckel to a review of Respondents' substantiation file, aims to pole holes in that evidence as a predicate for a decision that the claims are deceptive, and does not prove the presence of any evidence that would disprove product effectiveness or claims. If the Chief Administrative Law Judge finds the evidence supplied to him by the accused inadequate for any reason, FTC Counsel expect him to pronounce the advertising in question

deceptive. The universe of all germane proof is not consulted and FTC Counsel believe they need not prove the advertising false, just argue the support for the claims not enough. FTC Counsel believe they need only articulate one plausible yet uncorroborated interpretation of the ad that calls into question the proof relied upon by the accused and that alone suffices as support for a holding of deceptive advertising, regardless of the ultimate truth of the advertising statements. By contrast, FTC Counsel believe it is the duty of the accused to establish that there is no conceivable, actual or hypothetical, construction of the advertising content questioned that deceives, and unless that Herculean burden is met, then the Chief Administrative Law Judge is to find against the accused, regardless of the ultimate truth of the advertising statements. In other words, according to FTC Counsel, it is enough for them to argue the existence of a single conceivable interpretation of the claims that implies deception regardless of actual claim content; regardless of actual consumer perception of that content; and regardless of the extent to which scientific evidence supports the actual claim content. Under this construct, FTC Counsel has either no burden or the lowest burden of proof imaginable, and Respondents the highest. The deck is thus stacked against the accused. That is the antithesis of careful, narrowly tailored, regulatory approach called for by commercial speech precedent in the advent of *Central Hudson.* That construct violates the First and Fifth Amendments to the Constitution and disserves the public interest. To uphold the Constitution and his oath of office, the Chief ALJ must reject it. 5 U.S.C. § 3331.[67]

We ask the Chief Administrative Law Judge to uphold his oath of office first and foremost. He has sworn an oath to uphold the Constitution of the United States and the laws of

[67] *See also* United States of America Federal Trade Commission: A Brief Overview of the Federal Trade Commission's Investigative and Law Enforcement Authority. Revised September 2002.

the United States. 5 U.S.C. § 3331.[68] That oath is meaningless unless the First Amendment burden of proof, placed squarely on government to justify a restriction on speech, is honored in this case. FTC's Operating Manual Sec. 2.3. Under that burden, and under the Federal Trade Commission Act itself, FTC Counsel must establish that the plain language and meaning of the ads in question is inherently misleading (i.e., incapable of being rendered non-misleading through the addition of a reasonable qualification or disclaimer) before the FTC may impose any restriction on further utterance of the claims. Impliedly deceptive claims are by definition potentially misleading, not inherently misleading, so long as qualifications or disclaimers can dispel the alleged deceptive implication. If the ad content is backed by science and is, at worst, only potentially misleading, it may not be restricted from reaching consumers except to the extent that FTC Counsel can prove no qualification or disclaimer capable of rendering the content nonmisleading (a heavy constitutional burden). *See e.g.,* Bates, 433 U.S. 350, 374 (1977); Peel, 469 U.S. 91, 100 (1991); *Whitaker v. Thompson*, 248 F.Supp.2d 1, 16-17 (D.D.C. 2002) (citations omitted).

Rather, it is the duty of the FTC and the Chief Administrative Law Judge to impose an obvious, less speech restrictive alternative, a disclaimer or a claim qualification on speech that is, at worst, only potentially misleading, and to let it enter the market. See *Pearson*,164 F.3d. 650 (D.C.Cir. 1999); see also *Edenfield,* 507 U.S. 761, 770-771, 123 L. Ed. 2d 543, 113 S. Ct. 1792 (1993); *Bates*, 433 U.S. 350, 374 (1977). It is the FTC's burden to come up with the disclaimer or claim qualification that resolves its regulatory concern. See *Bates*, 433 U.S. 350, 374 (1977). That is because the burden of proof under the First Amendment does not shift; it remains with the FTC even after the complaint is filed.

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[68] N. 50, *supra.*

The Supreme Court has held commercial speech protected even if it conveys less than complete information so long as the information it does convey is, at worst, only potentially misleading. "Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all." *Bates v. State Bar of Arizona*, 433 U.S. 350, 374 (1977) (quoted in *Central Hudson Gas & Electric Co.*, 447 U.S. 564; 100 S. Ct. 2343; 65 L. Ed. 2d 341 (1980).

The proper constitutional resort when government is confronted with such speech is to compel use of qualifications or disclaimers that render the speech nonmisleading, not to impose restrictions that render regulable speech effectively illegal because it is prohibited from future utterance unless backed by an undefined level, degree, quality, or quantity or support. The proper constitutional resort is to ensure that potentially misleading speech is qualified or disclaimed to remove the potential (to favor disclosure over suppression whenever possible). *See 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 511 (1996); *Peel v. Attorney Disciplinary Commission*, 469 U.S. 91, 100 (1991); *In re RMJ*, 455 U.S. 191, 203 (1982); *Bates v. State Bar of Arizona*, 433 U.S. 350, 357 (1980). By contrast inherently misleading commercial speech is speech that is capable of no non-misleading interpretation. *See Peel v. Attorney Disciplinary Commission*, 469 U.S. 91, 100 (1991) (citing Brief of Federal Trade Commission as Amicus Curiae) (Commercial speech is "inherently misleading" when "the particular method by which the information is imparted to consumers is inherently conducive to deception and coercion").

The FTC has never addressed in an adjudicatory case the question of whether its method of proceeding and deciding these cases complies with the requirement that it distinguish potentially misleading commercial speech from inherently misleading commercial speech and relieve the former from the requirement that it not be communicated in future unless backed by

"competent and reliable scientific evidence." That question is now squarely before your Honor. If he is to follow constitutional law, the Chief ALJ must discern that the Complaint rests on a charge of implied not literal deception,[69] he must realize that the implied claims are, at worst, only potentially misleading, and he must compel FTC to identify qualifications or disclaimers that will render the claims non-misleading rather than impose an unconstitutionally vague restriction on an entire class of advertising via the threat of future prosecution if Respondents utter advertising not backed by the ever indefinite, elusive, and mysterious "competent and reliable scientific evidence." In lieu of the order demanded by FTC Counsel compelling the Respondents to refrain from running the ads in question in future unless and until "competent and reliable scientific evidence" is found, his Honor should either craft himself, or order FTC Counsel to identify, reasonable qualifications or disclaimers that can be used to eliminate potential misleadingness. No order should issue that would restrain Respondents' future speech until his Honor places within that order a clearly defined safe harbor into which Respondents may channel their speech with confidence that they will not again be prosecuted for the commercial communication. That is, at a minimum, your constitutional duty.

An order requiring self-censorship unless and until an undefined and ambiguous "competent and reliable scientific evidence" standard is met leaves the regulatee without any means to discern what proof will suffice to satisfy his government, without any confidence that new evidence appearing adequate to the regulatee will be accepted as sufficient by his government, without any safe harbor except permanent self-censorship, and with unbridled discretion left in the hands of speech regulators at FTC – the historic bane of the First

[69] Even were literal deception found, the segments would be segregable from the whole and the remaining whole would then be, at worst, only potentially misleading. An obvious, less speech restrictive alternative would still be to save through qualification and disclaimer the remnant that is, at worst, only potentially misleading.

Amendment. See *City of Lakewood*, 486 U.S. 750, 782 (1988) ("Recognizing the explicit protection accorded speech and the press in the text of the First Amendment, our cases have long held that when a licensing statute allegedly vests unbridled discretion in a government official over whether to permit or deny expressive activity, one who is subject to the law may challenge it facially without the necessity of first applying for, and being denied, a license"). An order of that kind very surely violates the First Amendment because it does not prescribe an obvious, less speech restrictive alternative that would eliminate misleadingness. It gives the regulatee no sure guidance to navigate away from law violation; indeed, the regulatee proceeds haphazardly by necessity because he or she has no way of knowing what the law is. Thus, without the required constitutional guidance in place, a pervasive chilling effect exists which places the regulatee in the position of having to refrain from communicating at all because the regulatee cannot know with reasonable certitude what communication will be deemed lawful by the FTC and is entirely beholden to the whim and caprice of the FTC's speech regulators.

The FTCA, Section 5, requires the FTC to prove advertising false and misleading to justify imposition of a regulatory burden upon it. On its face, the statute is thus constitutional. It keeps the burden to justify restrictions on speech on the FTC throughout. Under the Avoidance Doctrine, if a statute is capable of a constitutional construction, that construction must be favored over one that is unconstitutional. *See Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568 108 S. Ct. 1392; 99 L. Ed. 2d 645 (1988), *Machinists v. Street*, 367 U.S. 740, 749-750 (1961); *Crowell v. Benson*, 285 U.S. 22, 62 52 S. Ct. 285; 76 L. Ed. 598 (1932); *Lucas v. Alexander*, 279 U.S. 573, 577 (1929); *Panama R. Co. v. Johnson*, 264 U.S. 375, 390 (1924); *United States ex rel. Attorney General v. Delaware & Hudson Co.*, 213 U.S. 366, 407-408 (1909); *United States v. Rumely*, 345 U.S. 41, 45, 97 L. Ed. 770, 73 S. Ct. 543

(1953) (The court recognized that when a statute is fairly susceptible to more than one interpretation, the interpretation most consistent with constitutionality should be adopted); *Crowell v. Benson*, 285 U.S. 22, 62, 76 L. Ed. 598, 52 S. Ct. 285 (1932) (The court determined whether a constitutional construction of the ordinance is possible in order to avoid a question of an unconstitutional construction). In this case, if the Chief Administrative Law Judge imposes an order that prohibits future communication unless it satisfies the "competent and reliable scientific evidence" standard (rather than one that requires FTC to resort to the obvious, less speech restrictive alternative of qualifications or disclaimers), the effect would be to interpret the statutory section in a way that would condone an unconstitutional outcome, for the reasons stated above. That alternative construction is thus impermissible – a violation of Section 5 of the FTCA and the First Amendment.

The Commission's Prior Rejection of First Amendment Defenses Are Inapposite.

Certain cases relied upon by the FTC are readily distinguishable. The cases are *Sears, Roebuck and Co. v. FTC*, 676 F.2d 385 (9th Cir. 1982); *Kraft,* 970 F.2d 311 (7th Cir. 1992); *In re Telebrands,* FTC Docket 9313 (September 19, 2005), *Stouffer Foods*, 118 FTC 746 (1994).

The facts of *Sears Roebuck and Co. v. FTC*, 676 F.2d 385 (1982) are entirely inapposite. The Sears ad included the literally false claim that its dishwasher "completely eliminated" the need for pre-scraping and pre-rinsing (a claim directly contradicted by Sears' own product owner's manual). *Id.* at 387-388. Sears did not contest the literal falsity charge; Sears only challenged the scope of relief in the FTC's order. *Id.* at 388-389. Sears' First Amendment argument contested the propriety of the FTC Order's broad fencing in provision on the basis that it would reach not the speech it had made admitted to be deceptive but new ad content. The Ninth Circuit rejected the challenge but did so expressly limit its decision to "the context of the

particular advertising claims before" the Court which were "wholly commercial in nature" containing "no material or comments having any relation directly or indirectly to any non-commercial First Amendment interests." *Id.* at 399. The Court expressly limited its analysis "to advertisements of this nature." *Id.*

Given the presence of admitted literal falsity from a repeat offender (having committed "flagrant violations of the Act repeated over a four year period, *id.* at 399-400), the Court found no justification for restricting the fencing in order and found no basis to permit a First Amendment challenge. *Id.* at 398-400. Here, by contrast, there is no claim of literal falsity; no admission of guilt; and speech that is imbued with and supported by a wealth of science. The challenge is not to the imposition of an order after a finding of literal falsity. The case is this wholly inapposite and not controlling.

The facts of *Stouffer Foods*, 118 F.T.C. 746 (1994) are inapposite. Stouffer made a nutrient content low sodium claim determined to be false because the Lean Cuisine product contained almost 1 gram of sodium. *Id.* at n.*5. Stouffer did not challenge the charge that its low sodium claim was either material or false. *Id.* at n.*18. Rather, Stouffer argued that other claim language (that the product has a superior taste) contracts the low sodium message, yet offered no proof to that effect. *Id.* at n. *18. Stouffer argued that a valid consumer survey to test its theory was constitutionally required under the First Amendment. The Commission rejected the argument finding the ad itself to directly convey the low sodium message and finding the notion that representations of superior taste contradicted the express low sodium claim not credible. *Id.* at n. *7-9. Here, there are no literally false claims, and there is no admission of falsity. *Stouffer Foods* is thus not controlling.

Bristol-Myers v. FTC, 738 F.2d 554, 562 (2d Cir. 1984) concerned comparative claims of product superiority through the use of establishment claims (e.g., Bufferin relieves pain faster than aspirin; Bufferin will upset a person's stomach less frequently than aspirin; Excedrin is a more effective pain reliever that aspiring or any other OTC analgesic). *Id.* at 557. At the time, the FTC required objective proof to support the claims: "two adequate, well-controlled clinical studies [...]." *Id.* at 558. The Court thus determined the objective measure not unconstitutionally vague. Moreover, the claim of superiority was capable of specific scientific proof but that proof was not adequate, and, so, the claims were "open to substantial question." *Id.* at 559. Unlike in *Bristol-Myers*, here the alleged misleading implied claims have no quantitative standard against which they can be measured "rapid," "substantial," and "visibly obvious" and are wholly subjective, whereas a comparative claim of product superiority based on superior pain relief is objectively verifiable. In addition, the standard deferred to by the Court in *Bristol-Myers* was itself objective (two adequate, well-controlled clinical studies). That affords a clear safe harbor that "competent and reliable scientific evidence" does not. Thus, *Bristol-Myers* does not control disposition of this case – the facts are inapposite and the FTC deferred to is not longer followed by the FTC.

In *Pharmtech*, the advertiser represented that a dietary supplement containing "at most [the] equivalent [of] 4.2 servings of fresh cabbage per month," *id.* at 295, reduced cancer risk in the same way as daily consumption of cruciferous vegetables. *Id.* at 296-297. The statement was "false," *id.* at 300, because the single report and sole evidence relied upon to support the claim "flatly contradicted" the very claim made. *Id.* at 302. The court thus found no First Amendment defense for the demonstrably false statement. *Id.* Thus, *Pharmtech* is inapposite.

In *Kraft*, that company advertised that its imitation cheese singles had "five ounces [of milk] per slice" and equated the calcium in five ounces of milk with that in its imitation cheese single when cheese processing actually caused the imitation singles to have 30% less calcium than five ounces of milk. *Id.* at 314-315. *Kraft* argued that FTC's failure to rely on extrinsic evidence to prove the implications alleged violated the First Amendment. *Id.* at 320. The Court rejected the *Kraft* argument because the "alleged deception although implied" was "conspicuous," *citing Zauderer*, 471 U.S. at 652-653. The falsity (the fact that the imitation cheese singles were not equal to five ounces of milk in calcium content) was conspicuous because an objective measure of falsity was apparent without need for resort to extrinsic evidence assessing consumer perception. *Id.* Here, by contrast, there is no objective measure that is conspicuously false. The allegedly implied claims of "rapid," "substantial," and "visibly obvious" have no quantitative reference. They are wholly subjective and, unlike in *Kraft*, to prove that they mislead requires objective evidence of consumer perception but FTC Counsel has no such evidence. Hence, *Kraft* is not controlling.[70]

In the Matter of Telebrands Corp., involves literal falsity and no substantiation. It is entirely inapposite. The claims there in issue were, thus, inherently misleading and the First Amendment challenge was readily rebuffed. Here, the case depends on a charge of implied deception and concerns claims backed by a substantial quantum of scientific evidence proving the effectiveness of the products. The case is readily distinguishable.

Deceptive Advertising Standard. FTC applies a three part test to determine whether advertising is deceptive under Section 12 of the FTCA. The Chief Administrative Law Judge

[70] Indeed, Kraft calls on FTC to obtain that empirical proof. *See* "The way to avoid this chilling effect, according to Kraft, is to require the Commission to rely on objective indicia of consumer perceptions in finding implied claims," at 321, but FTC Counsel has not heeded that call.

must determine (1) whether the claim was made; (2) whether the claim was likely to mislead a reasonable consumer; and (3) whether the claim was material. *Novartis Corp. v. FTC*, 223 F.3d 783 (D.C. Cir. 2000).

Advertising may be deemed subject to regulation under the FTCA not only where there is proof of actual deception but also where the statements in issue have a capacity or tendency to deceive. A capacity or tendency to deceive is said to arise when there is a likelihood or fair probability that the reader, listener, or viewer will be misled. The advertising is to be reviewed to discern the ultimate impression upon the mind of the reader, listener, or viewer from the sum total of not only what is said but also what is reasonably implied. *See, e.g., FTC v. Sterling Drug, Inc.*, 317 F.2d 669 (2d Cir. 1963); see also FTC's October 14, 1983 Policy Statement on Deception, appended to *In re Cliffdale Associates*, 103 F.T.C. 110 (1984).

In this case there is not one shred of evidence of actual deception. FTC bases its case entirely on a theory of a likelihood of that consumers will be deceived by implications said, but not shown by empirical evidence, to arise from the claims.[71] The empirical evidence that does exist (see RX 828) contradicts the view of consumer perception offered by FTC Counsel and confirms that consumers in fact are highly skeptical of the ad claims.

FTC has alleged implied claims of "rapid" and "visibly obvious" for the Aminophylline gel products. Complaint; CX-001 at 8-9. It has implied that the PediaLean advertising represented that the product causes "substantial" weight loss. CX-001 at 16-17. Implied claims, under FTC's precedent, are found properly only when there is an examination of the representation itself, including an evaluation of such factors as the entire document, the

[71] One could say that FTC lacks competent and reliable evidence that the claims in issue deceive if that term is defined as credible empirical evidence that the ads in fact convey to consumers the meaning FTC presumes the ads to have. We ask the question: who has the burden of proof?

juxtaposition of various phrases in the document, the nature of the claim and the nature of the transaction. *In re American Home Products*, 98 FTC 136, 374 (1981) aff'd 695 F2d. 681 (3d Cir. 1982); *In re Warner-Lambert Co.*, 86 FTC 1398, 1489-90 (1975), aff'd 562 F.2d 749 (D.C.Cir. 1977); cert. denied, 435 US 950 (1978); *In re Firestone Tire & Rubber Co.*, 81 FTC 398, 456 (1972), aff'd, 481 F.2d 246 (6th Cir.), cert. denied 414 U.S. 1112 (1973). Under its own precedent, FTC must establish the existence of an objective product claim i.e., one, that can be proven true or false. *In re Thompson Medical Center*, 104 FTC 648 (1984); *In re Removatron* . FTC precedent on implied claims acknowledges a significant limitation: when an implied claim is not obvious, extrinsic evidence is required. *In re Telebrands Corp.*, Docket No. 9313, Opinion of the Commission at 8 (Sept. 19, 2005)(unpublished opinion) (citing *Novartis Corp.*, 127 FTC 580, 680 (1999), aff'd 223 F.3d 783 (D.C.Cir. 2000)). Moreover, implied claims cannot be deceptive if the ad contains contrary elements that effectively negate or qualify the implied claims. *In re Stouffer Foods*, 118 FTC 746, *18 (1994)(citing *Kraft*, 114 FTC at 123; *Removatron Int's Corp.*, 111 FTC 206 , 294 (1988), aff'd 884 F.2d 1489 (1st Cir. 1989)). Here the implied claims are not obvious. Given evidence of widespread consumer skepticism, they are counterintuitive. Moreover, the implied claims are so highly subjective in their terms as to lack sufficient meaning to be "obvious." Ambiguous terms as "rapid," "visibly obvious," and "substantial" elude all--lay people even FTC's linguist and market expert. Those terms beget no fixed objective reference and so are largely meaningless. They cannot form the basis of liability under *In re Telebrands*. Therefore FTC's failure to adduce empirical evidence to support them is damning. The FTC's argument on implied claims is unjustified and must be rejected.

Unlike *Kraft* and *Telebrands*, the challenged subjective implied claims here are not obvious from the face of the ads. For example, the Aminophylline gel ads give differing

timelines, 30 days or 19 days for when consumers can expect to see their results (or even 10 days when consumers might expect to begin to see results) from the topical application of the gel for localized fat loss. RX 828. Those time periods are not obviously "rapid." "Rapid" is a subjective term that could mean minutes, hours, days or weeks. Rapid in comparison to what one might ask? A frog is rapid in comparison to a slug but a frog is not rapid in comparison to a jack rabbit. That extreme subjectiveness and lack of a fixed reference makes the allegedly implied claim one that should not be the basis for prosecution.

The implied claims of "rapid," "visibly obvious" and "substantial" are subjective claims not provably false. They are not even capable of being defined by reference to further synonyms as seen in the Commission's own expert reports. "Rapid means fast" and "substantial means a lot." But "fast" is no less subjective than "obvious." "A lot" is no less subjective than "substantial." The subjectiveness of what would be "visibly obvious" when taken in the context of a fat loss agent applied topically to the tummy and thighs prevents proving the statement true or false. While a specific measurement of fat loss is shown in published studies of aminophylline, there is no way of knowing whether a reasonable consumer would consider those measured amounts to be "visibly obvious" despite the fact that they do indeed occur (that the substance caused fat loss when applied topically). The Commission has not brought advertising cases based on subjective claims (taste, feel, appearance, or smell) because subjective claims are "unlikely to deceive consumers acting reasonably." Deception Policy Statement RX 006. Similarly if "rapid" may be implied from the advertising then it is so obviously exaggerated as to be meaningless puffery, a claim that ordinary consumers in this weight loss marketplace will not take seriously. *Pfizer, Inc.*, 81 FTC 23, 64 (1972).

Empirical Evidence Contradicts FTC. There is empirical evidence directly contradicting the FTC's claimed deception. That evidence reveals consumers to be highly skeptical of weight loss advertising and to believe little or none of it. *See* Trottier, K, Polivy, J, Herman, P. Effects of Exposure to Unrealistic Promises about Dieting: Are Unrealistic Expectations about Dieting Inspirational? Int J Eat Disord 2005; 37:142-149, RX 828, RX055. (RX-416, Dermalin APg Information Communication Study); see also Andrews, JC, Netemeyer, RG, Burton S. Consumer Generalization of Nutrient Content Claims in Advertising. Journal of Marketing 62:62-75, Oct 1998.[72] For decades the marketplace has been inundated with information from the FTC and the private sector, challenging the ability of any non-drug means for achieving weight loss. *See* United States, Mexico, Canada (MUCH) Combat Weight Loss Fraud; http://www.ftc.gov/opa/2005/10/much.htm, October 24, 2005. There is simply no foundation for FTC Counsel's presumption that consumers expect Respondents' products to produce specific quantitative amounts of weight loss or fat loss.

In evaluating whether advertising claims are deceptive, the claims must be likely to mislead reasonable consumers under the circumstances. While the test is a reasonable consumer, FTC has interpreted (before *Central Hudson* elevated commercial speech to First Amendment protected status) that it was appropriate to view persons who do not understand the advertisement due to a lack of sophistication as appropriate subjects for a finding of deception. *In re Kirchner*, 63 FTC 1282 (1963). Post-*Central Hudson*, the Commission, consistent with the First Amendment, cannot paternalistically assume that consumers are ignorant and/or unsophisticated. It must prove that naivete with empirical evidence. *Pearson v. Shalala*, 164 F.3d. 650, 655

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[72] Calfee JE, Ringold, DJ. Consumer Skepticism and Advertising Regulation: What Do the Polls Show? Adv in Cons Res 15: 244-248, 1988; Ford, GT, Smith DB, Swasy, JL. Consumer Skepticism of Advertising Claims: Testing Hypotheses from Economics of Information. Journal of Cons Res 16: 433-441, 1990.

(D.C.Cir. 1999) (rejecting the Government's argument that consumers could not exercise judgment at the point of sale, stating: "It would be as if the consumers were asked to buy something while hypnotized, and therefore they are bound to be misled. We think this contention almost frivolous")(citing *Peel v. Attorney Registration and Disciplinary Comm'n of Illinois*, 496 U.S. 91, 105 (1990)(rejecting paternalistic assumption)); *see also Bates v. State Bar of Arizona,* 433 U.S. 350, 375 (1977)("We view as dubious any justification that is based on the benefits of public ignorance."); *cf. 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996)(opinion of Stevens, J., Kennedy, J., and Ginsburg, J.)("The First Amendment directs us to be especially skeptical of regulations [of indisputably non-misleading information] that seek to keep people in the dark for what the government perceives to be their own good").

Further, when an advertisement is targeted to a specific audience, the Commission must determine the effect of the practice on a reasonable member of that group. Deception Policy Statement attached to *Cliffdale Associates, Inc.* 103 FTC 110 (1984). Determining whether an ordinary reasonable consumer would be deceived is thus a multi-faceted test. That FTC Counsel has failed the test, for want of proof. None of FTC's experts have assessed the specific target audiences to which Respondents have directed their ads. The Commission must consider the totality of the ad or the practice, the clarity of the representation, the conspicuousness of the qualifying information, the importance of the omitted information (if any), and the familiarity of the public with the product or service. *In re D.L. Blair Corp.*, 82 FTC 234, 255-256 (1973)(body of ad corrected possibly misleading headline because contest entry required consumers read entirety of ad for entry).

The capacity of an advertisement to deceive consumers is judged by the impression conveyed by the entire advertisement, not by the impact of isolated words and phrases. *FTC v.*

Pharmtech Research, Inc., 576 F.Supp. 294, 301 (D.D.C. 1983)(citing *Beneficial Corp. v. FTC*, 542 F.2d 611, 617 (3rd Cir. 1976) cert. denied 430 U.S. 983 (1977); *Murray Space Shoe Corp. v. FTC*, 304 F.2d 270, 272 (2d Cir. 1962)). That standard contrasts sharply with the cursory analyses offered by FTC witnesses Drs. Mazis and Nunberg. Both weigh and analyze words selectively, in a hypothetical construct never tested in the real world, outside of the context of the entirety of the advertisements (in which they do not appear but are implied).

In contrast to the FTC policy of evaluating advertising as a whole and claims in context, FTC's witness Mazis gleans certain statements from the ads in his expert report, making no reference to their context and uses them to find implied claims and deceptive advertising. *FTC v. Sterling Drug*, 317 F.2d 669, 674 (2d Cir. 1963). He ignores clear and conspicuous disclaimers and qualifying language that alerts consumers to aspects of the product and its costs. Although Mazis does not employ a consumer sample, *we know that the inferences consumers will take away from each ad ("pragmatic implications" according to Mazis) will differ depending on each consumer's knowledge and past experiences.* His facial analysis does not contemplate this fact, does not address it, and provides no sense for what proportion of consumers would reach any particular conclusion. Rarely if ever will a consumer study provide results at all close to 100%, and findings of 5%, 10%, 20%, and so forth are common, in terms of consumer perceptions. The facial analysis appears to present everything as 100%, however, which is entirely unrealistic. This danger of failing to represent individual consumer differences is exacerbated by the fact that the facial analyses presented in the Mazis report do not make any evident effort to focus in on the specific target market of consumers for each product, and do not seem capable of taking the special levels of knowledge, interest, and/or experience of the targeted consumers into account.

Moreover, this is not a case of fine print or *pro forma* disclaimers. This is not a case where consumers would not take the time or care to read the "fine print disclaimer." *Cf. In re Giant Food, Inc.*, 61 FTC 326, 348 (1962). Nor is this a case where repetitive and all too familiar disclaimer language is proffered as curative of deceptive claims. *Warner Lambert*, 86 FTC 1398, 1414 (1975) aff'd 562 F.2d 749 (D.C.Cir. 1977). In bold and large print is the statement in the Dermalin, Cutting Gel, and Tummy Flattening Gel advertisements, "So What's the Catch?" Immediately after that consumers are told: that they need to exercise while using the gels so that the fat that is released is not redeposited and that consumers can't rub the gel all over their bodies at the same time because it would not be effective. CX-001 at 7. *See also* Trottier, K, Polivy, J, Herman, P. Effects of Exposure to Unrealistic Promises about Dieting: Are Unrealistic Expectations about Dieting Inspirational? Int J Eat Disord 2005; 37:142-149.

The Commission's ponderings of *Porter & Dietsch*, 90 FTC 770, 864-865 (1977) aff'd 605 F.2d 294 (7th Cir. 1979) cert. denied 445 US 950 (1980) are outdated in this marketplace 20 years later where years of FTC awareness efforts and inundation with weight loss product advertising has left the reasonable consumer skeptical and unimpressed with weight loss advertising claims. Moreover, any analysis of the disclaimers present in Respondents advertising must be evaluated under the recent Supreme Court precedent recognizing the importance of disclaimers in commercial speech for curing potential misleading speech. See also, *Pearson v. Shalala*, 164 F.3d at 567; *Bates v. State Bar of Arizona,* 433 U.S. 350, 376 (1977); *see also Peel v. Att'y Registration and Disciplinary Comm'n*, 496 U.S. 91, 110 (1990), *In re R.M.J*, 455 U.S.191, 206 n.20 (1982); *Shapero v. Kentucky Bar Ass'n*, 486 U.S. 466, 478 (1988). FTC's prior history of largely ignoring disclaimers or minimizing their effectiveness is based on case law pre-dating the current position of the Supreme Court and is based on conjecture rather than

actual study of consumers views of disclaimers. The most recent decisions of the Supreme Court on commercial speech make it clear that if the "Government can achieve its interest in a manner that does not restrict speech, or that restricts less speech, the government must do so." *Thompson v. Western States Medical Center*, 535 US 357, (2002).

The Commission has recognized in prior cases where empirical evidence was submitted to establish implied claims that consumers bring with them pre-existing beliefs about alleged advertising and that those beliefs create a potential for bias in a survey. *In re Stouffer Foods*, 118 FTC 746, * 35 (1994). That potential for bias further elevates the need for empirical evidence to measure consumer perception of a particular type of advertising among a particular category (or categories) of consumers. Without correcting for bias in a survey the survey suffers a critical defect. *Id.* (citing *Kraft*, 114 FTC at 123). Having not addressed any pre-existing beliefs of the identified target audience (or even evaluating the specific target audience), the facial analysis suffers the same kind of critical defect. It is but biased pronouncement unworthy of FTC credence. Mazis' analysis is thus flawed and directly contradicted by the contrary evidence that consumers are skeptical of weight loss advertising.

The Subjective Implied Claims Are Not Material. Materiality of claims is a foregone conclusion when the Commission is permitted to presume to be implied any claims that it sees fit. It can, as it has done in this case, find implied claims of purpose, safety, efficacy, or cost of a product. Here the Commission has implied claims of "rapid," "substantial,"and "visibly obvious." There is no reliable evidence, beyond the supposition of the Commission, that those implied claims would be the basis for a consumer in the target audience to make a purchasing decision. Similarly, the Commission considers express claims to be material. However, just because a claim is express does not mean a consumer would rely upon it in making a purchasing

decision. While FTC ordinarily presumes without evidence that the presence of a money back guarantee makes no difference to consumers in purchasing decisions, in this case Respondents have produced a mall study showing exactly the opposite. RX-416.[73] Moreover, the money back guarantee makes the injury reasonably avoidable so consumers can recoup their cost for a product that does not perform as expected. Section 5(n). Respondents' records show that, in fact, numerous consumers for whatever reason sought a refund under that guarantee and received it. Findings, *supra*. Under the "unfairness" test of Section 5 of the FTCA, one element is that the act caused unjustified consumer injury. Unjustified consumer injury is a three part test: (1) the injury must be substantial; (2) it cannot be outweighed by any offsetting consumer or competitive benefits that the sales practice also produces; and (3) the injury must be one consumers cannot reasonably have avoided. Unfair acts or practices challenged by FTC are typically sales techniques that unjustifiably prevent effective consumer decision making. Otherwise, in the past the Commission has taken the position that individual consumers are capable of making their own private purchasing decisions in a free market economy without regulatory intervention and second-guessing by the government. See *Orkin Exterminating Co., Inc.* 849 F.2d 1354, 1365 (11th Cir. 1988). Respondents' money back guarantee avoids any basis for finding an unavoidable economic injury.

While the reasonable consumer is a skeptic, the scientific evidence on point confirms the effectiveness of the non-drug products at issue. There is thus no basis for concluding that consumers expect any more scientific support than exists for the effectiveness of these products.

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[73] Respondents' money back guarantee was on every advertisement of the challenged products in typeface equal to the type in the majority of the rest of the advertisement (except headings). See RX 182, RX 269, RX 381, RX 456, RX 781.

Indeed, truth be told, consumers likely expect the products to be far less effective than they actually are based on the scientific evidence.

Respondents Had a Reasonable Basis for the Allegedly Implied Claims. Section 5 requires a manufacturer to have a 'reasonable basis' for any affirmative performance claims for a product. *Pfizer, Inc.*, 82 FTC 23, 62 (1972); *see also PharmTech*, 576 F.Supp. at 302 (citations omitted). Without a reasonable basis[74] the advertising is unfair. *Id.* In *Pfizer* the FTC found that the tests that form the reasonable basis for an advertiser's performance claims must have been conducted prior to, and actually relied upon in connection with, the marketing of the product in question. 81 FTC 23 (1972). That "prior substantiation doctrine" has not been applied to exclude exculpatory evidence that confirms pre-claim evidence to be true. That doctrine also predates the commercial speech precedent that is controlling law now. *See Central Hudson*, 447 U.S. 557 (1984)(12 years after *Pfizer*); *see also, In re R.M.J.*, 455 U.S. 191, *Bolger v. Youngs Drug Products*, 463 U.S. 60 (1983), *Thompson v. Western States Medical Center*, 791 F.2d 189. *Pfizer*'s prior substantiation doctrine is, thus, not good law on the facts of this case. Here, Respondents were aware of FDA's decision holding that lecithin gel is an appropriate delivery vehicle for topically applied active ingredients. RX 828. They also had, as Paul Lehman testified, test results confirming that the medium permeated through the dermis and would reach the adipose tissue and fat cells. *See* Paul Lehman Depo. (pending record exhibit). Thus, the post-complaint Greenway and Bray study reconfirming proof of the product's efficacy is exculpatory additional validation that should not be excluded.

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[74] In *Bristol-Myers v. FTC*, 738 F.2d 554, 560 (2d Cir. 1984) the Second Circuit noted that FTC has defined reasonable basis to consist of "competent and reliable scientific evidence" in the order in that case and in 21 litigated orders and 126 consent orders involving advertising substantiation.

In contrast to the commercial speech precedent above, the Commission states that it limits its consideration of post-claim substantiation to the following circumstances: (1) to determine whether a public interest exists in proceeding against the advertiser; (2) to assess the adequacy of the pre-claim substantiation that the advertiser had; and (3) to determine the appropriate scope of an order to be entered against a firm lacking adequate substantiation. Substantiation Policy Statement; RX-005 at 3. FTC states in its policy statement, in direct contrast to the position the Chief ALJ has proof confirming the adequacy of pre-claim substantiation is relevant and admissible. *Id.* Thus, the exculpatory evidence obtained post-claim is still relevant and determinative of the validity of the claims at issue and should be allowed under (a) above.

In *Pfizer* the FTC held that a consumer is entitled to expect an advertiser to have a reasonable basis for any performance claims. The burden of proof is on the advertiser to show that the evidence in support of its claims are sufficient and show a good faith belief that the claims are true. Under *Pfizer*, FTC will consider five factors to make that determination: (1) the nature of the product involved; (2) the nature of the claim; (3) the likelihood and degree of harm to consumers if the claim is false or misleading; (4) the degree of reliance on the claim by ordinary prudent consumers acting reasonably under the circumstances; (5) the accessability and cost of substantiating the subject product claim. Assuming for the moment that the Chief Administrative Law Judge and the Commission will evaluate this case using the *Pfizer* factors despite the fact that they pre-date *Central Hudson* and are not controlling therefore, it is obvious that under *Pfizer* FTC has failed to prove its case. It has no proof under two of the five elements necessary under *Pfizer*. It has no proof consumers had any particular expectation of a certain level of substantiation for the allegedly implied claims. The Commission also has no evidence

that the substantiation necessary to meet its standards (albeit yet unexplained to Respondents) is "accessible" and of a cost sufficiently reasonable to be performed.[75]

[* * REDACTED * *] *Id.*

There is empirical evidence directly contradicting the FTC's claimed deception. That evidence reveals consumers to be highly skeptical of weight loss advertising and to believe little or none of it. Trottier, K, Polivy, J, Herman, P. Effects of Exposure to Unrealistic Promises about Dieting: Are Unrealistic Expectations about Dieting Inspirational? Int J Eat Disord 2005;

[75] Indeed, if Heymsfield's impossibly high standard (beyond even that which FDA requires for weight loss drug approval) were required, not even $802 million (the average cost of a new drug approval application process) would suffice. Clearly beyond the means of Respondents. www.phrma.org/newmedicines/newmedsdb/phases.pdf

37:142-149.[76] For decades the marketplace has been saturated both from the FTC and the private sector with information challenging the ability of any non-drug means for achieving weight loss. *See* United States, Mexico, Canada (MUCH) Combat Weight Loss Fraud; http://www.ftc.gov/opa/2005/10/much.htm, October 24, 2005. There is simply no foundation for the Commission's presumption that consumers expect dietary supplements for weight loss to work, and that consumers expect dietary supplements, for weight loss to work to a degree that the Commission claims has been promoted and advertised here.

While the reasonable consumer is a skeptic the empirical data tells us, the scientific evidence on point confirms the effectiveness of the non-drug products at issue. And, there is no basis for concluding that consumers expect any more scientific support than exists for the effectiveness of these products. Indeed, truth be told, consumers likely expect the products to be far less effective than the scientific evidence confirms they are.

Moreover, it is both counterintuitive and unreasonable for the Chief Administrative Law Judge to presume that a reasonable consumer would expect only large scale, prospective, randomized, double-blind, placebo controlled clinical trials of conclusive result to be the only acceptable evidence to support the claims made (a position taken by FTC Counsel through its expert Dr. Stephen Heymsfield who would have Respondents conduct large scale, prospective, randomized, double-blind, placebo controlled clinical trials of the kind that cost $802 million to pharmaceutical companies). For the six products in issue here (four different formulas) that would require an outlay of 4.8 billion dollars according to the recent estimate to prove

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[76] Calfee JE, Ringold, DJ. Consumer Skepticism and Advertising Regulation: What Do the Polls Show? Adv in Cons Res 15: 244-248, 1988; RX 055; RX 416, Dermalin APg Information Communication Study); see also Andrews, JC, Netemeyer, RG, Burton S. Consumer Generalization of Nutrient Content Claims in Advertising. Journal of Marketing 62:62-75, Oct 1998; Ford, GT, Smith DB, Swasy, JL. Consumer Skepticism of Advertising Claims: Testing Hypotheses from Economics of Information. Journal of Cons Res 16: 433-441, 1990.

Respondents claims true to Dr. Heymsfield's satisfaction. No dietary supplement company could afford that. Only pharmaceutical companies such as Dr. Heymsfield's employer, Merck, can compete in such a marketplace. Not only did Respondents comb the literature that was publicly available for the design of their products and the advertising claims that would be substantiated by that literature, in the case of aminophylline, they conducted independent studies on the Aminophylline gel products. They have been diligent and have expended enormous resources to develop their products in accordance with the science.

There is in fact and in logic neither a likelihood nor a fair probability that a reader, listener, or viewer would be misled by the ads in question because he or she anticipated more substantiation for the weight loss or fat loss claims than expressly stated in the ads. Accordingly, under the appropriate standard of review, FTC has failed to satisfy its burden of proof; there is no basis for concluding that the ads are deceptive; and the Chief Administrative Law Judge should so hold.

Unfair and Deceptive Acts or Practices. Under Section 5 of the FTCA, the advertising practices here in issue are not unfair or deceptive.[77] There is no reasonable potential for deception by consumers acting reasonably under the circumstances. *See Southwest Sunsites, Inc. v. FTC*, 785 F.2d 1431 (9th Cir. 1986); *In the Matter of Cliffdale Associates, Inc.*, 103 F.T.C. 110, 1984 FTC LEXIS 71 (March 23, 1984) (A company is not liable for every interpretation or action by a consumer; an advertiser cannot be charged with liability for every conceivable misconception, however outlandish, to which his representations might be subject among the

[77] Section 12(b) of the FTCA states that the dissemination or the causing to be disseminated of any false advertisement with the provision of subsection (a) of this section shall be an unfair or deceptive act or practice in or affecting commerce within the meaning of section 45 of this title.

foolish or feeble-minded); *Heinz W. Kirchner*, 63 F.T.C. 1282, 1290 (1963).[78] As explained *supra*, the empirical evidence reveals the audience for weight loss advertising to be highly skeptical that products promoted for weight loss yield any weight loss. In this case, the products do produce, in the case of the ephedra, caffeine and aspirin dietary supplements, weight loss on average of 6 to 10 pounds per month; in the case of the fiber dietary supplements, fat loss equal to 20% or more of excess body fat; and in the case of the gels, localized fat reduction. The reasonable expectations of consumers in this market are exceeded by the performance of these products. They are not the equals of those products that promise physiological effects but lack ingredients capable of achieving them. They are not the *Telebrands* product – contrary to FTC Counsel's conjecture. Here the supportive evidence abounds; there the evidence was non-existent.

Respondents products did not, and are not likely to, cause substantial injury. To the contrary, use of them provides salutary benefits resulting from reduction in weight, reduction in fat, and improvement in appearance. There is, indeed, no reasonable potential for injury of any kind through use of the products as directed and, in fact, despite sales for over 5 years there has been no significant injury reported of any kind. Any potential injury derived from consumer misperception is more than outweighed by benefits to consumer health resulting from use of the products.

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[78] Some people, because of ignorance or misunderstanding, may be misled by even a scrupulously honest claim. Perhaps a few misguided souls believe, for example, that all "Danish pastry" is made in Denmark. Is it therefore an actionable deception to advertise "Danish pastry" when it is made in this country? Of course not. A representation does not become "false and deceptive" merely because it will be unreasonably misunderstood by an insignificant and unrepresentative segment of the class of persons to whom the representation is addressed. *Heinz W. Kirchner*, 63 F.T.C. 1282, 1290 (1963).

The FTC had no sound reason for believing that Respondents violated the FTCA prior to initiating this enforcement proceeding. The products include ingredients well known for their physiological properties and the advertising in question reflects the understood effects of those products. There was, from the products, no basis to believe they would be less than fully effective.

The FTC's action in prosecuting Respondents does not serve the public interest. The public interest is served by government action that complies with the requirements of the First and Fifth Amendments, the FTCA, the APA, and basic principles of equity. As explained herein, all of those have been violated in this case.

Thus, the advertising in question is not of a kind that reflects an unfair or deceptive practice under the FTCA. The absence of any basis for a holding of deception under Section 12 of the FTCA also belies a finding of an unfair or deceptive act or practice under Section 5.[79] *See, e.g., Simeon Management Corp.*, 87 F.T.C. 1184, 1219 (1976), aff'd, 579 F.2d 1137 (9th Cir. 1978); *Porter & Dietsch*, 90 F.T.C. 770, 873-74 (1977), aff'd, 605 F.2d 294 (7th Cir. 1979), cert. denied, 445 U.S. 950 (1980).*Chrysler Corp. v. FTC*, 561 F.2d 357, 363 (D.C. Cir. 1977); *Charles of the Ritz Dist. Corp.*, 143 F.2d 676, at 679-80 (2nd Cir. 1944)).

C. THE COMPETENT AND RELIABLE SCIENTIFIC EVIDENCE STANDARD IS A RULE OF GENERAL APPLICABILITY ADOPTED WITHOUT NOTICE AND COMMENT, AND INDEED WITHOUT ANY AUTHORITY, IN VIOLATION OF THE APA

[79] Section 5 of the Federal Trade Commission Act prohibits "unfair or deceptive acts or practices." There are three elements necessary for finding of deception: (1) there must be a representation, omission, or practice that is likely to mislead the consumer; (2) the act or practice must be considered from the viewpoint of a consumer acting reasonably under the circumstances; and (3) the representation, omission, or practice must materially mislead the consumers to their detriment. *See* FTC Policy Statement on Deception, appended to *In the Matter of Cliffdale Associates, Inc.*, 103 F.T.C. 110, 170 (1984).

In every case brought by the FTC against an advertiser of weight-loss products pursuant to Sections 5 and 12 of the FTCA, the Commission and the Chief Administrative Law Judge, in the advent of *Sterling Drug v. FTC*, hold that an advertiser deemed to have advertised without "competent and reliable scientific evidence" has violated Section 5 and 12 of the FTCA. *See Sterling Drug, Inc. v. FTC*, 741 F.2d 1146, 741 F.2d 1146; 1984 U.S. App. LEXIS 19141 (9th Cir. 1984); *Jerome Milton, Inc. v. FTC*, 734 F. Supp. 1416 734 F. Supp. 1416; 1990 U.S. Dist. LEXIS 2736 (N.D. Il. 1990); *Bristol-Myers Co. v. FTC*, 102 F.T.C. 21, 321, aff'd, 738 F.2d 554 (2d Cir. 1984), cert. denied, 469 U.S. 1189, 105 S. Ct. 960, 83 L. Ed. 2d 966 (1985); *In re Pfizer Inc.*, 81 F.T.C. 23 (1972); *American Home Products, supra*, 695 F.2d at 691-93. This holding, which results in a determination that no such advertising may lawfully be made in future absent "competent and reliable scientific evidence," is the application of a rule of general applicability. The Commission has expressly testified before Congress that this standard is "Commission law." RX 001. The Commission has also repeatedly instructed the regulated class that they are obligated under Sections 5 and 12 of the FTCA to possess "competent and reliable scientific evidence" before making a weight-loss claim in advertising. RX 005. In FTC Counsel's Complaint in this case, they once again seek an order forbidding Respondents from making any of the challenged claims and any similar claims without possessing in advance "competent and reliable" scientific evidence. FTC Complaint at 6. FTC attempts to separate itself in this case from its prior statements to industry and contradicts its position where it has argued to the Ninth Circuit that its Guides created liability. *See Garvey*, at 903; *see also* 16 C.F.R. Part 17 ("industry guides are administrative interpretations of laws administered by the Commission for the guidance of the public in conducting its affairs in conformity with legal requirements...Failure to

comply with the guides may result in corrective action by the commission under applicable statutory provisions").

All rules of general applicability wrought by administrative agencies cannot – consistent with the APA, 5 U.S.C.S. § 553(b) – be applied unless and until they have been adopted following notice to the public in the Federal Register of the agency's intent to adopt the rule and opportunity for comment. For a rule to be considered valid, an agency must provide notice in the Federal Register of its intentions to create such a rule and an opportunity for interested parties to comment on it. *See e.g., U.S. v. Seward*, 1981 U.S. App. LEXIS 21300 (10th Cir. 1981)(citations omitted).

There is nothing unique about weight loss and fat loss claims among that category of products. FDA has defined claims for low calorie, high vitamin C, and low tar in rule-making; there is nothing preventing FTC from defining in rule-making the substantiation necessary for specific weight loss claims. The statutory language in section 12 of the FTCA is

> It shall be unlawful for any person, partnership, or corporation to disseminate, or cause to be disseminated, any false advertisement...

False advertisement is defined in Section 15 as

> an advertisement, other than labeling, which is misleading in a material respect; and in determining whether any advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound or any combinations thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual.

Respondents do not take issue with that standard as Congress has articulated it. However, this agency has gone far beyond the statutory language for deceptive advertising and has held parties to have violated the FTCA based on a finding that their proffered substantiation failed to met a

standard for substantiation that does not appear in the FTCA or in rulemaking, a standard that is, in reality, impossible to pin down – so inexact as to evade the grasp of a reasonable mind.

The APA states, in pertinent part, that prior to the issuance of a substantive rule,[80] an agency such as FTC shall provide notice of its rulemaking intentions, and such notice shall be published in the Federal Register. 5 U.S.C. § 553.[81] The APA also requires an opportunity for public participation in the rulemaking process and publication of the final rule, including a concise statement of its basis and purpose, thirty days before its effective date. 5 U.S.C. 553 (b)-(d); *see also: North American Coal Corporation v. Director, Office of Workers' Compensation Programs*, 854 F.2d 386, 388 (10th Cir. 1988).

The Commission's competent and reliable scientific evidence standard is a substantive rule. It establishes a standard of conduct that has the force of law. It is a separate obligation owed by the regulated class. In addition to conveying messages that are truthful and non-misleading, the Commission requires that those messages be supported by a particular nature, degree, quality, and quantity of proof but never defines that proof requirement beyond the vacuous definition it offers for "competent and reliable scientific evidence." *See* Complaint, CX-001 at 19("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 "). The Commission has invoked its rulemaking powers to require

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[80] A substantive rule "establishes a standard of conduct" having "the force of law." *American Mining Congress v. Ray F. Marshall*, 671 F.2d 1251, 1263 (10th Cir. 1982). Once codified, a substantive rule serves as a standard against which facts are later compared to determine whether certain requirements have been satisfied. *American Mining Congress*, 671 F.2d at 1263.

[81] Adequate notice shall include "(1) a statement of time, place, and nature of public rule making proceedings, (2) reference to the legal authority under which the rule is proposed, and (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553.

more proof under the FTCA from its regulatees to speak with confidence of legality than the First Amendment permits. The FTC has never offered the rule for notice and comment and has applied it consistently since 1982 to every deceptive advertising case. The FTC has thus violated the APA. It may not here apply the "competent and reliable scientific evidence" standard in light of that law violation. *See also NLRB v. Wyman-Gordon Co.*, 394 U.S. 759, 394 U.S. 759, 89 S. Ct. 1426, 22 L. Ed. 2d 709 (1969); *Lincoln v. Vigil*, 508 U.S. 182, 508 U.S. 182; 113 S. Ct. 2024; 124 L. Ed. 2d 101 (1993); *Chrysler Corp. v. Brown*, 441 U.S. 281, 99 S. Ct. 1705, 60 L. Ed. 2d 208 (1979); *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 103 S. Ct. 2856, 77 L. Ed. 2d 443 (1983); *Federal Power Comm'n v. Texaco, Inc.*, 377 U.S. 33, 84 S. Ct. 1105, 12 L. Ed. 2d 112 (1964).

Moreover, FTC has not defined a standard through case-by-case adjudication either. FTC has not given Respondents or the regulated class any clear explanation of what they must do to satisfy FTC that their health benefit claims are non-deceptive. In this case, Respondents have repeatedly asked for, and FTC has never provided them with, a meaningful definition of what "competent and reliable scientific evidence" requires. They have asked the FTC to apprise them (as it has not done in any case before the present) of the nature, degree, quality, and quantity of scientific evidence the Commission expects to satisfy this standard based on the very claims in issue. FTC has refused to supply that information. There is no way, given the extreme ambiguity of the definition supplied for "competent and reliable scientific evidence," for the regulated class to advertise with any confidence that evidence on hand will satisfy the FTC. Thus, the regulated class proceeds with trepidation whenever it advertises a health benefit claim. If there is a meaningful definition, it is a secret standard, a mystery to all.

The inherent vagueness of the standard for speech restriction violates the APA. Indeed, the bare minimum required of the FTC, as with any regulatory agency, is that it articulate rules to govern speech that provide Respondents and the entire regulated class with sufficient guidance to discern lawful from unlawful conduct. *Smith v. Goguen*, 415 U.S. 566 94 S. Ct. 1242; 39 L. Ed. 2d 605 (1974); *E. g., Papachristou v. City of Jacksonville*, 405 U.S. 156, 162 (1972); *Cramp v. Board of Public Instruction*, 368 U.S. 278, 287 (1961); *United States v. Harriss*, 347 U.S. 612, 617 (1954); *Jordan v. De George*, 341 U.S. 223, 230-232 (1951); *Lanzetta v. New Jersey*, 306 U.S. 451, 453 (1939); *Connally v. General Construction Co.*, 269 U.S. 385, 391 (1926); *United States v. Cohen Grocery Co.*, 255 U.S. 81, 89 (1921); *International Harvester Co. v. Kentucky*, 234 U.S. 216, 223-224 (1914); *Gregory v. Chicago*, 394 U.S. 111, 120 (1969) (Black, J., concurring); *Interstate Circuit v. Dallas*, 390 U.S. 676, 684-685 (1968); *Ashton v. Kentucky*, 384 U.S. 195, 200 (1966); *Giaccio v. Pennsylvania*, 382 U.S. 399 (1966); *Shuttlesworth v. Birmingham*, 382 U.S. 87, 90-91 (1965); *Kunz v. New York*, 340 U.S. 290 (1951); *Saia v. New York*, 334 U.S. 558, 559-560 (1948); *Thornhill v. Alabama*, 310 U.S. 88, 97-98 (1940); *Herndon v. Lowry*, 301 U.S. 242, 261-264 (1937).

When it is not possible for the regulated class to know what nature, degree, quality, and quantity of scientific evidence is required before it may be assured that its advertising is legal, the FTC has failed to perform its most basic administrative law duty under the APA and under the FTCA.. This case amply reveals how the FTC has failed that duty. Neither the Commission, FTC Counsel, nor the Chief Administrative Law Judge has informed Respondents of what scientific evidence they would have to have in order to advertise the very claims here in issue confident in the knowledge that the standard has been satisfied. Neither the Commission, FTC Counsel, nor the Chief Administrative Law Judge will issue an advisory opinion informing the

Respondents of what is required. Respondents have asked repeatedly for an advisory opinion and have been informed that the FTC will not provide it. That failure to provide any means to elucidate the meaning of the standard in any particular case violates the APA. It reveals the standard to be wholly subjective, subject to whim and caprice, to unbridled discretion, something forbidden of speech regulators. *Lakewood v. Plain Dealer Publishing Co.*, 486 U.S. 750, 769-772 (1988) (4-to-3 decision); *Heffron v. International Society for Krishna Consciousness, Inc., supra*, at 649; *Freedman v. Maryland*, 380 U.S. 51, 56 (1965); *Thornhill v. Alabama*, 310 U.S. 88, 97 (1940). The APA compels the FTC to make clear its standard either through rulemaking or on a case by case basis. The FTC has violated every part of the APA governing adoption of rules or decisions by imposing an undefined rule on the regulated class, and on Respondents in this proceeding, without even attempting to satisfy the APA requirements in any respect.

For the foregoing reasons, the Chief Administrative Law Judge may not rely upon the "competent and reliable scientific evidence" standard in this case and may not include it in any ultimate order without violating the law. The relief requested by FTC Counsel is barred by operation of law and the APA.

D. THE "COMPETENT AND RELIABLE SCIENTIFIC EVIDENCE" STANDARD VIOLATES THE FIFTH AMENDMENT: IT IS VOID FOR VAGUENESS

The commercial speech here in issue is, at worst, potentially misleading. As explained above, potentially misleading commercial speech is protected under the First Amendment to the United States Constitution. *See Central Hudson Gas & Electric Corp. v. Public Serv. Comm'n.*, 447 U.S. 557; 100 S. Ct. 2343; 65 L. Ed. 2d 341 (1980); *Pearson v. Shalala*, 334 U.S. App. D.C.

71, 164 F.3d 650; 1999 U.S. App. LEXIS 464 (1999).[82] The right to advertise is a liberty right under the Fifth Amendment to the United States Constitution. *See Thompson Medical Company, Inc., v. FTC*, 791 F.2d 189 (D.C. Cir. 1986) (after stating the Court's preference for FTC orders that are "unequivocally legal," the D.C. Circuit expressly noted that the FTC's use of vague standards to regulate commercial speech are repeatedly "attacked on vagueness grounds" and often force the FTC to go through a lengthy and uncertain appellate process [...]"). *Id.* at 195-96.

Under the Fifth Amendment, the right to liberty may not be deprived without due process of law. *See* U.S. Const. Amend. V. A decision from the Chief Administrative Law Judge that has the effect of depriving Respondents of their liberty right to communicate future protected speech issue free from fear of prosecution under a vague standard thus constitutes a deprivation of a liberty right. It chills protected speech; through vagueness it sweeps within the ambit of deception speech that is constitutionally protected. "'It is established that a law fails to meet the requirements of the Due Process Clause if it is so vague and standardless that it leaves the public uncertain as to the conduct it prohibits...'" *City of Chicago v. Morales*, 527 U.S. 41, 56 (1999) (quoting *Giacco v. Pennsylvania*, 382 U.S. 399, 402-403 (1966)). The Supreme Court has held

[82] To illustrate the point, if the FTC were to establish with empirical evidence that consumers understand the ECA product ads to imply a set amount above 50 lbs. of weight loss for all who are 30lbs or more overweight (an absurd proposition but one FTC Counsel may cleave to), it would appear to suffice for FTC to require use of a disclaimer in the ads that ECA produces weight loss of varying amounts dependent upon the degree of overweight status in each user. If the FTC were to establish with empirical evidence that the consumer perceived PediaLean to be proven effective only by numerous clinical trials, rather than by the Livieri study, cited in the ad, it would appear to suffice for FTC to require use of a disclaimer in the ads that additional studies may need to be performed to determine if those results are replicated and confirmed. If the FTC were to establish with empirical evidence that consumers perceived the aminophylline gels to produce visible reduction in girth of the skin to which it is applied by a set date after the date of application, it would appear to suffice for FTC to require use of a disclaimer in the ads that results may be visible to some users. Respondents will accept any reasonable disclaimer or chosen qualification designed by FTC to eliminate misunderstanding.

that if a statute is unconstitutionally vague, issuance of a warning or notice of a violation does not cure that vagueness. *City of Chicago v. Morales*, 527 U.S. 41, 56 (1999):

> If the [conduct sought to be restricted] is in fact harmless and innocent, the dispersal order itself is an unjustified impairment of liberty...Because an officer may issue an order only after prohibited conduct has already occurred, it cannot provide the kind of advance notice that will protect the putative loiterer from being ordered to disperse. Such an order cannot retroactively give adequate warning of the boundary between the permissible and impermissible applications of law.

Like a dispersal order, the Complaint serves only "retroactive notice" of what constitutes a violation of the law. Thus, a Complaint does not cure the fatal vagueness of the FTC competent and reliable scientific evidence standard. See also, *Village v. Hoffman Estates, Inc.*, 455 U.S. 489, 499 (1982) ("Perhaps the most important factor affecting the clarity that the Constitution demands of a law is whether it threatens to inhibit the exercise of constitutionally protected rights. If, for example, the law interferes with the right of free speech or of association, a more stringent vagueness test should apply").

The minimum requirements of due process in the context of speech regulation require well-defined procedural safeguards to save protected speech from suppression or undue burden. The Court has explained that (1) an undue regulatory burden on commercial speech involves actions that proscribe utterance (render it illegal) when an obvious, less speech restrictive alternative, such as qualifications or disclaimers, are available to eliminate misleadingness. *See Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 100 S. Ct. 2343, 65 L. Ed. 2d 341 (1980); *Edenfield v. Fane*, 507 U.S. 761, 767, 113 S. Ct. 1792, 1798, 123 L. Ed. 2d 543 (1993). The Court has also explained that (2) the law governing what commercial speech may be communicated to the public extends constitutional protection not only to speech that is non-misleading but also to speech that is potentially misleading (i.e., speech capable of both misleading and non-misleading interpretations). *See Rubin v. Coors Brewing Co.*, 514 U.S.

476, 481-482, 115 S. Ct. 1585, 1589, 131 L. Ed. 2d 532 (1995) (*quoting Virginia Bd. of Pharm. v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 763, 96 S. Ct. 1817, 1826, 48 L. Ed. 2d 346 [1976]); *United States v. Playboy Entm't Group, Inc.*, 529 U.S. 803, 812, 120 S. Ct. 1878, 1886, 146 L. Ed. 2d 865 (2000). The speech here in issue is, at worst, potentially misleading and, so, is entitled to First Amendment protection. As such, it may not be suppressed through the Order requested by FTC Counsel but must be evaluated to determine what qualifications or disclaimers can be used to avoid misleadingness and the risk of future FTC prosecution. The Chief Administrative Law Judge must therefore assess the demand made by FTC for relief under the prongs of the *Central Hudson Gas & Electric* test, as modified by its progeny, i.e.: (1) is the government's interest in regulating the speech in issue substantial; (2) will the regulatory means recommended by FTC directly and materially advance that government interest; and (3) are there obvious, less speech restrictive alternatives to the means chosen by FTC. *See Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 100 S. Ct. 2343, 65 L. Ed. 2d 341 (1980); *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 623, 115 S. Ct. 2371, 2375, 132 L. Ed. 2d 541 (1995).

When government regulates an entire class of speech, here commercial speech, it must adopt clearly defined standards so that the regulatees can know the precise boundaries of the law. There must be a safe harbor where an advertiser can go cognizant of the fact that proceeding thusly will avoid prosecution. In the order urged upon the Chief ALJ by FTC Counsel, there is no safe harbor other than self-censorship. There is no clear standard, only unbridled regulatory discretion. That alternative is unacceptable under the First Amendment. In this very case, if his Honor finds any basis to restrict the advertising claims (which he should not), his Honor must identify a clear safe harbor, as explained above. Failing to do so denies Respondents the process

to which they are entitled if their First and Fifth Amendment rights are to be adequately protected.

Under the Fifth Amendment, when a liberty right is in issue, due process requires at a minimum that any standard applied to govern the exercise of that right be clear enough to the regulated class so that regulates may discern with reasonable certainty whether their conduct will violate that standard. Or, as the Court has put it, "the regulation cannot distinguish among the indistinct, permitting a variety of speech that entails the same harm as the speech which the government has attempted to limit." *Greater New Orleans Broad. Ass 'n, Inc. v. United States*, 527 U.S. 173, 190, 119 S. Ct. 1923, 1933, 144 L. Ed. 2d 161 (1999). A regulation—by vague or indefinite terms— may not confer "absolute discretion" to those enforcing or executing the law. *City of Chicago v. Morales*, 527 U.S. 41, 56 (1999) (internal citations omitted). "The power to determine the meaning of a statute carries with it the power to prescribe its extent and limitations as well as the method by which they shall be determined." *Smiley v. Kansas*, 196 U.S. 447, 455 (1905).

The FTC requires on threat of prosecution every advertiser who wishes to make a health benefit claim in advertising to possess in advance of advertising "competent and reliable scientific evidence" that the claim is substantiated. This same standard is in FTC Counsel's prayer for relief. The FTC has failed to define that standard sufficiently to permit the regulated class to discern what is expected of it, yet failure to comply with the unduly vague standard results in prosecution. The effect is a loss of First Amendment rights due to a pervasive chilling effect. *Riley v. National Federation of the Blind*, 487 US 781, 794 (1988). The chilling effect results in advertisers eliminating some advertising content on the assumption that it does not rise to the level of proof required by the standard while retaining other advertising content on the

assumption that it does, never knowing for sure what FTC will or will not regard as permitted speech under the FTCA.

Time and time again Respondents have been denied their due process rights associated with this proceeding. Prior to advertising Respondents examined FTC guidance materials to determine the substantiation necessary for their advertising and were left nearly clueless - with vague generalities and unspecified, minimal guidance. See RX-001, RX-003, RX-005, RX-006, RX-010. Then when Respondents came before FTC at the investigation stage they sought guidance to know what FTC would and would not accept as a reasonable basis for their advertising and were denied that guidance.[83] In no instance during this proceeding has a scientific standard for decision been articulated to them. That procedure violates the Fifth Amendment because it permits imposition of a sanction for the exercise of a liberty right without due process of law.

Respondents have also been denied due process (which presupposes a presumption of innocence until such time as the state proves guilt) by FTC shifting the burden of proof from itself to the regulated class before a final adjudication on the merits. The FTC may not compel proof of innocence against a charge of deceptive advertising. It must prove guilt by substantial

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[83] Respondents have been further harmed in this proceeding as their valuable and irreplaceable trade secrets were disclosed through wrongful action by those at FTC who bring these charges. Subsequent to the destruction of those trade secrets, the Commission refused to allow Respondents the opportunity to discover all aspects of the disclosure of the secrets (the identification of who was responsible for the disclosure and the identification of sufficient information to determine who accessed that information when it was made public). The Respondents have been denied the opportunity to seek further information using process in this proceeding to discover the complete scope and nature of the disclosure. Finally, the Presiding Officer has stated that the disclosure would not be considered a mitigating circumstance against any finding of liability for Respondents, if any, despite the fact that the "punishment" of that disclosure has caused significant harm to Respondents. All of those actions have forced Respondents to prepare for filing a Notice of Federal Tort Claims Act Complaint for Misappropriation of Trade Secrets that will be filed upon its completion with the agency.

evidence under the APA. 5 U.S.C. § 706; see also *Ingalls Shipbuilding, Inc. v. Director, Office of Workers' Comp. Programs*, 991 F.2d 163, 165 (5th Cir. 1993); quoting *NLRB v. Columbian Enameling & Stamping Co., Inc.*, 306 U.S. 292, 300 (1939).

E. THE "COMPETENT AND RELIABLE SCIENTIFIC EVIDENCE" STANDARD VIOLATES THE APA: IT FAILS TO GIVE THE REGULATED CLASS SUFFICIENT GUIDANCE TO KNOW WHAT IS EXPECTED OF IT AND FTC'S APPLICATION OF IT RESULTS IN ARBITRARY AND CAPRICIOUS, UNLAWFUL AND UNCONSTITUTIONAL AGENCY ACTION

Under the Administrative Procedure Act (APA), no rule of general applicability is lawful if it is arbitrary, capricious, or contrary to law. *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971) ("Under the APA, agency rules are "unlawful," and hence void, if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law") (*quoting* 5 U.S.C. § 7-6(2)(A).[84] Rules that fail to provide the regulated class with sufficient guidance to discern what is legal and what is not are arbitrary and capricious within the meaning of the APA. *See Adderley v. Florida*, 385 U.S. 39, 42 (1966) ([A] breach of the peace ordinance that is "indefinite, loose, and broad" is void for vagueness) (describing holding in

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[84] *See also See Long v. Board of Governors of the Fed. Reserve Sys.*, 117 F.3d 1145, 1151 (10th Cir. 1997); *City of Albuquerque v. Browner*, 97 F.3d 415, 424 (10th Cir. 1996). In addition, when the question before the court involves an agency's interpretation of a statute it administers, the Court will use the two-step approach announced in *Chevron. See, e.g., Sierra Club v. EPA*, 99 F.3d 1551, 1555 (10th Cir. 1996). When Congress has spoken to the precise question at issue, the court must give effect to the express intent of Congress. *See Chevron*, 467 U.S. at 842-43. However, if the statute is silent or ambiguous, the court will defer to the agency's interpretation, if it is reasonable. *See id.* at 843-44. The agency's interpretation of the statute need not be the only reasonable or most reasonable interpretation, *see id.* at 843 n.11, but an unconstitutional interpretation is not entitled to *Chevron* deference. In addition, deference to an agency interpretation is inappropriate not only when it is conclusively unconstitutional, but also when it raises serious constitutional questions. *See Rust v. Sullivan*, 500 U.S. 173, 190-91, 114 L. Ed. 2d 233, 111 S. Ct. 1759 (1991); *Edward J. DeBartolo Corp. v. Florida Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575-76, 99 L. Ed. 2d 645, 108 S. Ct. 1392 (1988); *Williams v. Babbitt*, 115 F.3d 657, 661-62 (9th Cir. 1997), *cert. denied sub nom. Kawerak Reindeer Herders Ass'n v. Williams*, 523 U.S. 1117, 118 S. Ct. 1795, 140 L. Ed. 2d 936 (1998); *Chamber of Commerce of the United States v. FEC*, 314 U.S. App. D.C. 436, 69 F.3d 600, 605 (D.C. Cir. 1995); *Kohler Co. v. Moen Inc.*, 12 F.3d 632, 634 n.2 (7th Cir. 1992).

Edwards v. South Carolina, 372 U.S. 229 (1963); *City of Chicago v. Morales*, 527 U.S. 41, 56 (1999) (*quoting Giacco v. Pennsylvania*, 382 U.S. 399, 402-403 (1966). Under the APA, agency rules are "unlawful," and hence void, if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 7-6(2)(A). Whether an agency acted in an arbitrary and capricious manner is determined by whether the agency's decision was based on a consideration of the relevant factors and whether it has made a clear error of judgment. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). An agency decision will be considered arbitrary and capricious if "the agency relied on factors **which Congress had not intended it to consider**, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicles Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)(emphasis added); *see also, Humana of Aurora v. Heckler*, 753 F.2d 1579, 1581 (10th Cir. 1985)(citations omitted). "A rational connection must be found between the facts before the agency and the rule-making choice made." *Id.* (citing *Motor Vehicle Mfrs.*, 463 U.S. 29; *see also, Burlington Truck Lines v. U.S.*, 371 U.S. 156, 168 (1962).

Moreover, under the APA, agency rules are "unlawful," and hence void, if they are "contrary to [a] constitutional right, power, privilege, or immunity." 5 U.S.C. § 7-6(2)(B). An agency rule is void if it fails to account for the constitutional ramifications of restricting commercial speech. *U.S. West, Inc. v. FCC*, 182 F.3d 1224, 1231-1240 (1999). *U.S. West* stated:

> Under the Administrative Procedure Act, we review a final FCC order to determine whether it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), or "contrary to constitutional right, power, privilege, or immunity," id. § 706(2)(B). *See Long v. Board of*

Governors of the Fed. Reserve Sys., 117 F.3d 1145, 1151 (10th Cir. 1997); *City of Albuquerque v. Browner*, 97 F.3d 415, 424 (10th Cir. 1996).

To the extent that the competent and reliable scientific evidence standard is considered an interpretation by FTC of the FTCA, it is entitled to no deference because it is unconstitutional.[85]

Here, the definition given for "competent and reliable scientific evidence" is: tests, 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.[86]

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[85] As discussed *supra*, an agency's interpretation of a statute requires the two-step approach announced in *Chevron*. *See, e.g.*, *Sierra Club v. EPA*, 99 F.3d 1551, 1555 (10th Cir. 1996). When Congress has spoken to the precise question at issue, we must give effect to the express intent of Congress. *See, Chevron*, 467 U.S. at 842-43. However, if the statute is silent or ambiguous, we defer to the agency's interpretation, if it is reasonable. *See id.* The agency's interpretation of the statute need not be the only reasonable or most reasonable interpretation, *see id.* at 843 n.11, but an unconstitutional interpretation is not entitled to Chevron deference. In addition, deference to an agency interpretation is inappropriate not only when it is conclusively unconstitutional, but also when it raises serious constitutional questions. *See Rust v. Sullivan*, 500 U.S. 173, 190-91, 114 L. Ed. 2d 233, 111 S. Ct. 1759 (1991); *Edward J. DeBartolo Corp. v. Florida Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575-76, 99 L. Ed. 2d 645, 108 S. Ct. 1392 (1988); *Williams v. Babbitt*, 115 F.3d 657, 661-62 (9th Cir. 1997), cert. denied sub nom. *Kawerak Reindeer Herders Ass'n v. Williams*, 523 U.S. 1117, 118 S. Ct. 1795, 140 L. Ed. 2d 936 (1998); *Chamber of Commerce of the United States v. FEC*, 314 U.S. App. D.C. 436, 69 F.3d 600, 605 (D.C. Cir. 1995); *Kohler Co. v. Moen Inc.*, 12 F.3d 632, 634 n.2 (7th Cir. 1992). When faced with a statutory interpretation that "would raise serious constitutional problems, the court[s] will construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress." *DeBartolo Corp.*, 485 U.S. at 575. We follow this approach because we assume that Congress legislates with constitutional limitations in mind and will speak clearly when it seeks to test those limitations. See Rust, 500 U.S. at 191; *DeBartolo Corp.*, 485 U.S. at 575; *Williams*, 115 F.3d at 662; *International Union, United Auto., Aerospace & Agric. Implement Workers of Am., UAW v. OSHA*, 291 U.S. App. D.C. 51, 938 F.2d 1310, 1317 (D.C. Cir. 1991) ("In effect we require a clear statement by Congress that it intended to test the constitutional waters"). The *Williams* court aptly explained the doctrine as it applies to agencies: Just as we will not infer from an ambiguous statute that Congress meant to encroach on constitutional boundaries, we will not presume from ambiguous language that Congress intended to authorize an agency to do so. At the core of *DeBartolo* lies the presumption that, if Congress means to push the constitutional envelope, it must do so explicitly.

[86] Federal Trade Commission's Policy Statement Regarding Advertising Substantiation ("Advertising Substantiation Statement").

From the definition, it is not possible for Respondents or, indeed, for anyone, to know with reasonable certainty what level, degree, quality or quantity of scientific evidence will satisfy the FTC in advance of advertising. The best that can be said is that a well-intentioned advertiser will have to hope for the best that the evidence he or she possesses, when called into question by the FTC, will cause those who do the calling to believe, subjectively, the evidence to be enough. There are no objective guidelines or measures. The subjective statement, just quoted, is beyond the ken of everyone—FTC (who when asked will not say); FTC's expert (who as late as the time of his deposition and despite testifying for the FTC on repeat occasions could not give the term any definite meaning); the Chief Administrative Law Judge (who can recite it but not define it beyond the definition given); and the Commission (who have never defined it with sufficient specificity to guide the regulated class). What then governs when a standard is so inexact as to provide no meaningful guidance? Subjective predilection, bias? That is the height of arbitrary and capriciousness, of the rule of man over the rule of law.[87]

As explained above, the rule has not only been left without intelligible definition or any practical utility such that regulatees comprehend what is expected of them, it has also been adopted without notice and comment rulemaking; is applied in a way that fails to provide protection for speech that is, at worst, only potentially misleading and, therefore, constitutionally protected; and arises from no case that defines it without any greater meaning than the vacuous "tests, analyses, research" language of the above-quoted definition. Accordingly, it violates the First and Fifth Amendments and it fails to comport with the plain language requirements of the

[87] If FTC has a clearly articulated rule of decision, it is kept secret so that the regulated class is denied required guidance. If "competent and reliable scientific evidence" is that standard, it is so ambiguous as to be arbitrary and capricious. If "reasonable basis" is the standard, Respondents are still left without any clear explanation of what level, degree, quality, or quantity of science FTC expects of Respondents now or in the future.

Federal Trade Commission Act. *See Village v. Hoffman Estates, Inc.*, 455 U.S. 489, 499 (1982); *Cohen v. California*, 403 U.S. 15 (1971) ("[W]e cannot indulge the facile assumption that one can forbid particular words without also running a substantial risk of suppressing ideas in the process. Indeed, government might soon seize upon the censorship of particular words as a convenient guise for banning the expression of unpopular views. We have been able [to] discern little social benefit that might result from running the risk of opening the door to such grave results," 403 U.S. at 26); *Chaplinsky v. New Hampshire*, 315 U.S. 568 (1942). Because it is arbitrary and capricious and contrary to law, it violates the APA and may not lawfully be applied in this case. FTC Counsel's requested relief is barred by operation of law.

F. AFTER THE FACT EVIDENCE WHEN EXCULPATORY, AS IS THE WESTER ET. AL., AMINOPHYLLINE STUDY, CANNOT BE EXCLUDED CONSISTENT WITH THE REQUIREMENTS OF THE FIRST AMENDMENT

The federal courts have repeatedly upheld the FTC requirement that an advertiser possess in advance of advertising all proof necessary to support the validity of advertising representations. *See Thompson Medical Co. v. FTC*, 791 F.2d 189, 194 (D.C. Cir. 1986); *Sterling Drug, Inc. v. FTC*, 741 F.2d 1145, 1156-57 (9th Cir. 1984) (*appending* Federal Trade Commission's Policy Statement Regarding Advertising Substantiation ("Advertising Substantiation Statement"); *Bristol-Meyers Co. v. FTC*, 738 F.2d 554, 561 (2d Cir. 1984); *In re Firestone Tire & Rubber Co.*, 81 F.T.C. 398, 463 *aff'd,* 481 F.2d 246 (6th Cir. 1972). The federal courts have never confronted the question presented here of whether, in the presence of proof supporting advertising representations possessed prior to advertising, an advertiser may rely on post-advertising evidence that confirms the conclusions of science relied upon pre-advertising (i.e., post-advertising proof that is exculpatory). This case presents that question.

In this case, Respondents possessed substantial scientific evidence that aminophylline was an effective localized fat reducing agent, as explained above. *See* Daniel B. Mowrey's Expert Report (RX-828). They also knew that the gel they used was the functional equivalent of the gel used in the studies confirming the effectiveness of topical application of aminophylline to the skin. *See* P. Lehman Depo. They also knew lecithin gel was approved by FDA as an active ingredient delivery vehicle to penetrate the dermis. RX 828. FTC successfully objected to the introduction of a key bit of confirmatory evidence, a study that confirmed the fact that the aminophylline gel used by the Respondents was the functional bioequivalent of the gel used in the studies documenting the success of aminophylline as a localized fat reducing agent.

That refusal to consider exculpatory evidence that confirms evidence on hand in advance of advertising constitutes an abuse of discretion. The exculpatory evidence has to be considered under the First Amendment to the United States Constitution because it provides proof that the evidence relied upon pre-advertising was, in fact, correct and is not reasonably subject to challenge. Refusal to admit the exculpatory evidence is thus an error of constitutional magnitude. His Honor should reconsider the ruling and note with deference to the First Amendment that this proof is exculpatory because it confirms that, indeed, the gel Respondents used is equally effective to the cream studied pre-advertising.

G. THE DENIAL OF THE RIGHT TO DEPOSE COMMISSIONERS OR CONFRONT THE COMMISSION ON THE FACTS CONSTITUTES A VIOLATION OF THE FIFTH AMENDMENT TO THE CONSTITUTION

Under the Fifth Amendment to the United States Constitution and the Federal Rules, those subject to civil sanction from their government have a right to confront those who accuse them and to take such depositions as are necessary to mount an effective defense. See Fed. R.

Civ. P. 26. Rule 26(b)(1).[88] Section 556(d) of the Administrative Procedure Act governs cross examination in administrative hearings. *Central Freight Lines, Inc. v. United States,* 669 F.2d 1063, 1068 (1982); 5 U.S.C. 556(d). That subsection states:

> Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof. Any oral or documentary evidence may be received, but the agency as a matter of policy shall provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence. A sanction may not be imposed or rule or order issued except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence. The agency may, to the extent consistent with the interests of justice and the policy of the underlying statutes administered by the agency, consider a violation of section 557(d) of this title sufficient grounds for a decision adverse to a party who has knowingly committed such violation or knowingly caused such violation to occur. A party is entitled to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts. In rule making or determining claims for money or benefits or applications for initial licenses an agency may, when a party will not be prejudiced thereby, adopt procedures for the submission of all or part of the evidence in written form.

5 U.S.C. § 556(d). "The fundamental right to a hearing 'embraces not only the right to present evidence, but also a reasonable opportunity to know the claims of the opposing party and to meet them.'" *National Trailer Convoy, Inc. v. U.S,* 293 F.Supp. 634, 636 (1968) (*quoting Morgan v.*

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[88] *See also* Federal Trade Commission Rules of Practice 3.33(a): In general. Any party may take a deposition of a named person or of a person or persons described with reasonable particularity, provided that such deposition is reasonably expected to yield information within the scope of discovery under §3.31(c)(1). Such party may, by motion, obtain from the Administrative Law Judge an order to preserve relevant evidence upon a showing that there is substantial reason to believe that such evidence would not otherwise be available for presentation at the hearing. Depositions may be taken before any person having power to administer oaths, either under the law of the United States or of the state or other place in which the deposition is taken, who may be designated by the party seeking the deposition, provided that such person shall have no interest in the outcome of the proceeding. The party seeking the deposition shall serve upon each person whose deposition is sought and upon each party to the proceeding reasonable notice in writing of the time and place at which it will be taken, and the name and address of each person or persons to be examined, if known, and if the name is not known, a description sufficient to identify them. The parties may stipulate in writing or the Administrative Law Judge may upon motion order that a deposition be taken by telephone or other remote electronic means. A deposition taken by such means is deemed taken at the place where the deponent is to answer questions.

United States, 304 U.S. 1, 18 (1938)). "Implicit in this concept [of a right to a hearing] is the 'traditional right of confrontation and cross-examination' in furtherance of fundamental fairness." *National Trailer Convoy, Inc. v. U.S*, 293 F.Supp. 634, 636 (1968) (*quoting Garvey*, 304 U.S. 1, 18 (1938)). *National Trailer Convoy* further held, "In all adjudicative proceedings cross-examination and confrontation are handmaidens of trustworthiness in the face of factual dispute. But unless material facts are in dispute[,] there is no right to cross-examination and confrontation." 293 F.Supp. at 637.

In this case the Chief Administrative Law Judge has refused to authorize the deposition of the extant and past Commissioners of the FTC. The refusal is categorical and unequivocal. The grounds stated for the refusal are that the mental processes of those decision-makers are not subject to evaluation, Order on FTC's Motion to Strike at 4-5, December 7, 2005, but the case precedent clearly allows deposition to determine the existence of salient facts of executive officials without regard to the exercise of their mental processes. *See United States v. Morgan*, 313 U.S. 409, 413, 61 S. Ct. 999 (1941); *Western Electric Co. Inc. v. Piezo Technology, Inc.*, 860 F.2d 428, 431 (Fed. Cir. 1988) ("*Morgan*, however, does not expressly prohibit an official exercising a quasi-judicial function from testifying as to relevant matters of fact as along as the factual matters do not probe into the mental processes employed in formulating the decision in question."); *Fischer & Porter Co. v. Corning Glass Works*, 61 F.R.D. 321, 322 (E.D. Pa. 1974).

In this case, Respondents are accused of implied claims said to be deceptive. The standard for review of those claims, "competent and reliable scientific evidence," is far too ambiguous to provide any regulate adequate guidance to discern what is expected of it. No party or expert to the case knows what facts are required to satisfy the standard. Indeed, no expert opines in the case on the facts needed to satisfy the standard. Instead, the Chief Administrative

Law Judge and, then, ultimately the Commission will say whether the standard is satisfied but in all decisions to date neither an Administrative Law Judge nor the Commission has explained what level, degree, quality, or quantity of scientific evidence would have to be present in order to satisfy the standard. Accordingly, Respondents should have been given the opportunity to depose the Commissioners on that very point but were not. The effect is to deny them a full and fair opportunity to adduce facts necessary to discern what evidence is required to meet the charges against them. That constitutes a denial of due process and a denial of the Fifth Amendment right to confront one's accusers. *See* U.S. Const. Amend. V., *see also Grannis v. Ordean*, 234 U.S. 385 234 U.S. 385; 34 S. Ct. 779; 58 L. Ed. 1363; 1914 U.S. LEXIS 1158 (1914) (A requisite to due process of law is the opportunity to be heard); *Louisville & N. R. Co. v. Schmidt*, 177 U.S. 230 177 U.S. 230; 20 S. Ct. 620; 44 L. Ed. 747; 1900 U.S. LEXIS 1792 (1900); *Lindsey v. Greene*, 649 F.2d 425 1981 U.S. App. LEXIS 13180 (6th Cir. 1981). It is a dispositive error that should result in denial of the Complaint in this case. *See, e.g., Mazaleski v. Treusdell*, 562 F.2d 701 (D.C. Cir. 1977) ("There is no question that a cause of action may be stated under the procedural due process component of the fifth amendment for equitable relief"); *see Davis v. Passman*, 47 U.S.L.W. 4643, 4647 (June 5, 1979); *Bell v. Hood*, 327 U.S. 678, 684 (1946); *Apton v. Wilson*, 506 F.2d 83 (D.C. Cir. 1974). *Carey v. Piphus*, "[...] the right to procedural due process is 'absolute' in the sense that it does not depend upon the merits of a claimant's substantive assertions." 98 S. Ct. 1042, 1054 (1978). Respondents ask here that his Honor reconsider.

H. THE EXCLUSION OF EIGHT EXPERT WITNESSES VIOLATES RESPONDENTS' FIFTH AMENDMENT DUE PROCESS RIGHTS AND PROCEDURAL DUE PROCESS RIGHTS

The Chief Administrative Law Judge has denied Respondents the right to present eight expert rebuttal witnesses. Those witnesses were identified at the time set, post-case stay, for witness identification. See Respondents' Revised Witness List submitted November 8, 2005. Nevertheless, with fully four and a half months to go before the trial, the Chief Administrative Law Judge determined that allowance of the witnesses would violate the procedural rules and afford FTC inadequate time to prepare for trial. The result of that decision is to deny Respondents the substantive benefit of expert testimony in support of their case on grounds that are procedural. The period from the time of witness identification to the time of trial was more than sufficient to permit deposition of the witnesses. The Chief Administrative Law Judge permitted FTC the opportunity to depose, after the discovery cut-off, two witnesses of the Respondents, including in one order allowing a deposition to be scheduled as late as 20 days before the hearing. *See* Order on FTC's Motion *In Limine* at 8, January 10, 2006.

Because the content in issue is speech protected by the First Amendment and because basic substantive due process demands an equal opportunity for Respondents to make their case as FTC, the decision to deny Respondents the right to present rebuttal witnesses violates the Fifth Amendment right of due process.[89] Moreover, the decision violates administrative due process

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[89] Even if there is "substantial evidence" in the record for an agency finding, the court must set the finding aside if the agency failed to follow the "procedures required by law" in making its determination. *Atkinson Lines, Inc. v. United States*, 381 F. Supp. 39, 41-42 (S.D. Ohio 1974) ("the substantial evidence standard . . . does not exhaust the scope of review;" reviewing court has a "duty to scrutinize all aspects of the agency proceedings in order to decide whether it has acted fairly and within the proper legal framework"); *see also U.S. v. Dist. Council of N.Y.C. and Vicinity of the United Brotherhood of Carpenters*, 880 F. Supp. 1051, 1066 (S.D.N.Y. 1995) ("an agency's decision can be 'arbitrary and capricious' if it was not the product of the requisite processes"). "The due process clause guarantees no person shall be deprived of life, liberty, or property without due process of law." *Guenther v. C.I.R.*, 889 F.2d 882, 884 (9th Cir. 1989). The essential ingredients of procedural due process necessarily include notice and an opportunity to be heard before an impartial and disinterested decision maker. The basic purpose of due process is to preserve "both the appearance and reality of fairness" in all adjudicative

rights accorded parties to federal administrative proceedings. In such cases, procedural rules may not be imposed in a manner that favors one side over another or that results in a party accused by the government being denied the opportunity to present evidence essential to its case. Untimeliness or procedural irregularity alone is insufficient to justify a denial of a substantive right in such proceedings, which results in substantial prejudice to Respondents.[90] *United States ex rel. Bilokumsky v. Tod*, 263 U.S. at 157, 44 S. Ct. at 57 (1923) ("In the words of Justice Brandeis, '[t]o render a hearing unfair the defect, or the practice complained of, must have been such as might have led to a denial of justice, or there must have been absent one of the elements deemed essential to due process'"); *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 542, 105 S. Ct. 1487, 1493, 84 L. Ed. 2d 494 (1985) (*quoting Mullane v. Central Hanover Bank & Trust Co.*, 339 U.S. 306, 313, 70 S. Ct. 652, 656, 94 L. Ed. 865 (1950) ("An essential principle of due process is that a deprivation of life, liberty, or property 'be preceded by notice and opportunity for hearing'"). Thus, Respondents Fifth Amendment Due Process and substantive procedural due process rights have been violated.

I. THE FILING OF THE COMPLAINT IN THIS ACTION DID NOT MEET THE REQUIREMENTS OF THE FTCA AND RESPONDENTS' FIFTH AMENDMENT DUE PROCESS RIGHTS

In order to file a complaint, the Commission must have "a reason to believe" under Section 5(b) of the FTCA that unfair or deceptive acts or practices have occurred.[91] FTC did not

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proceedings, "'generating the feeling, so important to a popular government, that justice has been done.'" *Marshall v. Jerrico, Inc.*, 446 U.S. 238, 242, 100 S. Ct. 1610, 64 L. Ed. 2d 182 (1980) (*quoting Joint Anti-Fascist Committee v. McGrath*, 341 U.S. 123, 172, 71 S. Ct. 624, 95 L. Ed. 817 (1951)).

[91] To comply with this statutory requirement, FTC Counsel had to have, at the time the complaint was filed, a standard against which they judged the substantiation Respondents produced to them. Despite repeated requests for FTC Counsel to articulate that standard, FTC Counsel has not done so. Respondents are entitled to know what that standard is, so that they can adequately

have that "reason to believe" because as explained *supra*, it had no meaningful standard in place to make such a determination. Moreover, the Complaint in this action did not give Respondents fair notice of the charges against them.

Section 5(b) of the FTCA requires that the Commission make a determination that there is a reason to believe that unfair or deceptive acts or practices have occurred. 15 U.S.C. §45(b). Without that check the prosecutorial discretion of the agency is unlimited. There would be no check or balance against the enforcement arm of the FTC in prosecuting advertisers where the advertising was in fact sufficiently substantiated under the FTCA. However, in order to make a judgment about the sufficiency of substantiation the Commission must know what the standard is against which the party's advertising and supporting documentation shall be judged. There is no distinct, definable standard for review. There is thus no standard against which to weigh the evidence. There is no distinct, definable definition for "rapid weight loss" or "substantial weight loss" or "visibly obvious." Thus, there is no standard against which to weigh those allegedly implied claims.

Without those standards the statutory requirement that the Commission have a reason to believe a violation has occurred is rendered meaningless. The Commission is obligated by the FTCA to have a reason to believe that there is a violation of Section 5. Moreover, without the Commission exercising that check to the prosecutorial power of the agency, the enforcement arm is given carte blanche for prosecution of advertisers, dependent mainly, if not wholly, on the whim or caprice of the prosecuting attorneys.

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defend themselves at trial. The Chief ALJ has improperly kept Respondents from being able to discover that standard, which is easily remediable. This is improper and unconstitutional and must be corrected prior to trial.

Without the Commission satisfying the reasonable belief requirement of the FTCA the potential of abuse of the FTCA for political purposes is great. The FTC has a wide sweeping investigative and enforcement power against any party that advertises in interstate commerce in the United States. Those parties are not without rights under the FTCA, the APA, and the Constitution. Without a check to that power before an enforcement action is begun, companies that are disfavored by the political climate could be subject to baseless prosecutions. The check that Congress created was meant to be a real one to eliminate the possibility that improper motives would drive the enforcement arm of the agency.

Moreover, since the violation of section 5 must be brought only after the Commission's determination that it has a reason to believe such a violation has take place, the Complaint must be specific as to the basis of that violation. The advertising claims that are the subject of the complaint must be specified and exclusive of any other advertising claims. The prosecutorial arm of the agency cannot use the Complaint as a jumping point to seek relief for violations of alleged acts not presented to the Commission as a part of its reasonable belief determination. Such an extension of the prosecutorial power would be in excess of the agency's authority under the FTCA.

A specific complaint is required under the Fifth Amendment. Parties before the FTC are due fair notice at every stage of a proceeding. A party under investigation should have fair notice of the investigation to determine whether its scope is lawful or whether he has grounds to object. Fair notice is required so that the party can make an informed decision at every stage of the proceeding. Moreover, fair notice becomes even more important when, as here, there is a two year delay between the time of the investigation and the filing of the complaint. There is an increased need for fair notice so that parties can make a meaningful choice to determine the

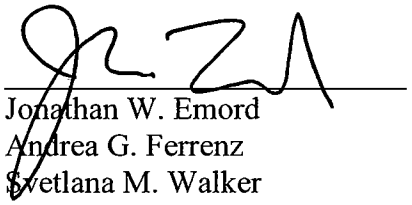
course of the defense of their rights before the agency. The Chief ALJ has ruled that the Complaint is merely a framework and that the FTC can prosecute Respondents in this case for claims not included in the Complaint and for advertising not attached to it. See Order dated July 20, 2004 at 3. Respondents thus completely lack fair notice of the allegations against them and are not afforded an adequate basis for mounting their defense.

In this case, there is no evidence that the Commission has satisfied the FTCA's requirement that it make a reasonable belief determination. There is no definition for the terms against which that determination would be made rendering that determination impossible. Moreover, the Complaint is so vague and has been ruled to be merely a framework upon which the prosecutors can expand at their will so as to render meaningless notice to the Respondents, all in violation of their Fifth Amendment rights.

V. CONCLUSION: RESPONDENTS DID NOT DECEIVE OR ENGAGE IN UNFAIR OR DECEPTIVE ACTS OR PRACTICES

For the reasons stated above, the Chief Administrative Law Judge should conclude that FTC has not satisfied its statutory and constitutionally required burden of proof; that the advertising in question is not deceptive within the meaning of the Federal Trade Commission Act; and that Respondents did not engage in unfair or deceptive acts or practices within the meaning of the Act. The evidence confirms that the products are effective. The FTC has failed to satisfy its burden of proof under the Act and the Constitution to support any restriction on the Respondents' advertising content. The competent and reliable scientific evidence standard may not be lawfully applied for the reasons stated above. The Chief Administrative Law Judge is legally barred from granting FTC Counsel the relief they request. His Honor should deny FTC's complaint and dismiss this action.

Respectfully submitted,



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Date: February 17, 2006

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES
WASHINGTON, D.C.

In the Matter of

BASIC RESEARCH, LLC **A.G. WATERHOUSE, LLC** **KLEIN-BECKER USA, LLC** **NUTRASPORT, LLC** **SOVAGE DERMALOGIC LABORATORIES, LLC** **BAN LLC d/b/a BASIC RESEARCH LLC** **OLD BASIC RESEARCH, LLC** **BASIC RESEARCH, A.G. WATERHOUSE,** **KLEIN-BECKER USA, NUTRA SPORT, and** **SOVAGE DERMALOGIC LABORATORIES** **DENNIS GAY** **DANIEL B. MOWREY d/b/a AMERICAN** **PHYTOTHERAPY RESEARCH** **LABORATORY, and** **MITCHELL K. FRIEDLANDER,** **Respondents**	**PUBLIC VERSION** **Docket No. 9318**

CERTIFICATE OF SERVICE

I hereby certify that on this 17th day of February, 2006 I caused the Public Version of the Corporate Respondents' Pretrial Brief be filed and served as follows:

1) an original and one paper copy filed by first class U.S. mail delivery and one electronic copy in PDF format filed by electronic mail to

Donald S. Clark
Secretary
U.S. Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Room H-159
Washington, D.C. 20580
Email: secretary@ftc.gov

1) two paper copies delivered by first class U.S. mail to:

The Hon. Stephen J. McGuire
Chief Administrative Law Judge
U.S. Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Room H-112
Washington, D.C. 20580

2) one paper copy by first class U.S. Mail to:

James Kohm
Associate Director, Enforcement
U.S. Federal Trade Commission
601 New Jersey Avenue, N.W.
Washington, D.C. 20001

3) one paper copy by first class U.S. mail and one electronic copy in PDF format by electronic mail to:

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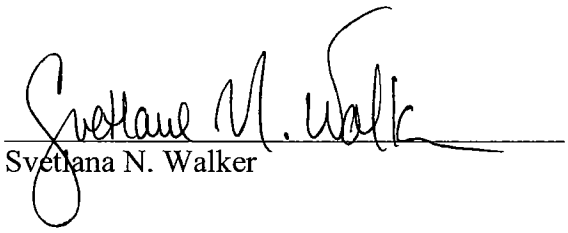

Svetlana N. Walker

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES
WASHINGTON, D.C.

In the Matter of

BASIC RESEARCH, LLC **A.G. WATERHOUSE, LLC** **KLEIN-BECKER USA, LLC** **NUTRASPORT, LLC** **SOVAGE DERMALOGIC LABORATORIES, LLC** **BAN LLC d/b/a BASIC RESEARCH LLC** **OLD BASIC RESEARCH, LLC** **BASIC RESEARCH, A.G. WATERHOUSE, KLEIN-BECKER USA, NUTRA SPORT, and SOVAGE DERMALOGIC LABORATORIES** **DENNIS GAY** **DANIEL B. MOWREY d/b/a AMERICAN PHYTOTHERAPY RESEARCH LABORATORY, and** **MITCHELL K. FRIEDLANDER,** **Respondents**	**PUBLIC VERSION** **Docket No. 9318**

CERTIFICATION OF PUBLIC FILING

I hereby certify that on this 17th day of February, 2006 I caused the Public Version of the Corporate Respondents' Pretrial Brief be filed and served in accordance with the terms specified in the Certificate of Service. The public version has been redacted to preserve confidential information only and is otherwise consistent with the non-public version of the Corporate Respondents' Pretrial Brief filed on February 10, 2006.

Respectfully submitted,

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