No. 09-10617-DD

IN THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

FEDERAL TRADE COMMISSION,
Plaintiff-Appellee,

v.

NATIONAL UROLOGICAL GROUP, INC., et al.,
Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF GEORGIA

BRIEF FOR PLAINTIFF-APPELLEE FEDERAL TRADE COMMISSION

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AMENDED CERTIFICATE OF INTERESTED PERSONS

No. 09-10617-DD

Federal Trade Commission v. National Urological Group, Inc., et al.

Pursuant to Circuit Rules 26.1-1 and 27-1(9), this is to certify that the following is a complete list of all attorneys, persons, and entities known to have an interest in the outcome of this appeal:

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Federal Trade Commission, Appellee

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Pannell, Jr., Charles A., United States District Judge

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Smith, Stephen, Appellant

Wheat, Jared Robert, Appellant

Wright, Terrill Mark, M.D., Appellant

STATEMENT OF ORAL ARGUMENT

The Federal Trade Commission believes that oral argument would assist the Court in resolving the issues in this case.

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STATEMENT OF JURISDICTION

The Federal Trade Commission, an independent agency of the United States, brought this action in the United States District Court for the Northern District of Georgia, pursuant to Sections 5, 12, and 13(b) of the Federal Trade Commission Act, 15 U.S.C. §§ 45, 52, and 53(b), seeking permanent injunctive relief to halt the defendants' deceptive promotion and sale of dietary supplements. The Commission also sought monetary equitable relief for injured consumers. The district court's jurisdiction is derived from 28 U.S.C. §§ 1331, 1337(a), 1345, and from 15 U.S.C. §§ 53(b).

On June 4, 2008, the district court (per Hon. Charles A. Pannell, Jr.) issued an order and decision granting the Commission's motion for summary judgment, and denying appellants' cross-motions – one filed collectively by all defendants and another filed separately by defendant Hi-Tech Pharmaceuticals, Inc. Doc. 219. On December 16, 2008, the court entered final judgments for permanent injunctive and equitable monetary relief. The court held the principal defendants – three closely-held corporations and their principals – jointly and severally liable in the amount of $15,882,436. Doc. 230. Their "expert" endorser, a physician who provided product endorsements for a fee, was held liable for injunctive relief and monetary equitable relief in the amount of $15,454 with respect to his false and unsubstantiated endorsements on defendants' behalf. Doc. 229.

A notice of appeal was timely filed on February 4, 2009, pursuant to Fed. R. App. P. 4(a)(1)(B).[2] Doc. 242. This Court has jurisdiction of this appeal pursuant to 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES PRESENTED

1. Whether, given defendants' express and clearly implied representations as to the safety and efficacy of their dietary supplements, there were any disputed issues of material fact as to the net impression conveyed by their advertising.

2. Whether, having failed to dispute widely-accepted standards applicable to the substantiation of health-related claims, defendants created disputed issues of material fact for trial with studies and reports that did not adhere to those standards.

3. Whether the district court properly found that there were no disputed issues of material fact as to the importance of defendants' express and clearly implied efficacy and safety representations to consumers' purchasing decisions.

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[2] Defendants reference "timely Notices of Appeal." Br. 3. In fact, there was a single notice of appeal from the district court's order of June 8, 2008, granting the FTC's motion for summary judgment and denying defendants' and Hi-Tech's motions for summary judgment, and the corresponding judgments, entered on December 16, 2008.

4. Whether, given undisputed facts demonstrating that the corporate defendants operated in an integrated fashion, the district court properly entered summary judgment for the Federal Trade Commission on allegations that the companies formed a common enterprise.

5. Whether, given that defendants' advertising was false and misleading commercial speech, the district court erred in holding that it was not entitled to any protection under the First Amendment.

STATEMENT OF THE CASE[3]

A. Nature of the Case, Course of Proceedings, and Disposition Below

This appeal arises from an action by the Federal Trade Commission ("FTC" or "Commission"), pursuant to Sections 5, 12, and 13(b) of the Federal Trade Commission Act ("FTC Act" or "Act"), 15 U.S.C. §§ 45, 52 and 53(b),[4] seeking

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[3] Page references to documents in the district court record conform to the pagination in headers in the Official Court Electronic Filing System, except in the case of deposition transcript pages without an electronic page number.

[4] Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), prohibits "unfair or deceptive acts or practices."

Under Section 12(b) of the Act, 15 U.S.C. § 52(b), false advertisements for food, drugs, devices, services, or cosmetics are by definition "unfair or deceptive."

Section 13(b) of the Act, 15 U.S.C. § 53(b) vests the district courts with authority to grant a permanent injunction and other equitable relief with respect to violations of any provision of law enforced by the FTC.

injunctive relief against defendants' false, deceptive, and unsubstantiated efficacy and safety claims for two weight loss products, Thermalean and Lipodrene, and a third product, Spontane-ES, which defendants represented was effective and safe in treating erectile dysfunction ("ED"). Doc. 1. The Commission also sought equitable monetary relief for consumers who collectively lost more than $15 million as a result of defendants' unlawful print, internet, and direct mail marketing campaigns. *Id.*

The principal defendants were three closely-held and interrelated companies – appellants National Urological Group, Inc. ("NUG"), Hi-Tech Pharmaceuticals, Inc. ("Hi-Tech"), and National Institute for Clinical Weight Loss, Inc. ("NICWL") – and their principals, appellants Jared Wheat, Thomasz Holda, and Stephen Smith. Doc. 1 ¶¶ 5-9, 11. Appellants Wheat, Holda, and Smith, were officers of NICWL and NUG, while Wheat and Holda were officers of Hi-Tech.[5] The Commission also named appellant Terrill Mark Wright, M.D. ("Wright") with respect to his false and unsubstantiated "expert" endorsements for Thermalean.[6] Doc. 1 ¶ 37.

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[5] Doc. 172-8 at 7, 10 (FTC SJ Exh. 4 ¶¶ 23-24, 40); Doc. 172-9 at 13 (FTC SJ Exh. 5 ¶ 55); Doc. 172-10 at 19 (FTC SJ Exh. 6 ¶ 94); Doc. 172-16 at 5, 8, 10 (FTC SJ Exh. 11 ¶¶ 11, 31, 50); Doc. 172-18 at 4-5 (FTC SJ Exh. 13 ¶¶ 11, 16-18; Doc. 172-17 at 4-5 (FTC SJ Exh. 12 ¶¶ 10, 15).

[6] Under a 2004 consent order with the Georgia Board of Medical Examiners, Dr. Wright's medical license was placed on probation for a period of five years.

On June 4, 2008, the district court (per Hon. Charles A. Pannell, Jr.) granted the Commission's motion for summary judgment and denied appellants' cross-motions. In a 99-page decision, the district court carefully examined defendants' advertising and concluded that they had violated Sections 5 and 12 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. §§ 45, 52, by making false, deceptive, and unsubstantiated claims regarding their supplements' safety, efficacy, and the level of scientific support for those claims. Doc. 219 at 70. The court also found that defendants had falsely represented that they maintained on-site facilities for medical research and clinical testing of their supplements. Doc. 219 at 72-73; see Doc. 172-9 at 17, 23; Doc. 172-10 at 18, 23.

On December 16, 2008, having considered defendants' objections to the FTC's form of proposed order, the district court entered an order permanently enjoining defendants (with the exception of now-dissolved NICWL) from, *inter alia*, making misrepresentations regarding the safety and efficacy of Thermalean, Lipodrene, Spontane-ES, or any other weight loss or erectile dysfunction product. Doc. 230 at 16-17. The court barred defendants' medical endorser, Dr. Terrill Mark Wright, from making any future misrepresentations regarding the safety or

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Doc. 172-28 at 42-56 (FTC SJ Exh. 23).

efficacy of weight loss products or the results of tests or studies. Doc. 229 at 6-10. Additionally, the court held the principal defendants – NUG, NICWL, Hi-Tech, Jared Wheat, Thomasz Holda, and Stephen Smith – jointly and severally liable for monetary equitable relief in the amount of $15,882,436. Doc. 230 at 18. The court ruled that Dr. Wright was liable in the amount of $15,454 for his false and deceptive endorsements for Thermalean. Doc. 229.

This appeal followed.

B. Facts and Proceedings Below

1. Background

Operating from a single address in Norcross, Georgia, defendants marketed a number of dietary supplements – primarily by direct mail advertising – throughout the United States. Defendants promoted Thermalean and Lipodrene to consumers who previously had purchased a weight loss or exercise product. Doc. 172-9 at 24, 35 (FTC SJ Exh. 5 ¶¶ 127, 188-89); Doc. 172-10 at 51 (FTC SJ Exh. 6 ¶¶ 266-67).[7] They made express and unmistakably implied claims about the efficacy and safety of these supplements for rapid and dramatic weight loss (*see*,

[7] They also advertised the products on a web site that was owned and operated by one of defendant Jared Wheat's companies. Doc. 172-9 at 34 (FTC SJ Exh. 5 ¶¶ 179, 181-83); Doc. 172-10 at 46-47 (FTC SJ Exh. 6 ¶¶ 238-40, 244-48); Doc. 172-14 at 36, 56, 65 (FTC SJ Exh. 10 at 191, 301, 310).

e.g., Doc. 1 at 33 ("Thermalean™ promotes fat loss by over 600% without causing dangerous side-effects."); Doc. 1 at 46 ("Lose up to 42% of your total body fat")), and embellished these claims by declaring that the promised dramatic results were supported by scientific and clinical proof.[8] Defendants also relied on supposed expert endorsements by bariatric (*i.e.*, weight-loss) physician, Dr. Terrill Mark Wright, whose pitch for Thermalean lent an aura of legitimacy to their extravagant claims. *See*, *e.g.*, Doc. 1 at 37 ("I consider myself an expert in the field of weight loss and never before have I seen a product (prescription or non-prescription) that is so complete"); Doc. 1 at 41 ("From the desk of Dr. Mark Wright M.D. . . . . Thermalean™ was engineered upon cutting-edge scientific and clinical data which supports our claim that Thermalean™ is unmatched by any other prescription or non-prescription diet aid currently available.").

Defendants pursued a similar approach in marketing Spontane-ES. They identified consumers who previously had purchased a male potency product and, beginning in 2002, began targeting those consumers with direct mail advertising. Doc. 172-10 at 23, 53, 56 (FTC SJ Exh. 6 ¶¶ 120, 275, 295-96). Those mail pieces contained numerous express and obviously implied claims about the product's

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[8] *See*, *e.g.*, Doc. 1 at 32-46; Doc. 172-15 at 75-82 (FTC SJ Exh. 10 at NUG0004109-16).

safety and efficacy (*see*, *e.g.*, Doc. 1 at 16, 48; Doc. 172-10 at 55 ("Can Spontane-ES HELP ME? The results have been extraordinary . . . with success rates as high as 90%")), which defendants embellished – again – with further express and clearly implied representations that those claims were scientifically and clinically proven. *See*, *e.g.*, Doc. 1 at 16; Doc. 172-10 at 55 ("Q. Is Spontane-ES safe? A. Extremely. With five years worth of research and development in each component going into Spontane-ES by the pharmacological staff at WARNER LABORATORIES we have not experienced any harmful side effects to date.").

Defendants, in actuality, had no clinical or scientific studies showing that their dietary supplements were either effective or safe. Indeed, they conceded, they did not conduct (and were not aware of) any such studies of their products.[9] Nor did defendants maintain any medical or scientific facilities for product testing, as they also had claimed. *See* Doc. 219 at 72-73.

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[9] Doc. 172-8 at 63-65 (FTC SJ Exh. 4 ¶¶ 334-41, 343-44); Doc. 172-9 at 62-63 (FTC SJ Exh. 5 ¶¶ 334-41, 343-44); Doc. 172-10 at 62-64 (FTC SJ Exh. 6 ¶¶ 334-41, 343-44); Doc. 172-14 at 39, 40 (FTC SJ Exh. 10 at 228, 237); Doc. 172-17 at 8-9 (FTC SJ Exh. 12 ¶¶ 35-42); Doc. 172-18 at 8 (FTC SJ Exh. 13 ¶¶ 36-43); Doc. 172-24 at 6-11, 13 (FTC SJ Exh. ¶¶ 19-27, 30, 33, 35, 38, 40, 43, 45-46, 55, 58); Doc. 172-28 at 17 (FTC SJ Exh. 23 at 105).

2. Proceedings Below

On November 10, 2004, the Commission, pursuant to Sections 5(a), 12, and 13(b) of the FTC Act, 15 U.S.C. §§ 45(a), 52, and 53(b), filed a nine-count complaint in the United States District Court for the Northern District of Georgia, charging defendants with engaging in unfair or deceptive acts or practices and with distributing false advertising in violation of Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52. The Commission asserted that defendants violated Sections 5 and 12 by making (1) false safety and efficacy claims for their dietary supplements, Thermalean, Lipodrene, and Spontane-ES; (2) unsubstantiated safety and efficacy claims for these products; and (3) false claims regarding research and medical facilities. The complaint also named Dr. Wright with respect to his false and unsubstantiated "expert" endorsements for Thermalean.[10]

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[10] Count One alleged that defendants falsely claimed that Thermalean (1) is clinically proven to be an effective treatment for obesity, (2) causes rapid and substantial weight loss, (3) is clinically proven to cause rapid and substantial weight loss, (4) is clinically proven to cause the loss of specific percentages of fat and a 76.9% increase in metabolic rate, and (5) is clinically proven to inhibit fat absorption, suppress appetite, and safely increase metabolism. Doc. 1 ¶ 21.

Count Two alleged that defendants lacked adequate substantiation for claims that Thermalean (1) is an effective treatment for obesity, (2) causes rapid and substantial weight loss, (3) causes the loss of specific percentages of weight, fat, and a 76.9% increase in metabolic rate, (4) inhibits fat absorption, suppresses appetite, and safely increases metabolism, (5) is equivalent or superior to the

On August 24, 2007, the defendants and the FTC filed cross-motions for

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prescription drugs Meridia®, Xenical®, and Fastin®, and (6) is safe. Doc. 1 ¶ 23.

Count Three alleged that defendants falsely claimed that Lipodrene (1) causes substantial weight loss, (2) is clinically proven to enable users to lose specific percentages of fat and weight and to increase their metabolic rate by up to 50%, (3) is clinically proven to be safe, and (4) is clinically proven to cause virtually no side effects. Doc. 1 ¶ 25.

Count Four alleged that defendants lacked adequate substantiation for the foregoing claims. Doc. 1 ¶ 27.

Count Five alleged that defendants falsely claimed that Spontane-ES is clinically proven to be effective in treating erectile dysfunction and is free from harmful side effects. Doc. 1 ¶ 29.

Count Six alleged that defendants lacked adequate substantiation for claims that Spontane-ES is effective erectile dysfunction and is safe. Doc. 1 ¶ 31.

Count Seven alleged that Dr. Wright falsely claimed that Thermalean is clinically proven to (1) be an effective treatment for obesity, (2) cause rapid and substantial weight loss, (3) cause users to lose specific percentages of fat and to increase metabolic rate by 76.9%, and (4) inhibit fat absorption, suppress appetite, and safely increase metabolism. Doc. 1 ¶ 34.

Count Eight alleged that Dr. Wright lacked a reasonable basis for representations that Thermalean (1) is an effective treatment for obesity, (2) causes rapid and substantial weight loss, (3) causes users to lose specific percentages of fat and to increase metabolic rate by 76.9%, (4) inhibits fat absorption, suppresses appetite, and safely increases metabolism, (5) is equivalent or superior to the weight loss drugs Meridia®, Xenical®, and Fastin®, and (6) is safe. Doc. 1 ¶ 36.

Count Nine alleged that defendants made false representations that Warner Laboratories and NICWL are bona fide research or medical facilities that engaged in scientific or medical research and testing at on-site facilities. Doc. 1 ¶ 38.

summary judgment. Docs. 168, 172. Hi-Tech, although also joining in defendants' collective motion, filed a separate motion for summary judgment (Doc. 170), contending that the products that Hi-Tech had marketed as "Lipodrene" were different from the Lipodrene that NUG had marketed in advertisements cited by the FTC, and, therefore, that it was not involved in the Lipodrene advertising challenged by the FTC. Doc. 219 at 14.

On June 4, 2008, the district court denied Hi-Tech's motion for summary judgment (Doc. 170), ruling that all three of the corporate defendants operated as a common enterprise, and therefore should share liability for all the advertisements at issue. Doc. 219 at 15-16. The court noted that the companies operated under the common control of the individual defendants, Wheat (who served as the "primary decision maker") and Holda, and were at least "influenced by" Smith. Doc. 219 at 16. Furthermore, the court explained, the companies worked together to develop and advertise their products (Doc. 219 at 18-19),[11] and ran them out of

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[11] In this regard, the court noted that Hi-Tech's assertions that it was not responsible for the Lipodrene advertising challenged by the FTC could not be reconciled with Hi-Tech's assertions in a trademark infringement action that it had worked on developing the original Lipodrene formula with a self-described "sister company" – United Metabolic Research Center ("UMRC") – and that UMRC went on to market it by mail order until the product was reformulated. *See* Doc. 219 at 18-19 & n.8.

the same office space in an "integrated fashion," with Hi-Tech – the only company with its name on the door – assuming responsibility for ordering goods and acting as addressee for the other companies, and with NICWL serving as payroll manager for itself, NUG, and all the other affiliated companies. Doc. 219 at 17-18. The court found no evidence that the companies were reimbursed for services that they performed on the other companies' behalf. Doc. 219 at 17 n.7. Indeed, the court noted, the companies were so integrated in their operations that in its own pleadings and documents defendants were unable to maintain a consistent distinction among them.[12] Doc. 219 at 18-19 n.8. Given the "overwhelming

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[12] The district court noted inconsistencies between (1) Hi-Tech's allegations in the trademark infringement suit that it had collaborated with UMRC in developing Lipodrene, and that UMRC went on to market the product until it was reformulated; and (2) Hi-Tech's assertions in the instant action that Warner Laboratories, *a division of NUG*, marketed Lipodrene, and then transmitted the income to NUG. *See* Doc. 219 at 18-19 n.8; Doc. 170-2 at (Memorandum in Support of Hi-Tech Pharmaceutical, Inc.'s Motion for Summary Judgment); Doc. 171 at 10 ¶ 25.

Defendants provided yet another version of the status of UMRC in its statement of material facts in the present case, in which Hi-Tech had joined. According to that document, NUG sold the original Lipodrene under the name "Warner Laboratories," which defendants described as *a division of UMRC*. *See* Doc. 219 at 18-19 n.8; Doc. 198 at 5 ¶ 19.

evidence of the corporations' interrelated functions," the court held that NUG, NICWL, and Hi-Tech must share liability for the advertisements. Doc. 219 at 20.

Turning to defendants' joint motion for summary judgment, the district court rejected their two-pronged attack on the constitutionality of the FTC's advertising standards – *i.e.*, that the standards violate their First Amendment rights and are unconstitutionally vague and overbroad. Doc. 219 at 21-27. With regard to defendants' First Amendment claims, the court held that defendants' reliance on *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557 (1980), was misplaced. The court explained that the three-part analysis in *Central Hudson* was designed to assist courts in determining whether a government regulation that limits protected commercial speech is constitutional; it was not designed to resolve the antecedent question – *i.e.*, whether speech is protected. Doc. 219 at 23. Given that the question before the district court was whether the challenged advertising was deceptive – and therefore not deserving of *any* First Amendment protection under governing law – it concluded that defendants' attempt to apply *Central Hudson* here was "circular," "confusing," and "illogical." *Id.*

The district court rejected the rest of defendants' constitutional challenge as well, ruling that the overbreadth doctrine does not apply to commercial speech.

Doc. 219 at 23-24 (*citing Village of Hoffman Estates v. Flipside*, 455 U.S. 489, 497 (1982)). The district court held that defendants' assertion of unconstitutional vagueness was similarly lacking in merit, given the existence of widely accepted guidelines (including the FTC's own) for defining "competent and reliable scientific evidence"[13] and the relative ease with which an advertiser – by conferring with appropriate professionals – can identify "competent and reliable scientific evidence" for specific products or claims. Doc. 219 at 24-26.

The court addressed next the FTC's motion for summary judgment. First rejecting defendants' untimely attempt to assert affirmative defenses of res judicata and collateral estoppel (Doc. 219 at 29), the court addressed each of the challenged advertising claims, applying the traditional three-part test (*see* Doc. 219 at 30-31) – *i.e.*, whether defendants made (a) a representation (b) that was likely to mislead and (c) that was material. Doc. 219 at 30-37.

With regard to the meaning of the advertisements, the court considered their "overall, net impression" and concluded that defendants' express and obviously

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[13] *See* Doc. 168-10 at 13 (Dietary Supplements: An Advertising Guide for Industry at 9) (Exhibit H to Defendants' Motion for Summary Judgment).

implied representations conveyed all but one of the asserted claims.[14] Specifically, as to Thermalean, the court found that – "in light of the advertisements in full" and Dr. Wright's "expert" endorsements – defendants made express and clearly implied representations that Thermalean is an effective treatment for obesity; is "clinically proven" to enable users to lose a substantial amount of body fat; is "clinically proven" to suppress appetite, increase metabolism, and inhibit fat absorption; and is "safe." Doc. 219 at 43-53. The court squarely rejected defendants' novel proposition that "the clinical trials and the results thereof were explicitly referring to the *ingredients* rather than the product as a whole." Doc. 219 at 45 (emphasis added). Rather, the court found, defendants' "generic reference" to "'Thermalean's proprietary components'" emphasized the "overall product, and thus achiev[ed] the advertisement's goal of promoting the product [they were] attempting to sell." Doc. 219 at 45-46.

The court found similar express and obviously implied claims in defendants' Lipodrene advertisements, concluding that they "clearly represent[ed] that Lipodrene causes substantial weight loss" and enables users to lose body fat and

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[14] The court, however, did not agree with the FTC that – in the absence of extrinsic evidence of consumer understanding – it was possible to conclude that the advertising conveyed the claim that Thermalean was "clinically proven" to treat obesity. Doc. 219 at 43.

increase their metabolic rate, and that these results are "clinically proven." Doc. 219 at 55-58. As to whether the advertising also conveyed the claim that Lipodrene was "clinically proven to be safe," the court held that it did not "need to look further than the express language in the internet printout – *i.e.*, "**Clinically PROVEN to be SAFE AND EFFECTIVE!**." Doc. 219 at 58. Similarly, the court held, a claim that Lipodrene was "clinically proven to cause virtually no side effects" followed directly and obviously from their repeated reference to clinical studies and "Phase I trials." *Id.* at 58-60.

The district court found similar safety and efficacy claims in defendants' advertising for Spontane-ES. Citing, *inter alia*, the "obvious and implied meaning" of specific phrases (*e.g.*, "success rates as high as 90%," "preliminary testing," "research and development," "Letter from the Doctor"), the court concluded that the "obvious, overall implication of the advertisement is that Spontane-ES has a 90% success rate" in treating erectile dysfunction and that this level of success was achieved in clinical trials. Doc. 219 at 61-62. Viewing the advertisements as a whole, the court concluded that they "unambiguously" conveyed the representation that Spontane-ES is safe and clinically proven to be

free from harmful side effects, as alleged in the Commission's complaint. Doc. 219 at 63-64.

Having concluded that defendants' advertising clearly made virtually all of the challenged claims, the district court turned to the second prong of the three-part test – *i.e.*, whether the claims were unsubstantiated or false. Doc. 219 at 34-35, 64. As to the appropriate level of substantiation, the court, citing uncontroverted expert testimony, held that safety and efficacy claims for dietary supplements require "competent and reliable scientific evidence" consisting of well-designed, randomized, double-blind and placebo-controlled clinical trials "on the product itself" – and not, as defendants would allow, on a product that uses a different combination or lower doses of a product's active ingredients.[15] Doc. 219 at 64-66. Given defendants' admission that they did not conduct clinical or scientific testing on their dietary supplements (and, indeed, were not aware of such studies), it followed that all of defendants' safety and efficacy claims were unsubstantiated and also that their specific representations that clinical tests were performed on the products were "inherently false." Doc. 219 at 67-68. The court also concluded

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[15] Defendants did not introduce any evidence of their own as to the proper level of substantiation. They merely contended that they did not make the alleged claims and that the studies regarding the products' ingredients supported their ingredient-specific claims. Doc. 219 at 66 & n.21.

that the Commission had established that defendants' claims that Thermalene and Lipodrene cause substantial and rapid weight loss were false, based on its submission of testimony by a leading expert that "there is no evidence that the active ingredients used in Thermalene and Lipodrene can provide anything more than two pounds per month of weight loss." Doc. 219 at 67-68. The court further explained that defendants had failed to show a substantial issue of material fact as to these conclusions because their only attempt to refute that expert testimony was by "vague" and "ambiguous" reference to their Statement of Material Facts. *Id.*

The court turned next to the last prong of the three-part test – *i.e.*, whether defendants' claims were material to consumers' purchasing decisions. Doc. 219 at 68. Although defendants had conducted two surveys purportedly relating to materiality, the court found that the surveys merely tested small portions of defendants' claims, misstated those claims, or tested irrelevant claims. Doc. 219 at 69-70. Accordingly, the court held, they were not sufficient to controvert the well-established principle that health, safety, and efficacy claims are material to a consumer's purchasing decision. Doc. 219 at 36-37, 68-70. Furthermore, the court reasoned, with the impressive sales that defendants' Thermalean and Lipodrene advertising generated – more than $10.6 million in three years – "no reasonable

jury could find that the advertisements were ineffective and immaterial to consumers as a whole." Doc. 219 at 69.

The court addressed separately the Commission's allegations that, in addition to product safety and efficacy claims, defendants falsely represented that they conducted scientific and medical research and testing at on-site facilities. *See, e.g.*, Doc. 1 at 8, 13-14, 28-29 ("At the National Institute for Clinical Weight Loss our research and development team has developed a non-prescription formulation;" "With five years worth of research and development in each component going into Spontane-ES by the pharmacological staff;" "the professional staff and Medical Board at WARNER Laboratories aligned with one of the nation's largest manufacturing facilities to begin Phase I testing;" "From the desk of: Dr. Mark Wright, M.D., Chief of Staff, NICWL;" "[F]rom Dr. Mark Wright, M.D. – Medical Director for Warner Laboratories"). The court reviewed the foregoing statements and concluded that they represented that NICWL and Warner Laboratories engage in scientific medical research and on-site product testing. Doc. 219 at 72. With regard to defendants' response – *i.e.*, that NICWL and NUG reviewed the research of independent entities regarding some of the ingredients in the products – the court concluded that such "secondary research" regarding some of the ingredients

provided no support for the overall message that they conducted clinical trials and other primary research. Doc. 219 at 73 n.22. Given that defendants did not conduct clinical tests or independent research on the products themselves, and did not offer any evidence to rebut the materiality of these false claims, the court concluded that defendants' medical and research facility claims violated Section 5.[16] Doc. 219 at 73.

Turning to the question of liability, the district court concluded that, because the corporate defendants operated as a common enterprise, they were jointly liable for any deceptive advertising that was attributable to any of them. Doc. 219 at 76. With regard to their principals, Wheat, Holda, and Smith, the court ruled that they had the ability to control the corporate defendants, participated in the unlawful conduct, and knew of, or at least were recklessly indifferent to, the misrepresentations that the advertisements made. Accordingly, the court ruled, they were liable for the corporate defendants' violations of the FTC Act under governing law. Doc. 219 at 78.

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[16] The court also rejected defendants' allegation that most of the advertising claims were "non-actionable puffery." Doc. 219 at 74. The court explained that, even though the ads were riddled with puffery, the proper focus was on "claims derived from each of the advertisements as a whole," not on specific sentences or phrases. *Id.* at 75.

As for defendants' supposed expert endorser, Dr. Terrill Mark Wright, the court held that his involvement in marketing Thermalean warranted liability. The district court reviewed the record and determined that it was "clear" that Dr. Wright helped develop the product, participated in the advertising, and knew that the advertising misrepresented the product, or at the very least was "recklessly indifferent" to its truth or falsity. Doc. 219 at 79. Furthermore, despite knowing that defendants had not conducted clinical trials, Dr. Wright allowed himself to be called "Chief of Staff" and "Medical Director," and endorsed defendants' product without the substantiation that an expert in his field would require. Doc. 219 at 79-80. Accordingly, the court ruled that Dr. Wright was individually liable both for participating in the corporate defendants' misconduct and for making deceptive endorsements. Doc. 219 at 79, 81.

SUMMARY OF ARGUMENT

The Commission presented uncontroverted evidence that defendants made express and clearly implied efficacy and safety claims for their dietary supplements, Thermalean, Lipodrene, and Spontane-ES. Defendants' claims were particularly pernicious because the accompanying representations about clinical

and scientific testing lent them great weight, creating a risk consumers would forgo medical treatment.

Contrary to defendants' assertions, there are no genuine issues of fact as to whether their advertising conveyed the alleged safety and efficacy claims. The district court conducted a careful review of the ads, and concluded that it was not necessary to look beyond their text to find that they communicated virtually all of the claims alleged in the FTC's complaint. Defendants' bald contention that their advertising merely conveyed claims about specific ingredients in the products, but not about the promoted products, is contrary to reason and well-established principles of advertising interpretation. The tendency of an advertisement to deceive is determined by the "net impression" that it conveys, not its constituent parts. The district court therefore properly determined that no disputed issues of material fact remained for trial as to the meaning of defendants' ads.

There were likewise no disputed material facts as to whether defendants' claims for their supplements were false and deceptive. The studies and reports that defendants submitted to support their claims related only to some of the ingredients in their products, not to the products themselves. Moreover, the expert testimony of physicians showed that defendants' materials did not satisfy the standards that

are applicable to health-related claims. Given that defendants did not dispute those standards, their opposition to the Commission's motion for summary judgment created no disputed issues of material fact as to whether their claims were "false" and "deceptive" under the pertinent provisions of the FTC Act.

Defendants' contention that disputed factual issues remain about the materiality of their claims is also meritless. Claims about the efficacy and safety of a product intended for human consumption are deemed material under governing law. Thus, the Commission satisfied its initial burden when it submitted defendants' advertising. Defendants' contention that other factors "potentially explain" consumers' buying decisions is sheer speculation. Moreover, as the district court ruled, the surveys that defendants submitted to dispute the Commission's showing did not test the claims at issue and therefore were not sufficient to avert summary judgment. Defendants' related contention that their advertising contained at most nonactionable "puffery" is similarly unavailing. Given that defendants claimed very specific results for products that purportedly effect changes in bodily functions, it defies all reason to suggest that consumers would view their advertising as conveying mere expressions of opinion.

The district court likewise did not err in granting summary judgment on the Commission's allegation that the corporate defendants formed a common enterprise. The undisputed record shows that the operations and finances of the corporate defendants were interrelated and subject to common control. Although defendants asserted that they maintained separate bank and vendor accounts and each corporation filed its own tax returns, the district court ruled correctly that such distinctions were "superficial" and therefore did not controvert other, undisputed evidence that they functioned essentially as one.

Lastly, the district court did not err in determining that defendants' advertising was not entitled to any protection under the First Amendment. It is well established that false and deceptive claims are not protected commercial speech. Because defendants' claims were false and deceptive and therefore devoid of all value in the marketplace, the district court properly refused to weigh the public interest in restricting their advertising against defendants' purely private interests in conveying their commercial message to the public.

ARGUMENT

I. The District Court Properly Determined That There Were No Genuine Issues of Material Fact for Trial

A. Standard of Review

This Court reviews the district court's grant of summary judgment *de novo*, applying the same standards as the district court. *See, e.g., Bost v. Federal Express Corp.*, 372 F.3d 1233, 1237 (11th Cir. 2004). It may affirm on any basis that is supported by the record, whether or not it has been relied on by the district court. *See, e.g., Smith v. Allen*, 502 F.3d 1255, 1280 (11th Cir. 2007).

B. The District Court Did Not Resolve Disputed Issues of Material Fact in Finding "Unfair or Deceptive Acts or Practices"

1. Legal Framework

Section 5 of the FTC Act prohibits "unfair or deceptive acts or practices in or affecting commerce." 15 U.S.C. § 45(a)(1).[17] An advertisement is "deceptive"

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[17] Section 12 of the FTC Act, 15 U.S.C. § 52, is specifically directed to false advertising of foods, drugs, devices, or cosmetics. An advertisement is "false" under Section 12 of the Act (and therefore an "unfair or deceptive practice" in violation of Section 5) if it is "misleading in a material respect." 15 U.S.C. § 55. Pursuant to Section 15, 15 U.S.C. § 55, an advertisement which is "misleading in a material respect" is "false." In determining whether an advertisement is misleading, "there shall be taken into account * * * not only representations made or suggested by statement, word, design, device, sound, * * * but also the extent to which the advertisement fails to reveal facts material in the light of such representations * * *."

if the representations, omission, or practices likely would mislead consumers, acting reasonably, to their detriment, and they are material.[18] *See, e.g., FTC v. Tashman*, 318 F. 3d 1273, 1277 (11th Cir. 2003); *FTC v. World Travel Vacation Brokers, Inc.*, 861 F.2d 1020, 1029 (7th Cir. 1988). Deception may be by implication rather than outright false statements, and a statement may be deceptive even if the constituent words may be literally true. Thus, the tendency of an advertisement to deceive is determined by a common sense net impression of the advertisement as a whole, not its constituent parts. *See, e.g., FTC v. Stefanchik*, 559 F.3d at 924, 928 (9th Cir. 2009); *FTC v. Cyberspace.com*, 453 F.3d 1196, 1200 (9th Cir. 2006); *Tashman*, 318 F.3d at 1283; *Kraft, Inc. v. FTC*, 970 F.2d 311, 315 (7th Cir. 1992).

Deception may be shown in one of two ways: (1) the express or implied message is misleading, or (2) there is no "reasonable basis" for an advertiser's objective performance claims. *See, e.g., FTC v. Garvey*, 383 F.3d 891, 901 (9th Cir. 2004); *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1096 (9th Cir. 1994); *Thompson*

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[18] A material claim involves information that is important to consumers, and hence, likely to affect their choice of a product. *See, e.g., Novartis Corp. v. FTC*, 223 F.3d 783, 786 (D.C. Cir. 2000); *FTC v. Amy Travel Serv., Inc.*, 875 F.2d 564, 573 (7th Cir. 1989). Express claims and claims that involve health, safety, or efficacy are presumed to be material. *See Novartis*, 223 F.3d at 786-87; *Thompson Medical Co.*, 104 F.T.C. 648, 816 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986).

Medical Co. v. FTC, 791 F.2d 189, 193-94 (D.C. Cir. 1986); *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 958-59 (N.D. Ill. 2006), *aff'd*, 512 F.3d 858 (7th Cir. 2008). To determine whether an advertiser has a "reasonable basis" for a claim, a court first must determine what level of substantiation is appropriate for the claim made. *See, e.g., Pantron I*, 33 F.3d at 1096. It is well-established that health-related efficacy and safety claims require competent and reliable scientific evidence. *See, e.g., Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1492-93 (1st Cir. 1989). In the specific context of dietary supplements, such evidence consists of well-controlled clinical tests on the product itself, or a comparable formulation. *See* pp. 31-32, *infra.*

2. Defendants' Advertisements Conveyed Express and Obviously Implied Claims

In the present case, the district court correctly determined that there was no genuine issue of material fact as to whether defendants' claims for all three of their dietary supplements were false, deceptive, and unsubstantiated under the foregoing standards. As to the meaning of the ads, it was not necessary to look beyond the ads themselves, with their promises of "amazing" and "extraordinary" results, all

purportedly supported by scientific testing. For Thermalean, defendants proclaimed:

> After four full years of product development and feedback from hundreds of thousands of participating clients, we are very proud to announce that **Thermalean™** is the **FIRST** over-the-counter (O.T.C.) nutriceutical to incorporate all three aspects of obesity into one amazing product called **Thermalean™** . . . and the results have been extraordinary . . . . without side effects!

Doc. 1 at 33; Doc. 172-9 at 27(FTC SJ Exh. 5 ¶ 148).

> The introduction of **Thermalean™** reflects the cumulative efforts of many top bariatric (weight loss) physicians, and researchers to bring the public a safe and effective, scientifically-based formulation that will have a significant impact on your weight loss goals!

Doc. 1 at 42; Doc. 172-9 at 33 (FTC SJ Exh. 5 ¶ 175).

> **Q. How much weight can I expect to lose with Thermalean™? A.** Clinical trials based upon **Thermalean™'s** proprietary components have yielded weight loss to nearly 15% of beginning body weight within the first two months! **Example:** (To put this statistic in perspective) Starting Date: June 1st [.] Starting Weight: 200 lbs. Weight after 60 days: 170 lbs. Weight loss in 60 days: 30 lbs.

Doc. 1 at 37; Doc. 172-9 at 29(FTC SJ Exh. 5 ¶ 155).

> Clinical studies show the active components in Thermalean™ yield the following extraordinary results: • Loss of up to 19% total body weight. • Increase metabolic rate by 76.9% without exercise! • Reduction of 40-70% overall fat under the skin. • Loss of 20-35% of abdominal fat!

Doc. 1 at 33; Doc. 172-9 at 26 (FTC SJ Exh. 5 ¶ 146).

> Does **Thermalean™** really work? Yes. **Thermalean™**'s scientifically proven formula has yielded the following results in independent university sponsored trials.

Doc. 1 at 37; Doc. 172-9 at 37 (FTC SJ Exh. 5 ¶ 154).

> **Thermalean™**'s proprietary components have been proven to accomplish the following: • Inhibit Lipase for obesity management by inhibiting the absorption of dietary fats. • Slows the rate at which the body 'metabolizes' serotonin therefore suppressing the appetite. • Safely increasing the metabolic rate without dangerous side-effects associated with prescription drugs.

Doc. 1 at 41; Doc. 172-9 at 32 (FTC SJ Exh. 5 ¶ 172).[19] Similar express claims appeared at Thermalean's web site.[20]

Defendants made similar claims for Lipodrene, which they embellished with further representations about the outcome of purported scientific and clinical testing.[21] For example, defendants admitted claiming the following:

> <u>Clinically PROVEN Weight Loss!</u>

Doc. 172-10 at 42 (FTC SJ Exh. 6 ¶ 218).

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[19] *See also* Doc. 172-9 at 26-35 (FTC SJ Exh. 5 ¶¶ 147, 149-53, 156-59, 169-71, 173-74, 176-78, 186-87).

[20] Doc. 172-9 at 34 (FTC SJ Exh. 5 ¶¶ 179-83).

[21] *See, e.g.*, Doc. 1 at 43-46; Doc. 172-15 at 75-82.

Clinically PROVEN to be SAFE AND EFFECTIVE!

Doc. 1 at 46; Doc. 172-10 at 48 (FTC SJ Exh. 6 ¶ 252).

> **SYNOPSIS: Upon review of 25,000 women and men participating in the PHASE I Trials, Lipodrene™ has shown to yield an 88% SUCCESS RATE with virtually no side effects.**

Doc. 1 at 44; Doc. 172-10 at 45 (FTC SJ Exh. 6 ¶ 233).[22]

Defendants admitted making similar dramatic safety and efficacy claims in advertising Spontane-ES, again highlighting the purported scientific and medical support for those results. *See* Doc. 172-10 at 55-56 (FTC SJ Exh. 6 ¶¶ 291-94).

3. Defendants Lacked Substantiation for Their Claims

In actuality, as shown by the expert reports of two leading physicians, defendants had no scientific or medical support for their advertising claims.[23] With regard to weight loss, the Commission's expert, Dr. Aronne,[24] explained that there

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[22] *See also* Doc. 172-10 at 42-43, 45-46, 48-49, 50-51 (FTC SJ Exh. 6 ¶¶ 219-23, 234-36, 253-54, 261-65).

[23] *See* Doc. 172-29 at 10-109 (Dr. Melman); Doc. 172-26 at 24-62 (Dr. Aronne).

[24] Dr. Louis J. Aronne, is a leading expert in the field of weight loss and obesity research and a Clinical Professor of Medicine at Cornell University Medical College. He has conducted clinical trials and studies of obese patients and has published articles in peer-reviewed journals, book chapters, books, and abstracts, including numerous articles relating to the cause, prevention, and

must be a reliable clinical study – *i.e.*, an independent well-designed, well-conducted, randomized, double-blind, placebo-controlled clinical trial, given at the recommended dosage involving an appropriate sample population in which reliable data on appropriate endpoints are collected over an appropriate period of time.[25] Defendants' submissions, however, did not satisfy these standards. Doc. 172-26 at 62. Indeed, some of defendants' submissions were animal studies that do not provide reliable support for weight loss in humans. Doc. 172-26 at 41. Other studies did not test the ingredients in Thermalean or Lipodrene; were not designed to measure weight loss, involved a reduction in calories or exercise; or tested formulations that were not sufficiently similar to Thermalean or Lipodrene. Doc. 172-26 at 41-56. Furthermore, Dr. Aronne explained, the active ingredients in Thermalean and Lipodrene – ephedrine and caffeine – provide at best a modest two pounds of weight loss per month. Doc. 172-26 at 56. As for safety, Dr. Aronne found no evidence that ephedrine and caffeine combinations are free from harmful side effects, as defendants had claimed. To the contrary, he reported, ephedrine and caffeine have been associated with serious adverse consequences, including

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treatment of obesity. Doc. 172-26 at 24-25, 64-72.

[25] Doc. 172-26 at 30-32, 38.

heart palpitations and an increased risk of hemorrhagic strokes. Doc. 172-26 at 60-61.

A prominent expert in the field of erectile dysfunction, Dr. Arnold Melman,[26] likewise found no reliable scientific evidence to support defendants' claims for Spontane-ES. Doc. 172-29 at 12-14, 19-20, 23, 26. A major problem was the absence of well-designed clinical trials demonstrating the efficacy of the Spontane-ES formula or any other product containing a comparable formula. Doc. 172–29 at 19-26. Existing clinical data on specific ingredients in Spontane-ES did not support defendants' claims either. Doc. 172-29 at 26-40. As Dr. Melman explained, ingredient-specific tests provide no support for the efficacy or safety of a product whose effects are the result of an interaction between ingredients. Doc. 172-29 at 23-24, 26. In any event, the evidence with respect to the primary active ingredient, Yohimbine, indicates that at most it "may" be effective for the small minority of men who are suffer from "psychogenic ED." Doc. 172-29 at 14. As for another active ingredient, L-arginine, it has been studied only in larger doses than found in Spontane-ES and "may be effective" only at treating ED in men with

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[26] Dr. Melman is Professor and Chairman of the Department of Urology at Albert Einstein College/Montefiore Medical Center in New York City. Doc. 172-29 at 10-11.

deficient nitric oxide levels. Doc. 172-29 at 19. With regard to the product's touted safety, Dr. Melman found no clinical trials on the Spontane-ES formula; indeed, the primary ingredient has been shown to elevate blood pressure and speed up a user's heart rate. Doc. 172-29 at 14. Based on these deficiencies and others, Dr. Melman concluded that defendants lacked medical and scientific support for their claims. Doc. 172-29 at 39, 44-45.

4. Defendants' Opposition Failed To Show That Disputed Issues of Material Fact Remained for Trial

The Commission's submission satisfied its initial burden under applicable law. The burden of going forward then switched to defendants to show that a genuine issue remained for trial. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986). It was defendants' obligation to "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). A bald assertion that a genuine issue of material fact exists does not preclude the use of summary judgment. Rather, according to the plain language of Fed. R. Civ. P. 56(e), "an opposing party may not rely merely on allegations or denials in its own pleading," but must come forward with "specific facts showing a genuine issue for trial." *Matsushita*, 475 U.S. at 587; *see International Stamp Art, Inc. v. United States*

Postal Serv., 456 F.3d 1270, 1274 (11th Cir. 2006); *Barfield v. Brierton*, 883 F.2d 923, 934 (11th Cir. 1989).

Defendants did not satisfy these standards. As to the meaning of the ads, defendants did not offer any consumer surveys, declarations, or any other probative evidence of consumers' perception of their claims. They responded instead with the assertion that their claims related to individual ingredients in the products, and not to the branded dietary supplements that they were promoting. *See* Br. 13-16, 28-32. As the district court ruled, this assertion did not create a genuine issue of fact for trial. *See* Doc. 219 at 66-67. First, the idea that consumers would perceive only representations as to specific ingredients in the supplements is belied by the ads themselves, which highlight the names of the promoted products repeatedly throughout the ads. *See*, e.g., pp. 28-29, *supra*. [27] It therefore defies all reason to suggest that consumers would interpret the ads as promoting only a specific unnamed ingredient's benefit in lieu of that of the promoted products. Second, the very *purpose* of defendants' advertising was to promote their branded products.[28]

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[27] Indeed, the two-page Lipodrene ad that is attached as Exhibit D to the Commission's complaint contains at least 20 references to "Lipodrene," but not even one reference to a specific ingredient in the product. *See* Doc. 1 at 44-45.

[28] Hi-Tech conceded this obvious point by bringing a trademark infringement action in which it alleged that it incurred substantial costs, including

Thus, it is not surprising that, to the extent the advertisements provided information about ingredients, it clearly was to reinforce the main message – *i.e.*, that defendants' branded products were both effective and safe. *See, e.g.*, Doc. 1 at 44 ("With the Explotab delivery, **Lipodrene** is quickly and efficiently absorbed in [sic] tract, ensuring maximum availability of the active components and * * * maximum potency."); *id.* ("With **Lipodrene**, we are sure to be delivering nearly 100% of the active components * * * a measure which helps tremendously in maintaining the integrity of our research and product claims.").

Defendants' unconventional approach is also at odds with fundamental principles of ad interpretation. It is always possible to deconstruct an ad into its component parts. But, as this Court and others have recognized, the relevant reference point is the *net impression* of the ad as a whole. "The entire mosaic should be viewed rather than each tile separately. The buying public does not ordinarily carefully study or weigh each word in an advertisement. The ultimate impression upon the mind of the reader arises from the sum total of not only what is said but also of all that is reasonably implied." *FTC v. Sterling Drug, Inc.*, 317

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for advertising, in order to establish consumer recognition of the Lipodrene brand as a class of weight loss products. *See Hi-Tech Pharm., Inc. v. Demelo*, No. 1:07-cv-1934 (N.D. Ga., filed Aug. 15, 2007).

F.2d 669, 674 (2d Cir. 1963) (internal citation omitted); *see Tashman*, 318 F.3d at 1283; *accord*, *Stefanchik*, 559 F.3d at 928; *Cyberspace.com*, 453 F.3d at 1200; *Kraft, Inc.*, 970 F.2d at 315. That is precisely how the district court viewed defendants' ads. *See* Doc. 219 at 75-76.

Nor is there any merit to defendants' contention that the district court improperly resolved disputed issues of material fact as to the adequacy of their substantiation. *See* Br. 35-43. Defendants describe various studies that they contend constituted adequate substantiation because they were "independent, double-blind, placebo-controlled clinical trials of the ingredients and/or a meta analysis of those clinical trials." Br. 35. But the existence of such materials is not enough to create disputed issues of material fact – *i.e.*, ones that affect the outcome of the case under governing law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The Commission submitted expert testimony that defendants' claims can be substantiated only through well-controlled clinical tests of the products, or a substantially similar formulation. *See* Doc. 172-26 at 40 (Dr. Aronne) ("[S]tudies of a particular ingredient or combination of ingredients to treat a particular condition cannot be relied upon as scientific evidence of another non-identical treatment to treat that condition unless scientists know enough about how

combinations of the different ingredients will interact."); Doc. 172-29 at 23 (Dr. Melman) ("An ingredient that has been shown to be effective or safe for the treatment of a condition may not be effective when combined with other active ingredients."). That testimony is consistent with widely-accepted standards for substantiation of health-related claims, including weight loss. *See, e.g.*, *Removatron Int'l*, 884 F.2d at 1498 (1st Cir. 1989); *Simeon Mgmt. Corp. v. FTC*, 579 F.2d 1137, 1143-44 (9th Cir. 1978); *FTC v. Natural Solution, Inc.*, U.S. Dist. LEXIS 60783 at *12 (C.D. Cal. Aug. 7, 2007) (human clinical trials required to evaluate cancer treatment product); *QT, Inc.*, 448 F. Supp. 2d at 943; *SlimAmerica*, 77 F. Supp. 2d at 1274.

But the materials that defendants offered in opposing summary judgment did not satisfy those standards. Rather, they offered studies that were not adequate because they were ingredient-specific, did not study the products at issue or a comparable formulation, or had other flaws that for a number of reasons did not provide adequate substantiation for the kinds of claims they made. *See discussion* pp. 30-32, *supra*. Having failed to dispute those standards with evidence of their

own (*see* Doc. 219 at 66 & n.21), defendants' proffer plainly fell far short of what was needed to justify a trial.[29]

Finally, there is no merit to defendants' contention that disputed issues of material fact remain as to the materiality of their advertising claims. Br. 45-48. The gist of their contention is that "the FTC failed to produce any evidence that the alleged false or material claims were material to any consumer's single purchasing decision." No such showing was required. It is presumed that express and clearly implied claims as to the safety and efficacy of a product intended for human consumption are material to a consumer's decision to purchase the product. Thus, the Commission carried its initial burden when it submitted advertising containing such claims. *See, e.g., Novartis Corp. v. FTC*, 223 F.3d at 786; *FTC v. Bronson Partners, LLC*, 564 F. Supp. 2d 119, 135 (D. Conn. 2008).

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[29] Defendants also contend (Br. 43) that the district court improperly resolved material disputed facts in regard to the claims alleged to be false – *i.e.*, that a clinical test was performed. *See* Doc. 219 at 67. This contention is premised on the assumption that the district court erred in failing to acknowledge "the disputed fact as to whether the Defendants' advertisements related to the ingredients or components of the product, rather than the product itself. Br. 43-44. In fact, as shown above (pp. 34-36, *supra*), defendants' response to the Commission's summary judgment motion was not adequate to create a dispute as to whether the advertisements related to ingredients or components of the products. Thus the disputed issue as to whether the claim was false does not arise.

Defendants contend that reasons, other than the ads themselves, "potentially explain consumers' buying decisions such as word-of-mouth, discussions with customer service representatives, and prior experiences." Br. 46-47. But, given the nature of the claims they made, defendants do not stave off summary judgment by speculating that other factors "potentially explain consumers' buying decisions."[30] Br. 46. *See Cordoba v. Dillards, Inc.*, 419 F.3d 1169, 1181 (11th Cir. 2005) ("'[Unsupported speculation * * * does not meet a party's burden of producing some defense to a summary judgment motion. Speculation does not create a *genuine* issue of fact; instead, it creates a false issue, the demolition of which is a primary goal of summary judgment.'") (*quoting Hedberg v. Indiana Bell Tel. Co.*, 47 F.3d 928, 931-32 (7th Cir. 1995) (emphasis in original)).

Defendants' contention that the district court improperly based its decision regarding materiality on the large volume of sales the ads generated is also meritless. Br. 47. The district court did not base its decision regarding materiality

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[30] Even assuming that these factors could explain the buying decision for some unidentified subset of consumers, it is outlandish to suggest that they could account for more than $15 million in sales. Many factors are likely to affect a consumer's choice of a product. *See, e.g., American Home Products Corp. v. FTC*, 98 F.T.C. 136, 368 (1981) (requirement of materiality is satisfied by a showing that a particular claim is likely to affect a consumer's choice of a product), *aff'd*, 695 F.2d 681 (3d Cir. 1982). There is no requirement that the Commission prove that it is solely attributable to the challenged claims.

on this alone. In fact, the court recognized the well established presumption that health and safety claims are material to a consumer's purchasing decision. Doc. 219 at 68. Recognizing that defendants had the opportunity to rebut that presumption, the court reviewed defendants' surveys. The court ruled, however, that those surveys had tested the wrong advertising claims, and therefore that they did not rebut the presumption that health and safety claims are material. Doc. 219 at 68-69. According to the district court, the large volume of sales also showed that "the advertising appealed to many people and whetted their desire to purchase the Thermalean and Lipodrene products." Doc. 219 at 69.

Finally, there was no impropriety in the district court's treatment of defendants' consumer surveys. Defendants contend that the surveys created an issue of material fact as to the materiality of their advertising claims. Br. 48. But the surveys did not test the advertising claims at issue. Rather, they tested "small portions of those claims, misstatements of the claims, or claims wholly irrelevant to the case."[31] Doc. 219 at 69-70. Given these circumstances, defendants' surveys

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[31] The Commission's expert, Dr. Stewart, examined defendants' surveys and concluded that their "failure to define the relevant population in terms of consumers in the market for the products at issue was a fatal flaw and made his results of no value for understanding what messages are communicated to or important to members of the relevant population." Doc. 189, Exh. A at 7. *See also* Doc. 189, Exh. A at 12 ("Dr. Richey does not ask questions that would allow him

were plainly inadequate to create a disputed issue of fact as to the materiality of defendants' claims and therefore did not preclude summary judgment.

C. The District Court Did Not Resolve Disputed Issues of Material Fact in Finding a Common Enterprise

Defendants also contend that the district court improperly weighed the evidence and resolved disputed issues of fact in finding that the corporate defendants formed a "common enterprise." Br. 20-25. According to defendants, the existence of separate bank accounts, vendor accounts, tax filing, and product lines were not "superficial in nature," as the district court had concluded. Thus, they contend, there was enough for a "reasonable fact finder to draw more than one inference as to the distinct nature of Hi-Tech, NUG, and NICWL." Br. 21.

As defendants acknowledge (Br. 20), when two or more entities form part of a common enterprise, each may be held liable for the unlawful practices of the others. *See, e.g.*, *Sunshine Art Studios v. FTC*, 481 F.2d 1171, 1175 (1st Cir. 1973); *Delaware Watch Co. v. FTC*, 332 F.2d 745, 745-46 (2d Cir. 1964); *Waltham Precision Instrument Co. v. FTC*, 327 F.2d 427, 431 (7th Cir. 1964). A number of factors are relevant to the existence of a common enterprise – *e.g.*, a common control group, sharing of office space and officers, commingling of funds,

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to determine whether the claims in the complaint are communicated * * *.").

unified advertising, conducting business through a maze of interrelated companies, and any other factors that reveal that no real distinction exists. *See, e.g., Sunshine Art Studios*, 481 F.2d at 1171; *Delaware Watch Co. v. FTC*, 332 F.2d at 746; *FTC v. Neovi, Inc.*, 2008 U.S. Dist. LEXIS 107443 at *28 (S.D. Cal. Sept. 16, 2008). But ultimately the question is whether – looking at all the relevant factors – it can be said that the companies functioned as a single economic unit. *See Delaware Watch Co.*, 332 F.2d at 746 ("[T]he pattern and frame-work of the whole enterprise must be taken into consideration.").

Defendants reliance on the existence of separate bank accounts, product lines, vendor accounts, and tax filings is unavailing because other, undisputed evidence reflects a complete absence of independent decision making among the corporate defendants.[32]

All of the corporate defendants functioned under common management. As defendants' outside accountant explained, the corporate defendants formed part of

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[32] Indeed, as explained in Wheat's deposition testimony, "the main reason [they] set up the numerous corporations," each with a separate product line, was a matter of convenience – namely, to gain the perceived ability to protect the other members of the corporate family in the event of a product liability suit against one of them. Doc. 198-45 at 45.

a group of five interrelated Sub-chapter S corporations.[33] *See also* Br. 22 ("It is true that the individual Defendants were officers in all three companies at various times."). Defendants assert that "the only owner common to all the [defendant] companies was Defendant Wheat, and his ownership interest in each company varied." *Id.* But the undisputed fact of common control is precisely the point. Even assuming that ownership shifted over various times in the manner suggested in defendants' brief, that would not diminish in importance the undisputed fact that all five corporations were principally controlled by a single person during the relevant time period.[34]

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[33] He described the arrangement with respect to Mr. Wheat as follows:

> Jared Wheat, the Chief Executive Officer of the companies identified above [Hi-Tech, NUG, NICWL, American Weight Loss Clinic, Inc., and UMRC], receives modest salaries from the companies. Mr. Wheat's services go beyond traditional CEO services and include product design and formulation, marketing, CFO services and other activities. In the Product Statements of Income, the Salaries - Officers line item reflects the allocable portions of these modest salaries as an expense. However, the primary source of Mr. Wheat's remuneration is received in the form of distributions of profits from the companies rather than salaries.

Doc. 172-11 at 38 (FTC SJ Exh. 7 at NUG00066355).

[34] Moreover, according to defendants' calculations (Br. 5, 8, 10-11), at all times during the relevant period defendants Wheat and Holda together owned more than 50% of each defendants company and were officers in all three companies.

Furthermore, apart from common control, undisputed evidence shows that the companies' finances were thoroughly intertwined. As shown in the product liability statements of income for the three products at issue, the corporations shared indirect costs and expenses across numerous categories – *e.g.*, depreciation, consulting fees, professional fees, and travel.[35] Indeed, a single corporation, NICWL, paid the salaries of all non-management personnel at all five companies.[36] Defendants, citing Wheat's conclusory testimony, assert that "the mail order companies did reimburse each other for the use of their respective employees." Br. 23 n.8. But that self-serving assertion was not enough to controvert the Commission's showing that the companies' operations were intertwined. *See FTC v. Publ'g Clearing House, Inc.*, 104 F.3d 1168, 1171 (9th Cir. 1997) (self-serving affidavit, lacking detailed facts and supporting evidence). Defendants point to no evidence of a factual nature that the companies reimbursed each other for expenses that were paid on a sister company's behalf, either for using a sister company's employees or for anything else.

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[35] Doc. 172-11 at 20-22 (FTC SJ Exh. 7 at NUG0006337-39).

[36] Doc. 172-11 at 20 (FTC SJ Exh. 7 at NUG0006337).

Indeed, as shown in defendants' product statements of income, their calculations of the profitability of each of the three products in essence acknowledged that all five companies formed a common enterprise. Specifically, to allocate indirect expenses to each of the three products, defendants first computed the *total* of each indirect expense *for all five companies* during the period of sales of that product. Next, defendants calculated that product's total sales revenue as a percent of the *total* sales revenue *of all five companies* during the relevant period. Their final step was to apply the resulting percent-sales figure to the five-company expense total for each indirect expense.[37] In other words, defendants' allocation methodology treated each indirect cost not as separable and measurable for each of the five companies, but instead as a cost that was indivisible and common to all five companies.

As for defendants' claim that Hi-Tech had a completely different business model, was not involved in the challenged advertising, and did not share in the costs and expenses associated with marketing or producing Lipodrene (Br. 23-24),

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[37] *See* Doc. 172-11 at 17 ("Product Statements of Income Thermalean, Lipodrene and Spontane-ES"), 20-22 (note to "Allocation of Indirect Costs and Expenses" for each product states as follows: "[g]enerally, indirect costs and expenses are allocated to the product in the ratio of product sales *to total sales of all dietary supplement products by the five companies* * * *.") (emphasis added).

undisputed evidence shows to the contrary. Indeed, as the district court noted (Doc. 219 at 18-19), the notion that Hi-Tech was not involved in marketing Lipodrene is inconsistent with Hi-Tech's allegations in a pending trademark infringement suit, *Hi-Tech Pharm., Inc. v. Demelo*, No. 1:07-cv-1934 (N.D. Ga.). In that case, Hi-Tech alleged that it developed the original Lipodrene formula with another one of Wheat's corporations, United Metabolic Research Center ("UMRC"),[38] and that it owns the Lipodrene trademark as the result of an assignment by defendant Jared Wheat. *See* Doc. 194-9 at 17-19. Additionally, portions of text in the promotional Lipodrene brochure that Hi-Tech attached to its trademark complaint is virtually the same as the text that appears in materials that its sister corporation, NICWL, used in marketing Thermalean by direct mail. *Compare* Doc. 194-9 at 77-91 (Lipodrene) *with* Doc. 1 at 32-42 (FTC Complaint Exh. A) (Thermalean). Defendants' practice of transferring verbatim or nearly verbatim claims from one company's product to another further demonstrates that all of Wheat's corporate entities – rather than operating at arms length – functioned essentially as one.

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[38] Although UMRC appears as a separate entry in the accounting materials, defendants "essentially concede[d]" that NUG and UMRC were the "same entity." Doc. 219 at 18-19 n.8. As the district court explained, Hi-Tech used NUG's and UMRC's names interchangeably throughout its Response to the FTC's Statement of Additional Facts (Doc. 202-2). Indeed, the court noted, Hi-Tech referred to them jointly as "NUG/UMRC" in its reply memorandum. *See* Doc. 202 at 5 n.3.

To summarize, the ultimate question is whether the strategic decisions of each company were the product of independent decision making. That was not the case here. Instead, undisputed evidence shows that all of the corporate entities were tightly interwoven in their business strategy and operations. That is the mark of a common enterprise.

D. There Was No Disputed Question of Fact Regarding "Puffing"

Finally, defendants contend that, even if all the foregoing rulings were correct, their advertising was non-actionable "puffery." Br. 48-50. According to defendants, once the district court identified puffery in the ads, "it should have ceased any further analysis, * * * denied summary judgment, * * * and let the case proceed to trial." Br. 50.

As defendants recognize, puffing refers generally to an expression of opinion that is not offered as a representation of fact. *See, e.g., FTC v. Febre*, 1996 U.S. Dist. LEXIS 9487 at *9 (N.D. Ill. 1996); *FTC v. U.S. Sales Corp.*, 785 F. Supp. 737, 746 (N.D. Ill. 1992). It defies all reason to suggest that efficacy and safety claims for products that purportedly will cause users to experience weight loss or other changes in how their bodies function could possibly be viewed as a mere expression of opinion. Undoubtedly, as the district court ruled (Doc. 219 at 75), the

ads contained some puffing. But those innocuous expressions of opinion do not diminish defendants' express and nearly express performance and safety claims. Indeed, defendants touted very specific results for their products, expressed, in many instances, in terms of specific percentages of weight or fat that users can expect to lose. *See*, e.g., pp. 28-29, *supra*. In marketing Thermalean, for example, they enlisted the aid of an "expert" testimonial by a physician (*see* p. 19, *supra*), again an obvious ploy to ensure that consumers would regard their claims seriously. Their frequent references to studies, tests, and the like were all also obviously designed to ensure that their ads would carry some weight. They fall well outside the category of claims for which consumers would not expect documentation.

II. The District Court's Analysis of Defendants' Advertising Claims Did Not Abridge Their First Amendment Rights

A. Standard of Review

Whether the district court's analysis of defendants' dietary supplement advertising violated their First Amendment rights is a question of law that is determined by this Court *de novo*. *See*, *e.g.*, *MONY Secs. Corp. v. Bornstein*, 390 F.3d 1340, 1342 (11th Cir. 2004).

B. Defendants' Advertising Is Not Protected Speech

Appellants' contention that the district court erred in rejecting their First Amendment claims rests primarily on an erroneous premise – that in evaluating their First Amendment claims the court should have applied the three-part test that the Supreme Court articulated in *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980). *See* Br. 52-58.

In *Central Hudson*, the Supreme Court addressed the question whether a prophylactic regulation that limits or prohibits an entire class of protected commercial speech – in that case, a state-imposed ban on promotional advertising by electric utilities – could pass constitutional muster. The Court held that the challenged ban violated the utilities' First Amendment rights because it was more extensive than necessary to advance the state's legitimate interests in energy conservation and the utilities' advertising was not misleading or unlawful. *Central Hudson*, 447 U.S. at 566; *see, e.g., Mainstream Mktg. Servs. v. FTC*, 358 F.3d 1228, 1237 (10th Cir. 2004) (applying *Central Hudson* to FTC regulation prohibiting commercial calls to consumers in "do-not-call" registry).

By contrast to *Central Hudson*, the instant case does not involve a prior restraint or regulation of protected commercial speech. It involves a different

question – namely, whether the claims that defendants conveyed in their ads were false or deceptive, and therefore not entitled to any protection under the First Amendment. *See Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 645-46 (1985) (assessing deceptive advertising under the FTC Act is a "qualitatively different task" than assessing the validity of a state advertising regulation). Thus, as the district court properly ruled (Doc. 219 at 22-23), defendants' attempt to use a *Central Hudson* analysis was "circular," "confusing," and "illogical."[39]

Defendants' related contention that they were entitled to a *Central Hudson* analysis because their advertising was at most only "potentially misleading" is also meritless. Br. 54. Contrary to defendants' implication, courts have analyzed commercial speech as "potentially misleading" under *Central Hudson* not where particular instances of deception are implied rather than express, but where the government has sought to suppress an entire class of statements because of concerns that consumers might, in some instances, fall under a misimpression. For example, in *Borgner v. Brooks*, 284 F.3d 1204 (11th Cir. 2002), this Court applied such analysis to a blanket restriction on the use of certain specialty designations – such as "implant dentistry" – unless specified disclaimers were used. *See also*

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[39] Moreover, given that the *Central Hudson* factors do not apply at all, the FTC did not "fail[] to meet its burden" in declining to apply them. Br. 55-57.

Mason v. Florida Bar, 208 F.3d 952 (11th Cir. 2000) (general restriction on lawyers' use of ratings in advertisements). Here, by contrast, the district court imposed liability only upon advertising claims that it concluded, after a careful review, actually to be false and deceptive.[40] That was a determination the district court was entitled to make.

It is well established that the district courts are competent to construe advertising and to determine whether it conveys false or deceptive claims, even in the absence of extrinsic evidence of consumer understanding. *See, e.g., Zauderer*, 471 U.S. at 652-53 ("[w]hen the possibility of deception" is "self-evident," consumer survey is not required); *FTC v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 41 (D.C. Cir. 1985) (when an alleged deception rises to the commonplace, a court may find it "self-evident" without market research or surveys); *Kraft*, 970

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[40] Defendants suggest that the district court ignored "hundreds of pages of scientific material, testimony and even experts" in determining that the claims were "inherently false." Br. 54 n.17. They do not specify which materials they have in mind. But it is clear that the district court reviewed the entire record and determined that there was nothing that created a genuine issue of material fact either as to the meaning of the ads or the question whether defendants had the required level of substantiation for their claims. *See* Doc. 219 at 66-68, 72-73. The mere existence of "hundreds of pages" of material does not justify a trial. There must be a dispute of a material fact – *i.e.*, one that affects the outcome of the case under governing law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

F.2d at 320 ("when confronted with claims that are implied, yet conspicuous, extrinsic evidence is unnecessary * * *."). Indeed, courts routinely make this determination on summary judgment. *See, e.g., FTC v. Bay Area Bus. Council, Inc.*, 423 F.3d 627, 635 (7th Cir. 2005); *FTC v. Bronson Partners, LLC*, 564 F. Supp. 2d 119 (D. Conn. 2008); *FTC v. Natural Solution, Inc.*, 2007 U.S. Dist. LEXIS 60783 (C.D. Cal. Aug. 7, 2007); *FTC v. SlimAmerica, Inc.*, 77 F. Supp. 2d 1263, 1272-74 (S.D. Fla. 1999) (express claims in weight-loss advertisement); *FTC v. Gill*, 71 F. Supp. 2d 1030, 1043 (C.D. Cal. 1999) (action challenging implied claims after determining the ads' "overall net impression").

Likewise lacking in merit is defendants' novel contention that First Amendment considerations require a showing that defendants "knew or should have known that consumers would perceive the specific inaccurate implications asserted by the FTC." Br. 55. As the district court found, defendants' advertising involved multiple express or obviously implied claims relating to the central features of defendants' products – *i.e.*, their safety and efficacy. *See, e.g.*, Doc. 219 at 41-44, 58, 61-63. It strains credulity to believe that defendants would make those claims the centerpiece of their advertising campaign without any assurance or belief that consumers would perceive and understand them. Furthermore, defendants cite no

support for the proposition that the First Amendment requires a special showing of an advertiser's intent. Br. 55-56. Under the FTC Act, the only relevant questions are whether (1) the advertisement conveys a representation, either expressly or by implication; (2) the representation is likely to mislead consumers; and (3) the misleading representation is material. *See, e.g.*, *Tashman*, 318 F.3d at 1283. Courts have specifically rejected the proposition that the Commission also must prove intent.[41] *See, e.g.*, *FTC v. Bay Area Bus. Council*, 423 F.3d 627, 635 (7th Cir. 2005); *FTC v. Freecom Commc'ns, Inc.*, 401 F.3d 1192, 1202 (10th Cir. 2005); *Amy Travel Serv.*, 875 F.2d at 574; *Orkin Exterminating Co. v. FTC*, 849 F.2d 1354, 1368 (11th Cir. 1988). Defendants apparently believe that the absence of an intent requirement is not sound public policy. But given that false and misleading speech enjoys *no* protection under the First Amendment, the Commission's failure to prove that false and misleading speech was intentional could never assume constitutional proportions. *See Zauderer*, 471 U.S. at 638 ("The States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading."); *In re R. M. J.*, 455 U.S. 191, 203 (1982)

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[41] It certainly is not a constitutional imperative. *See, e.g.*, *Florida Bar v. Went For It*, 515 U.S. 618, 632 (1995) (least restrictive means test has no application to commercial speech).

("Misleading advertising may be prohibited entirely."); *Central Hudson*, 447 U.S. at 563-64 ("The government may ban forms of communication more likely to deceive the public than to inform it * * *."); *Bristol-Myers Co. v. FTC*, 738 F.2d 554, 562 (2d Cir. 1984) ("[D]eceptive advertising enjoys no constitutional protection.").

Equally meritless is defendants' startling assertion that, as a predicate to enforcing the prohibitions of the FTC Act against false and deceptive advertising, the Commission – to avoid chilling commercial speech – must first promulgate a rule relating to standards for advertising interpretation and substantiation. Br. 57-58. The Commission has broad discretion in deciding how to best remedy "unfair or deceptive acts or practices." This includes a decision to proceed by means of case-by-case adjudication in lieu of rulemaking. *See NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 294 (1974); *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947); *Montgomery Ward & Co. v. FTC*, 691 F.2d 1322, 1328 (9th Cir. 1982). Moreover, defendants' concern with the possibility of chilling effect rings hollow. Due to financial incentives, commercial speech is more durable than other forms of expression. Therefore, there is "little likelihood of its being chilled by proper regulation and foregone entirely." *Virginia State Bd. of Pharmacy v. Virginia*

Citizens Consumer Council, 425 U.S. 748, 772 (1976). The ability of commercial speakers "to evaluate the accuracy of their messages and the lawfulness of the underlying activity" further minimizes the risk of chilling commercial messages. *Central Hudson*, 447 U.S. at 564. Indeed, a well-developed body of FTC advertising law and policy statements provided defendants with ample guidance as to the requirements for their dietary supplement advertising. *See* Dietary Supplements: An Advertising Guide for Industry (April 2001);[42] FTC Policy Statement on Deception (appended to *Cliffdale Associates, Inc.*, 103 F.T.C. 110, 174 (1984));[43] FTC Policy Statement Regarding Advertising Substantiation (reprinted in *Thompson Medical Co.*, 104 F.T.C. 648, 839 (1984), *aff'd*, 791 F.2d189 (D.C. Cir. 1986)).[44] Defendants' failure to adhere to those guidelines leaves them with little reason to complain.

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[42] *Available at* http://www.ftc.gov/bcp/edu/pubs/business/adv/bus09.shtm.

[43] *Available at* http://www.ftc.gov/bcp/policystmt/ad-decept.htm.

[44] *Available at* http://www.ftc.gov/bcp/guides/ad3subst.htm.

CONCLUSION

For all the forgoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitation set forth in Fed. R. App. P. 32(a)(7)(B). This brief contains 12,206 words.

June 15, 2009

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CERTIFICATE OF SERVICE

This is to certify that on this 15th day of June 2009, copies of the foregoing Brief for Plaintiff-Appellee Federal Trade Commission were mailed by overnight courier to the Clerk, United States Court of Appeals for the Eleventh Circuit, and to each of the following:

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