No. 12-12382-AA

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 12-12382-AA, *Federal Trade Commission v. Garden of Life, Inc.*

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No. 12-12382-AA, *Federal Trade Commission v. Garden of Life, Inc.*

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STATEMENT REGARDING ORAL ARGUMENT

The Federal Trade Commission believes that oral argument will assist the Court in resolving the issues presented in this appeal.

TABLE OF CONTENTS

PAGE

CERTIFICATE OF INTERESTED PERSONS C-1

STATEMENT REGARDING ORAL ARGUMENT i

TABLE OF CONTENTS ii

TABLE OF CITATIONS v

STATEMENT OF JURISDICTION 1

STATEMENT OF THE ISSUES PRESENTED 1

STATEMENT OF THE CASE 3

A. Nature of the Case, Course of Proceedings, and Disposition Below 3

B. Facts and Proceedings Below 4

1. Background 4

2. The Civil Contempt Proceedings 9

I. THE DISTRICT COURT ABUSED ITS DISCRETION IN DENYING THE COMMISSION'S MOTION TO HOLD DEFENDANTS IN CONTEMPT FOR MAKING UNSUBSTANTIATED SUPERIORITY CLAIMS AND MISREPRESENTING STUDIES OF THEIR CALCIUM PRODUCTS 17

A. The Court Erred as a Matter of Law in Ruling that the Stipulated Final Order Does Not Apply to Defendants' Superiority Claims 18

B. The Court Erred as a Matter of Law in Ruling that a Prohibition of Unsubstantiated Comparative Claims Would Be an Unenforceable "Obey-the-Law" Injunction . . . 21

C. The Court Abused its Discretion in Ruling that Defendants Did Not Make Unsubstantiated Superiority Claims 27

CONCLUSION 43

CERTIFICATE OF COMPLIANCE

CERTIFICATE OF SERVICE

TABLE OF CITATIONS

CASES **PAGE**

American Home Prods. Corp. v. FTC,

695 F.2d 681 (3d Cir. 1982) 21, 27

Beneficial Corp. v. FTC,

542 F.2d 611 (3d Cir. 1976) 27

Carter Prods., Inc. v. FTC,

323 F.2d 523 (5th Cir. 1963) 28

Citizens for Police Accountability Political Comm. v. Browning,

572 F.3d 1213 (11th Cir. 2009) 13

Combs v. Ryan's Coal Co., Inc.,

785 F.2d 970 (11th Cir. 1986) 26

FTC v. Colgate-Palmolive Co.,

380 U.S. 374, 85 S. Ct. 1035 (1965) 25

FTC v. Direct Mktg. Concepts, Inc.,

624 F.3d 1 (1st Cir. 2010) 37

FTC v. Lane Labs-USA, Inc.,

No. 00-cv-3174, 2011 U.S. Dist. LEXIS 133144

(D.N.J. Nov. 18, 2011) 39

FTC v. Lane Labs-USA, Inc.,

624 F.3d 575 (3d Cir. 2010) 19, 20, 23, 30, 38, 39

FTC v. Nat'l Urological Grp., Inc.,

645 F. Supp. 2d 1167 (N.D. Ga. 2008),

aff'd, 356 Fed. Appx. 358 (11th Cir. 2009) 25, 37

FTC v. Ruberoid Co.,

343 U.S. 470, 72 S. Ct. 800 (1952) 25

Hughey v. JMS Developmental Corp.,

78 F.3d 1523 (11th Cir. 1996) 21, 22, 23, 24, 25, 26

Kraft, Inc. v. FTC,

970 F.2d 311 (7th Cir. 1992) 21, 27

, 5 . . . . *2*

NLRB v. Alterman Transp. Lines, Inc.,

587 F.2d 212 (5th Cir. 1979) 26

Schmidt v. Lessard,

414 U.S. 473, 94 S. Ct. 713 (1974) 23

SEC v. Goble,

2012 U.S. App. LEXIS 10813 (11th Cir. May 29, 2012) 14, 23, 25

SEC v. Sky Way Global, LLC,

710 F. Supp. 2d 1274 (M.D. Fla. 2010) 24

SEC v. Smyth,

420 F.3d 1225 (11th Cir. 2005) 23

Sterling Drug Inc. v. FTC,

741 F.2d 1146 (9th Cir. 1984) 20

Thomas v. Blue Cross & Blue Shield Ass'n,

594 F.3d 814 (11th Cir. 2010) 13

Thompson Medical Co., Inc. v. FTC,

791 F.2d 189 (D.C. Cir. 1984) 27

Turner v. Orr,

759 F.2d 817 (11th Cir. 1985) 13

FEDERAL STATUTES

Federal Trade Commission Act

15 U.S.C. § 45 . . . . 1, 3

15 U.S.C. § 52 . . . . 1, 3

15 U.S.C. §§ 53(b) 1

28 U.S.C. § 1291 1

28 U.S.C. § 1331 1

28 U.S.C. § 1337(a) 1

28 U.S.C. § 1345 1

MISCELLANEOUS

Federal Trade Commission, *Dietary Supplements: An Advertising Guide for Industry* (2001) 28, 37

STATEMENT OF JURISDICTION

The Federal Trade Commission ("FTC" or "Commission") initiated the underlying action in the United States District Court for the Southern District of Florida seeking relief for defendants' violations of Sections 5 and 12 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. §§ 45, 52. The district court's jurisdiction over this matter derives from 28 U.S.C. §§ 1331, 1337(a), and 1345, and 15 U.S.C. § 53(b).

In this appeal, the Commission seeks review of an order entered by the district court on February 27, 2012, denying the Commission's motion to hold defendants in contempt for violations of a previously-entered Stipulated Final Order and Judgment for Permanent Injunction and Other Equitable Relief ("Stipulated Final Order" or "Order") entered in this case. That order denying contempt sanctions is final and reviewable under 28 U.S.C. § 1291. The Commission timely filed its Notice of Appeal on April 26, 2012.

STATEMENT OF THE ISSUES PRESENTED

1. Whether the district court incorrectly construed the Stipulated Final Order's prohibition of unsubstantiated claims about the "comparative health benefits" of defendants' products, when it ruled that this provision does not apply to defendants' baseless claims that their calcium supplements confer greater bone

benefits than other calcium supplements.

2. Whether the district court abused its discretion in ruling that, even if the Stipulated Final Order does prohibit unsubstantiated superiority claims, defendants did not violate this provision, where the court ignored defendants' express claims about their calcium's purported superiority and disregarded the net impression conveyed by defendants' advertisements.

3. Whether the district court abused its discretion in denying the Commission's motion to hold defendants in contempt of the Stipulated Final Order's prohibition of the misrepresentation of studies, where the evidence was undisputed that defendants' calcium advertisements falsely represented the results of a study.

4. Whether the district court abused its discretion in denying the Commission's motion to hold defendants in contempt of the Stipulated Final Order for making unsubstantiated claims about the health benefits of their cod liver oil supplement for children, where defendants failed to present evidence "based on the expertise of professionals in the relevant area," as the Order requires.

STATEMENT OF THE CASE

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

This appeal arises from an action brought by the FTC in 2006 against defendants for deceptive practices in violation of Sections 5(a) and 12 of the FTC Act,[1] in connection with their advertising and sale of various dietary supplements. The case settled, and the district court entered a Stipulated Final Order permanently enjoining defendants from making claims about the health benefits of any product unless they possess competent and reliable scientific evidence to substantiate those claims.

In August 2011, the Commission initiated this civil contempt proceeding against defendants, based on new advertisements for new products, including calcium supplements claimed to be superior to others in stimulating bone growth, and a cod liver oil supplement claimed to boost cognitive development in children. In seeking contem1ing

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[1] Section 5(a) of the FTC Act prohibits "unfair or deceptive acts or practices in or affecting commerce." 15 U.S.C. § 45(a). Section 12 of the FTC Act, prohibits the dissemination of "any false advertisement" to induce the purchase of "food, drugs, devices, services, or cosmetics." 15 U.S.C. § 52(a).

district court entered a Stipulated Final Order and Judgment for Permanent Injunction and Other Equitable Relief against them. Doc. 8.

Among other things, the Stipulated Final Order prohibits defendants from "making . . . directly or by implication . . . any representation" about "the absolute or comparative heath benefits, efficacy, performance, safety, or side effects" of any dietary supplement, "unless, at the time the representation is made, defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation." *Id*. at 4-5. "Competent and reliable scientific evidence" is 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." *Id*. at 3. The Stipulated Final Order also prohibits defendants from misrepresenting "the existence, contents, validity, results, conclusions, or interpretations of any test or study." *Id*. at 5.

In 2009, defendants introduced RAW Calcium, a calcium supplement derived from marine algae (AlgaeCal); Grow Bone System, which pairs RAW Calcium with a strontium supplement (Growth Factor S); and Oceans Kids DHA Chewables, a cod liver oil supplement. Doc. 9 - Ex. 36 at 3; Ex. 37 at 3; Doc. 42-1

at 2 (¶ 9). Once again, to induce consumers to purchase their products, defendants made baseless claims about the health benefits of these products and false boasts about their clinical support.

Defendants' advertisements and ma

[2] *See also* Doc. 9 - Exs. 1 (Attachs. P, Q, and T), 15, 18, 19, 20, and 21.

[3] *See* Doc. 9 - Ex. 18 ("Clinical Studi

defendants’ advertisements proclaimed that, in a clinical study of the Grow Bone System:

[4] After the Commission asked defendants to provide substantiation for these claims, and after learning that the Co

Grow Bone have superior health benefits to other calcium supplements, misrepresenting the results and validity of tests and studies of their calcium products, and making unsubstantiated claims about the health benefits of Oceans Kids. Doc. 9. The Commission also alleged that defendants had violated the Stipulated Final Order by making unfounded claims that certain products contained "no soy allergens," when they were aware that GOL's ingredients manufacturer used soy (and, indeed, testing prompted by the Commission's request for substantiation detected high levels of soy allergens in these products).[5] The Commission sought an award to compensate consumers who purchased defendants' products marketed with these unsubstantiated and false claims, as well as coercive sanctions until defendants removed these claims from their marketing materials and product packaging.[6]

The Commission supported its contempt motion with declarations from experts in each of the relevant areas of study – bone health, cognitive development, and food allergies – who evaluated defendants' purported substantiation for these

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[5] *See* Doc. 9 - Ex. 5; Ex. 7 at GOL-F4/F5-00004; Ex. 41 at 3; *see also* Doc. 9 - Ex. 2 at 8-10. Defendants' "no soy allergens" claim is not at issue in this appeal.

[6] The Commission later moved to modify the Stipulated Final Order to add enhanced injunctive relief to better protect consumers from defendants' contumacious conduct. Doc. 69. The district court denied that motion. Doc. 81.

product claims. Defendants in turn submitted a declaration from Dr. Weisman. Notably, defendants did not attempt to justify their claims that RAW Calcium and Grow Bone System confer greater bone benefits than other calcium supplements, but simply denied that they made calcium superiority claims.

After briefing by the parties, on February 27, 2012, the district court denied the motion for contempt, concluding that the Commission had failed to sustain its burden of proving by clear and convincing evidence that defendants violated the Stipulated Final Order. With regard to defendants' claim of "no soy allergens," the court found that, even though GOL was aware that its ingredient manufacturer used soy in some ingredients, GOL had appropriately relied on the manufacturer's representations that the ingredients in the products at issue here did not contain soy allergens. Doc. 77 at 4-8. The district court also rejected the Commission's challenge to defendants' claims about the "brain boosting" powers and other benefits of Oceans Kids. The court relied on Dr. Weisman's view that studies support these claims, without addressing the Commission's argument that Dr. Weisman lacked requisite expertise in the field of cognitive development to validate defendants' claims. Doc. 77 at 8-10.[7]

The district court also rejected the Commission's challenges to defendants'

[7] *See* Doc. 67 at 9-10.

advertising claims for RAW Calcium and Grow Bone System. The court found that the Stipulated Final Order's prohibition of unsubstantiated representations "[a]bout the absolute or comparative health benefits" of a product did not prohibit defendants from making unsubstantiated claims that their products are superior to competing products. Instead, the court interpreted this provision as applying only to "absolute claims" that a product has certain health benefits "or a claim that individuals who take a product will notice an improvement in their health compared to those who do not." Doc. 77 at 11. In the court's view, interpreting this provision to prohibit the superiority claims challenged by the Commission "would transform . . . [it] into a mere 'obey the law' provision, which is unenforceable." *Id*. at 12. Furthermore, the court concluded that, even if this provision enjoined defendants from making unsubstantiated representations about their products' superiority to other products, defendants did not violate it. The court found that the Commission had taken statements in the ads out of context, and that "GOL only discussed the benefits of Grow Bone System in generic terms and did not compare its product to any other specific product." *Id*. at 13. Lastly, the district court rejected the Commission's argument that defendants had violated the Stipulated Final Order's prohibition against misrepresentations of studies, because defendants' consultant had reviewed and approved their representations about the clinical support for these products. *Id*. at 14-16.

STANDARD OF REVIEW

This Court "review[s] for abuse of discretion the denial of a motion to show cause why a party should not be held in contempt." *Thomas v. Blue Cross & Blue Shield Ass'n*, 594 F.3d 814, 821 (11th Cir. 2010). "'A district court abuses its discretion if it applies an incorrect legal standard, applies the law in an unreasonable or incorrect manner, follows improper procedures in making a determination, or makes findings of fact that are clearly erroneous.'" *Id*. (quoting *Citizens for Police Accountability Political Comm. v. Browning*, 572 F.3d 1213, 1216-17 (11th Cir. 2009)). In contempt cases involving violations of consent decrees, "[c]onstruction of [the] consent judgment is . . . a question of law subject to *de novo* review." *Turner v. Orr*, 759 F.2d 817, 821 (11th Cir. 1985).

SUMMARY OF ARGUMENT

The district court fundamentally misunderstood what the Stipulated Final Order entered in this case requires of defendants. The court mistakenly believed that the Order's requirement that defendants have competent and reliable scientific evidence substantiating any claims they make about the "absolute or comparative health benefits" of their products leaves defendants free to make baseless claims that their calcium products are better able than other calcium supplements to increase bone density. But the district court was wrong: the plain, unambiguous language of the Stipulated Final Order and relevant FTC case law compel a finding

that defendants are barred from making such superiority claims if they lack scientific evidence substantiating those claims. (Part I.A, *infra*.)

The district court also erred in concluding that interpreting this provision of the Stipulated Final Order as prohibiting unsubstantiated claims that defendants' product provides health benefits superior to other products would make it an unenforceable "obey-the-law" injunction. This provision does not in any respect resemble injunctions that this Court has held do no more than order a defendant to obey the law, without identifying the acts a defendant is supposed to do (or refrain from doing). To the contrary, it specifically identifies what conduct is prohibited (making unsubstantiated claims about the "absolute or comparative health benefits, efficacy, performance, safety, or side effects" of defendants' dietary supplements) and what defendants must do to comply with the injunction (before making such claims, ensure that they have "competent and reliable scientific evidence," as defined in the Order, that substantiates the claim). This is so, regardless of whether the prohibition of unsubstantiated claims extends to unsubstantiated superiority claims (which it does). Particularly in light of this Court's most recent decision regarding "obey-the-law" injunctions, *SEC v. Goble*, 2012 U.S. App. LEXIS 10813 (11th Cir. May 29, 2012), it is clear that the district court erred in this respect. (Part I.B, *infra*.)

The district court further erred when it ruled that, even if the Stipulated Final

Order prohibits defendants from making baseless claims that their products have superior health benefits compared to other products, defendants did not violate this provision because they did not compare their calcium products to other calcium supplements. In so ruling, the district court ignored evidence of defendants' express claims of superiority, and focused on isolated statements in defendants' advertisements apart from their context, disregarding a fundamental principle regarding the construction of advertising claims: one must look at the overall, net impression conveyed by the advertisement. As a result, the court failed to perceive the clear message conveyed by defendants' advertisements: that defendants' algae-derived calcium supplements provide greater bone health benefits than conventional rock-source calcium supplements; that defendants' supplements are uniquely able to stimulate bone growth, while other calcium supplements can only slow bone loss. Defendants lacked any substantiation for these claims, as the undisputed evidence shows. (Part I.C, *infra*.)

The district court also abused its discretion in denying the Commission's motion to find defendants in contempt of the Stipulated Final Order for misrepresenting the results of studies in the advertising of their calcium supplements. In so ruling, the court ignored undisputed evidence – including defendants' own admission – that, to support their unsubstantiated superiority claims, defendants falsely reported the increases in bone mineral density

experienced by participants in a clinical study of defendants' products. (Part I.D, *infra*.)

Lastly, the district court abused its discretion in denying the Commission's motion to hold defendants in contempt for making unsubstantiated claims that Oceans Kids, their cod liver oil supplement, boosts "brain and eye development," "cognitive function," "mental focus," and "positive mood and behavior" in children "ages 2 and older." The Commission presented testimony by an expert in children's cognitive and behavioral development that the studies cited by defendants did not constitute competent and reliable scientific evidence substantiating these claims, among other reasons because they involved distinct test populations (fetuses, infants, children with diagnosed disorders), the findings

ARGUMENT

I. THE DISTRICT COURT ABUSED ITS DISCRETION IN DENYING THE COMMISSION'S MOTION TO HOLD DEFENDANTS IN CONTEMPT FOR MAKING UNSUBSTANTIATED SUPERIORITY CLAIMS AND MISREPRESENTING STUDIES OF THEIR CALCIUM PRODUCTS.

The Stipulated Final Order that defendants agreed to in 2006 expressly requires them to have substantiation for health-related claims they make, "directly or by implication," about their dietary supplements – including, specifically, claims about the "comparative health benefits" of their products. Defendants disregarded this requirement, advertising their calcium supplements as producing bone-health benefits superior to other calcium supplements, without a speck of evidence that such claims are true. Accordingly, defendants are in contempt.

The district court, however, gave short shrift to the Commission's motion to hold defendants in contempt for their unsubstantiated calcium claims. It rejected outright the notion that the Stipulated Final Order even applies to defendants' unsubstantiated superiority claims, viewing a prohibition on unsubstantiated superiority claims as unenforceable. It rejected the notion that defendants even made superiority claims. And it rejected the notion that defendants in any way misrepresented the scientific proof for their product claims. But the district court erred, both in its application of the law and in its assessment of the evidence.

A. The Court Erred as a Matter of Law in Ruling that the Stipulated Final Order Does Not Apply to Defendants' Superiority Claims.

The Stipulated Final Order prohibits defendants from making representations about the "comparative health benefits" of their products, unless they have competent and reliable scientific evidence for those claims. Doc. 8 at 4-5. The Commission challenged precisely such comparative claims: claims that RAW Calcium and Grow Bone System have superior health benefits to (that is, are more beneficial *compared* to) other calcium supplements. In particular, the Commission challenged defendants' claims that their calcium "is the only calcium supplement that can truly make th[e] claim" that it can stimulate bone growth – that "[u]ntil now, calcium supplementation, at best, helped to slow down the rate of bone loss." *See* pp. 6-7, *supra*. The district court, however, found such claims to be entirely outside the scope of the Stipulated Final Order's prohibition of unsubstantiated claims about the comparative health benefits of their products, interpreting "comparative" as encompassing only claims that "individuals who take a product will notice an improvement in their health compared to those who do not." Doc. 77 at 11.

The district court's exceedingly narrow interpretation of this provision is patently erroneous. It is contrary to the plain and unambiguous language of the Stipulated Final Order, which places no such limitation on the comparative health

[9] With respect to another superiority claim challenged by the Commission – the defendants' claim that their calcium was three to four times more absorbable than other calcium supplements – the court found that, though this claim might conceivably be substantiated with respect to individuals with an inability to produce stomach acid (a condition known as achlorhydria), there was no scientific support for this claim as to the general population. The court remanded for further factual findings on whether defendants lim

Act by making unsubstantiated claims about its pain-relief products' superiority to other products); *American Home Prods. Corp. v. FTC*, 695 F.2d 681 (3d Cir. 1982) (aspirin producer found to have violated the FTC Act by making unsubstantiated claims about its product's superiority to other aspirins); *see also Kraft, Inc. v. FTC*, 970 F.2d 311 (7th Cir. 1992) (manufacturer of processed cheese found to have violated the FTC Act by misrepresenting the calcium benefit of its product compared to other products). It is no surprise, then, that in cases such as this, the FTC obtains injunctive relief that prohibits not only unsubstantiated claims that a product provides certain health benefits but also unsubstantiated claims that a product is more beneficial compared to other products.

The district court's restrictive interpretation of the Stipulated Final Order is at odds with this case law as well as the plain language of the Stipulated Final Order, and thus is erroneous as a matter of law.

B. The Court Erred as a Matter of Law in Ruling that a Prohibition of Unsubstantiated Comparative Claims Would Be an Unenforceable "Obey-the-Law" Injunction.

The district court also erred in concluding that to interpret the prohibition of unsubstantiated claims about the "compa

did not suggest that this provision as a whole – *e.g.*, the requirement that defendants have substantiation for claims about the "absolute" health benefits of their products – is an unenforceable "obey-the-law" injunction.[10] The court merely took issue with the Commission's broader interpretation of "comparative." But the decisions of this Court do not support the district court's conclusion.

In *Hughey*, the developer of a residential subdivision was enjoined from discharging storm water into the waters of the United States "if such discharge would be in violation of the Clean Water Act." 78 F.3d at 1531. Every rainstorm caused some discharge that was beyond the developer's control. Vacating the injunction, the Court described it as "incapable of enforcement as an operative command," because it failed to identify how the defendant should prevent discharges: "Was [the defendant] supposed to stop the rain from falling? Was [the defendant] to build a retention pond to slow and control discharges? Should [the defendant] have constructed a treatment plant to comply with the requirements of the [Clean Water Act]?" *Id.* at 1531-32. The injunction did not "identify the acts

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[10] Although defendants argued below that both this provision (in its entirety) and the prohibition against misrepresentations of test and studies are unenforceable "obey-the-law' injunctions, Doc. 40 at 12-17, the district court did not so rule. Rather, the court implicitly accepted that the Stipulated Final Order imposes an enforceable obligation on defendants to have competent and reliable scientific evidence for their claims about the absolute health benefits of their products and not to misrepresent test and studies (though it concluded that defendants had complied with those obligations).

that [the defendant] was required to do or refrain from doing," but merely directed the defendant to obey the law. *Id*. at 1532.[11]

Most recently, this Court addressed the issue of "obey-the-law" injunctions in *SEC v. Goble*, 2012 U.S. App. LEXIS 10813, *29-40 (11th Cir. May 29, 2012), reviewing an injunction that enjoined the defendant from violating certain securities statutes and regulations. The Court recognized that, in some circumstances, an injunction that merely orders a defendant to comply with a statute may be appropriate, *e.g.*, where the terms of the statute are sufficiently specific to inform the defendant what actions are required (or prohibited). *Id.* at *34-35 (citing *McComb v. Jacksonville Paper Co.*, 336 U.S. 187, 69 S. Ct. 497 (1949)).[12] Indeed, the Court found that the regulations referenced in the injunction

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[11] The Court noted that, "[i]n the absence of specific injunctive relief, informed and intelligent appellate review is greatly complicated, if not made impossible." *Hughey*, 78 F.3d at 1531 (quoting *Schmidt v. Lessard*, 414 U.S. 473, 476, 94 S. Ct. 713 (1974)). But the Third Circuit's decision in *Lane Labs* demonstrates that appellate review in a contempt case involving an injunction such as this is neither unduly complicated nor impossible. *See* pp. 19-20, *supra*.

[12] The court observed that an injunction that merely prohibited violations of § 10(b) of Securities and Exchange Act would not give defendants sufficient guidance on how to conform their conduct to the terms of the injunction because "defendant would need to review hundreds of pages of the Federal Reporters, law reviews, and treatises before he could begin to grasp the conduct proscribed by § 10(b) and in turn the injunction." 2012 U.S. App. LEXIS 10813, at *35-36. *See SEC v. Smyth*, 420 F.3d 1225, 1233 n.14 (11th Cir. 2005) (Court stated, in *dicta*, that injunction that merely prohibited the defendant from violating certain provisions of the securities statutes, reciting the relevant statutory language, was an

at issue did contain sufficiently "specific commands" that a defendant "would be able to determine what conduct the injunction addressed" – had the language of the regulations been incorporated into the injunction. 2012 U.S. App. LEXIS 10813, *36-37. But the injunction did not incorporate that language; it merely cross-referenced the pertinent statutes and regulations, leaving the defendant unable to determine – within the four corners of the injunction – what it was ordered to do or not to do. For that reason, the court held, the injunction was unenforceable. *Id*. at *38-40.

In contrast, the injunction entered in this case does not "merely enjoin[] a party to obey the law." *Hughey*, 78 F.3d at 1531. It does not merely say "don't engage in conduct that violates Sections 5(a) and 12 of the FTC Act." Instead, the provision at issue identifies specifically what conduct is prohibited (making unsubstantiated representations about "the absolute or comparative heath benefits, efficacy, performance, safety, or side effects" of a dietary supplement, food, or drug) and how defendants should comply with the injunction (before making any such representation, make sure you have "competent and reliable scientific evidence," as defined in the Order, that substantiates it). *See SEC v. Sky Way Global, LLC*, 710 F. Supp. 2d 1274, 1288-89 (M.D. Fla. 2010) (contrasting SEC

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unenforceable "obey-the-law" injunction).

orders that have been deemed "obey-the-law" injunctions with "reasonably detailed" injunctions proposed by the FTC); *see also FTC v. Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d 1167 (N.D. Ga. 2008) (FTC's requirement that health-related advertising claims be substantiated by competent and reliable scientific evidence "articulate[s] a definite standard"), *aff'd*, 356 Fed. Appx. 358 (11th Cir. 2009).

While this prohibition covers a substantial range of conduct, such breadth does not make an injunction unenforceable. As the Court noted in *Goble*, "restraints may be broad in terms of the scope of the conduct captured by the injunction," so long as "'the restrained party [has] fair notice of what conduct will risk contempt.'" 2012 U.S. App. LEXIS 10813, at *37 (quoting *Hughey*, 78 F.3d at 1531). In particular, in the context of civil law enforcement actions such as this, "injunctions of some breadth" are entirely appropriate. *Id.* at *38 ("where the public interest is involved, the court's equitable power has a broader and more flexible character") (internal quotation marks omitted). Indeed, it is well established that the FTC appropriately obtains broad injunctive relief to prevent defendants from engaging in similar deceptive practices in the future in a slightly different form. *See FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 395, 85 S. Ct. 1035, 1048 (1965) ("The Commission is not limited to prohibiting the illegal practice in the precise form in which it is found to have existed in the past."); *FTC v. Ruberoid Co.*, 343 U.S. 470, 473, 72 S. Ct. 800, 803 (1952) (the Commission

C. The Court Abused its Discretion in Ruling that Defendants Did Not Make Unsubstantiated Superiority Claims.

The district court further erred when it ruled that, even if the Stipulated Order prohibits unsubstantiated superiority claims, defendants did not violate that provision because they did not compare their calcium supplements to other products and had substantiation for whatever claims they did make. In so ruling, the court disregarded applicable legal principles regarding the construction of advertising claims and ignored undisputed evidence showing that defendants lacked any substantiation for their claims that their algae-derived calcium supplements are superior to conventional "rock-source" calcium supplements.

1. The Court Failed to Consider the Overall Impact of Defendants' Advertisements.

It is settled law that to assess the representations conveyed by an advertisement, a court must look at the advertisement's overall net impression. "[T]he tendency of the advertising to deceive must be judged by viewing it as a whole, without emphasizing isolated words or phrases apart from their context." *American Home Prods. Corp.*, 695 F. 2d at 687 (quoting *Beneficial Corp. v. FTC*, 542 F.2d 611, 617 (3d Cir. 1976)). "The impression created by the advertising, not its literal truth or falsity, is the desideratum." *Id*. *See Kraft*, 970 F.2d at 322 ("even literally true statements can have misleading implications"); *Thompson Medical Co., Inc. v. FTC*, 791 F.2d 189, 197 (D.C. Cir. 1984) ("[t]he tendency of a

particular advertisement to deceive is determined by the net impression it is likely to make upon the viewing public"); *Carter Prods., Inc. v. FTC*, 323 F.2d 523, 528 (5th Cir. 1963) ("[t]he Commission need not confine itself to the literal meaning of the words used but may look to the overall impact of the entire commercial"); *Murray Space Shoe Corp. v. FTC*, 304 F.2d 270, 272 (2d Cir. 1962) ("we are not to look to technical interpretation of each phrase, but must look to the overall impression these circulars are likely to make on the buying public").[13]

It is evident that the district court disregarded this legal principle. Confining its analysis to one of GOL's advertisements (styled as an article entitled "The Bone Ultimatum"), the court observed that "GOL only discussed the benefits of Grow Bone System in generic terms and did not compare its product to any other specific product," and "merely stated the intended results of the Grow Bone System and compared plant-form calcium to rock-source calcium." Doc. 77 at 13. The court chided the Commission for taking statements from defendants' ads out of context. *Id*. But, in fact, it is the district court itself that improperly construed defendants' claims by ignoring defendants' express claims, considering isolated statements

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[13] *See also* Federal Trade Commission, *Dietary Supplements: An Advertising Guide for Industry* 3-4 (2001) ("[w]hen an ad lends itself to more than one reasonable interpretation, the advertiser is responsible for substantiating each interpretation"), in the record as Doc 55-4 at 8-9 (attachment to March 2009 report prepared by Dr. Weisman for GOL, *see* Doc. 44-1 at 15, 17 (¶ 28.i)).

apart from their context, and failing to consider the overall message imparted by the ads.

Contrary to the court's characterization, defendants did not simply discuss the benefits of RAW Calcium and Grow Bone System "in generic terms" without any comparison to other products. Instead, defendants' advertisements expressly contrast the bone benefits provided by their calcium supplements with the bone benefits provided by other calcium supplements. Defendants' article "The Bone Ultimatum" starts by lamenting the shortcomings of conventional calcium supplements:

> The best that can be said is that calcium supplementation helps slow down or stop bone loss. While slowing bone loss is a great goal, it's a far cry from making them stronger or healthier by increasing bone mineral density.

Doc. 9 - Ex. 16 at GOL-A2-00038. But, the article goes on to say, their supplements do more:

> There is good news on the horizon, however, for the millions of women and men looking to support healthy, strong bones. Garden of Life is proud to introduce their new Vitamin Code Grow Bone System with RAW Calcium and Grow Bone Factor S.
>
> Far from "just another calcium supplement" intended to reduce the risk of osteoporosis, the Grow Bone System is intended to stimulate bone growth, increase bone strength and bone mineral density.

Id. at GOL-A2-00039. Defendants' clear message is that their supplements provide greater bone health benefits than other calcium supplements – that their

supplements stimulate bone growth and increase bone mineral density; other calcium supplements do not, but merely slow bone loss.

Defendants' product packaging and other advertisements (which the district court did not discuss) likewise make express claims of unique bone benefits. *See* Doc. 9 - Ex. 1, Attach. O at FTC-CONTEMPT-0000101 ("Until now, calcium supplementation at best helped to slow down the rate of bone loss."); Ex 27 at GOL-A2-00078 (Grow Bone System has been "clinically studied to increase bone mineral density, increase bone strength and stimulate bone density growth" and "is the only supplement that can truly make this claim"). Contrary to what the district court supposed, these are superiority claims for which defendants must have substantiation. *See Lane Labs*, 624 F.3d at 583-84 (finding defendants in contempt for making unsubstantiated claims that, while other calcium supplements could only slow bone loss, their calcium could increase bone density).

The district court likewise erred in treating defendants' representation that "plant-form calcium has huge advantages over rock-source calcium," Doc. 9 - Ex. 16 at GOL-A2-00039, as a mere non sequitur having no bearing on defendants' claims about how their products compare to other calcium supplements. The ads make it clear that by "plant-form calcium" defendants mean their algae-derived calcium ("the only raw, organic plant form of calcium that Garden of Life has ever found"), by "rock-source calcium" they mean traditional calcium supplements

("[m]ost calcium supplements come from ground-up rock"), and by "huge advantages" they mean better for "bone-building" and "bone health." *Id*. The clear take-away: our plant-form calcium supplement is better for your bones than traditional rock-source calcium supplements. The court failed to perceive this, however, because it ignored defendants' express claims of superiority and gave no consideration to the overall impression created by the advertisements. This is error that warrants reversal.

2. Undisputed Evidence Shows that Defendants Had No Substantiation for their Superiority Claims.

Because the district court did not apprehend that defendants made superiority claims, it did not evaluate whether competent and reliable scientific evidence substantiates these claims. In fact, defendants have no such substantiation.

The Commission's expert witness, Dr. Connie Weaver, a professor at Purdue University and an expert in the role of calcium and other related nutrients in bone health, evaluated whether there is competent and reliable evidence to support defendants' claims that RAW Calcium and Grow Bone System are superior to other calcium supplements. Doc. 9 - Ex. 4. Dr. Weaver explained that:

- the type of calcium that defendants have identified as the calcium in their products is calcium carbonate, which is found in many other widely-

available calcium supplements;[14]

- once absorbed by the body, all calcium is the same and confers the same bone benefits;
- if one type of calcium is more absorbable that another calcium, it may confer a greater bone benefit, but simply increasing the dose of the less bioavailable source may eliminate the difference in benefit; and
- certain types of calcium found in plant foods are much more difficult to absorb than calcium carbonate, which is principally derived from mining.

Doc. 9 - Ex. 4 at 8-9.

Dr. Weaver further explained that, to be substantiated by competent and reliable scientific evidence, a claim that one bone health supplement is superior to another requires proof from a clinical trial comparing one supplement to another. *Id*. at 6, 11. But Dr. Weaver found no evidence of any clinical trial that compared RAW Calcium or Grow Bone System (or the raw ingredients of either product) with any other calcium supplement. Dr. Weaver thus concluded that there is no competent and reliable scientific evidence to support claims that RAW Calcium and Grow Bone System are superior to other calcium supplements. *Id*. at 11-12.

Defendants' expert, Dr. Weisman, agreed with Dr. Weaver that proof that a

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[14] *See* 44-1 at 12 (¶ 21).

calcium supplement is superior to another requires clinical trials comparing one product against another. Doc. 44-1 at 39. He explained that GOL did not ask him to evaluate whether substantiation existed for claims that RAW Calcium and Grow Bone System are superior to other calcium products, nor was he aware of any clinical studies comparing the bone benefits of algal sources of calcium (including AlgaeCal, the calcium in defendants' products) with other sources of calcium. *Id.* at 39-40.

Thus, the undisputed evidence shows that defendants lacked competent and reliable scientific evidence to substantiate their claims that RAW Calcium and Grow Bone System confer bone benefits superior to other calcium supplements.

D. Undisputed Evidence Shows that Defendants Misrepresented the Clinical Support for their Calcium Products.

The Commission presented undisputed evidence that, to support their unsubstantiated claims of their products' superiority, defendants misrepresented the results of studies, boasting that, in a clinical study of the Grow Bone System ingredients:

> In just six months, participants experienced a significant average INCREASE in bone mineral density of 2.8% . . . [and] participants that were deemed highly compliant experienced an INCREASE in bone mineral density by an amazing 3.7%.

Doc. 9 - Ex. 18 at GOL-A2-00042; Ex. 23; Ex. 27 at GOL-A2-00077. But, in reality, study participants experienced average bone mineral density increases that

were only half that. *See* Doc. 9 - Ex. 22 at GOL-A2-00059 (GOL press release announcing that this study "revealed an average increase in bone mineral density of 1.4%"). Although defendants, in the proceeding below, defended their other, more general claims of clinical proof, they did not dispute that this particular claim misrepresented the study results. Indeed, they conceded that their claim that participants in this study experienced average increases in bone mineral density of 2.8% and 3.7% within six month was "technically erroneous." Doc. 40 at 25.

As Dr. Weaver explained, none of the groups in this study experienced the bone mineral density increases claimed by defendants. Doc. 9 - Ex. 4 at 16. Instead, defendants took six-month data for one study group (Group 2) that the study authors had doubled (annualized) to compare with one year data for another study group and passed off the doubled numbers as the bone mineral density increases actually experienced by study participants "[i]n just six months."[15] Defendants' expert, Dr. Weisman, made no effort to defend this claim in the contempt proceeding. *See* Doc. 44-1 at 39-43. Thus, it was undisputed that

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[15] *See* Doc. 66-4 at 6 ("Since the study period for Plan 1 was one year and the study period was six-months for Plans 2 and 3, BMD [bone mineral density] changes and comparisons were reported as a mean annualized percent change (MPAC)."). Dr. Weaver further explained that, with regard to bone mineral density, it is improper to annualize six-months results in this manner because changes in bone with an intervention are not uniform across time, and increases in bone mineral density generally do not continue after the first six months. Doc. 9 - Ex. 4 at 19.

defendants misrepresented the results of this study – a clear violation of the Stipulated Final Order.

The district court ignored this undisputed evidence, however, and simply deemed this claim "substantiated" because it was among the claims that Dr. Weisman gave a nod to when defendants introduced these products. Doc. 77 at 15. But the fact that Dr. Weisman initially may have failed to comprehend the distinction between the actual results experienced by study participants and the extrapolation of that data for analytical purposes does not make defendants' representations about the study any less inaccurate. Moreover, any suggestion that defendants themselves failed to understand what the actual study results were is belied by GOL's initial press release announcing that this study "revealed *an average increase in bone mineral density of 1.4%*, which was *extrapolated* to be an annualized increase of 2.8%." Doc. 9 - Ex. 22 at GOL-A2-00059 (emphasis added). Defendants took no such care in their product advertising, however, to distinguish between the more modest six-month results actually experienced by study participants and the annualized data.

The district court abused its discretion in disregarding this undisputed evidence showing that defendants misrepresented the results of studies and thereby disobeyed the Stipulated Final Order. In addition, the district court demonstrated a fundamental misunderstanding of the Stipulated Final Order when it concluded

that the prohibition against the misrepresentation of "the existence, contents, validity, results, conclusions, or interpretations of any test or study" does not require that the studies referenced in defendants' advertisements be reliable. Doc. 70 at 15. When defendants in their ads claim that a study demonstrates the benefits

field of clinical pharmacology, it was undisputed that he had no qualifications whatever in the field of children's cognitive and behavioral development. Doc. 44-1 at 1-3; Doc. 45-1. This lack of expertise was crucial because the Stipulated Final Order specifies that "competent and reliable scientific evidence" that will substantiate a health-related claim means evidence "based on the expertise of professionals in the relevant area." Doc. 8 at 3.

This requirement that substantiation for a claim be assessed by a professional in the relevant area of study is a key component of the definition of "competent and reliable evidence." *See FTC v. Direct Mktg. Concepts, Inc.*, 624 F.3d 1, 8 (1st Cir. 2010) (whether a health-related claim is substantiated depends on "what evidence would in fact establish such a claim in the relevant scientific community") (internal quotation marks omitted); *Nat'l Urological Grp.,* 645 F. Supp. 2d at 1186 (substantiation "depend[s] on what pertinent professionals would require for the particular claim made").[16] The necessity of such expertise is particularly salient when it comes to questions about whether limited study findings support broader claims of health benefits. As the Commission has advised, "[a]dvertisers should not rely on research based on a specific test

[16] *See Dietary Supplements*, note 13, *supra*, at 10 ("the amount and type of evidence that will be sufficient is what experts in the relevant area of study would generally consider to be adequate") (Doc. 55-4 at 15).

population without first considering whether

[17] Because there was some evidence that the defendants had directed their marketing toward individuals at risk of achlorhydria, the court remanded for further factual findings this issue. *Lane Labs*, 624 F.3d at 585-86. On remand, the district court found that the defendants' calcium advertising was, in fact, aimed at the general population, not just individuals at risk for achlorhydria, and they were thus in violation of the stipulated order for making claims for which they lacked

behavioral development, including particular factors that interfere with these aspects of development, to evaluate defendants' claims about the health benefits of Oceans Kids. Doc. 9 - Ex. 3 at 1-4. Dr. Bellinger explained that the studies cited by defendants are not competent and reliable scientific evidence that omega-3 fatty acid supplementation provides benefits for brain development, eye development, cognitive function, mental focus, and mood or behavior in generally healthy children "ages 2 and older," because those studies:

- did not assess health outcomes relevant to defendants' claims;
- examined the effect of omega-3 supplementation in children with diagnosed cognitive or behavioral disorders, and those findings cannot be generalized to healthy children; or
- examined the effect of omega-3 supplementation at earlier developmental stages (in fetuses and infants), and those findings cannot be generalized to older children.

Id. at 4-7. With regard to the latter point, Dr. Bellinger further explained that there are "critical windows of vulnerability" prior to the age of two (*in utero* and in infancy) when certain aspects of neurological development progress most rapidly, and the fact that exposure to an agent during that early developmental stage has been shown to have an impact does not mean that it will have a similar impact in children at a later age. Doc. 67-2 at 3-4.

Dr. Bellinger identified four studies (two cited by Dr. Weisman and two identified by Dr. Bellinger himself) that were potentially relevant to defendants' claims of benefits to cognition and behavior in children ages two and up, but concluded that these studies likewise failed to support defendants' specific claims. Doc. 9- Ex. 3 at 8-12. Among other problems, two of the studies involved distinct test populations, the findings regarding which cannot not be extrapolated to the Oceans Kids target population. Doc. 9 - Ex. 3 at 9-11.[18] In the two other studies, the omega-3 fatty acid dosage was substantially greater (in one study, more than three times greater) than the daily dosage of Oceans Kids, making it impossible to draw inferences from these studies about the benefits of taking Oceans Kids. Doc. 9 - Ex. 3 at 12-15.[19] Significantly, each of the studies' authors expressly state the limitations of their study.

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[18] One study involved "marginally nourished" children in India; another involved children in low socio-economic community in South Africa, many of whom were stunted in height, underweight, or iron deficient. Doc. 9 - Ex. 3 at 9-10.

[19] Notably, the study involving DHA dosage more than three times the amount in Oceans Kids found no differences in cognitive test scores between the group receiving DHA supplementation and the control group. Doc. 9 - Ex. 3 at 12. The other study's findings were so inconsistent they were difficult to interpret (as the study's authors themselves observed). *Id.* at 15.

between ingestion of omega-3 fatty acids and cognition in school-age children); Doc. 66-3 at 20 ("[f]uture studies are needed"); Doc. 65-4 at 11 (results "might be merely a chance finding" and "[f]urther investigations are necessary"). Dr. Bellinger concluded that, based on the evidence available at this time, it "would not be scientifically or medically sound" to conclude that omega-3 fatty acid supplementation has the benefits that defendants claimed. Doc. 9 - Ex. 3 at 15-16.

Although Dr. Weisman accused Dr. Bellinger of applying an "elevated standard and narrow criteria," Doc. 44-1 at 34, he sidestepped Dr. Bellinger's fundamental criticisms of the mismatch between the studies cited by defendants and their specific claims. In particular, Dr. Weisman failed to explain why or how studies of the effects of omega-3 supplementation on cognitive function or behavior at an earlier developmental stage or in children with diagnosed disorders can be generalized to healthy children over the age of two. This is not surprising, considering that Dr. Weisman had no expertise in cognitive or behavioral development that would qualify him to render an opinion on this matter. Nor did he have the requisite expertise in this field to assess the relevance of the other four studies discussed by Dr. Bellinger to the Ocean Kids target population.[20] But such

[20] Dr. Weisman failed to rebut Dr. Bellinger's criticisms of these studies. For example, Dr. Weisman did not dispute that studies involving significantly higher levels of DHA and EPA than is found in Oceans Kids do not support claims about the benefits of Oceans Kids. He merely asserted that, in any event, "other

expertise was necessary to ascertain whether the research proffered by defendants substantiated their specific claims.

Thus, the record below reflects not a "battle of experts" taking competent but opposing views on a disputed scientific proposition,[21] but a complete lack on defendants' part of the kind of support specifically required by the Stipulated Final Order. Given defendants' failure of proof, it was an abuse of discretion for the district court to deny the Commission's contempt motion with regard to defendants' Oceans Kids claims.

CONCLUSION

For all the reasons stated above, appellant respectfully requests that this Court reverse the decision of the district court, and remand this case to the district

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studies" evaluated amounts of fatty acids similar to the levels found in Oceans Kids (begging the question whether these other studies adequately substantiated defendants' claims). Doc. 44-1 at 38 (¶ 42). Nor did Dr. Weisman dispute that studies of marginally nourished populations do not support claims of benefits in generally healthy kids, but replied that, in any event, other studies did not involve nutritionally compromised populations (again, begging the question whether these other studies adequately substantiated defendants' claims). *Id*. at 37 (¶ 40). Dr. Weisman's further observation that "dietary supplements are intended for use in many populations," including undernourished individuals, *id.*, likewise begs the question whether benefits to the Oceans Kids target population have been adequately demonstrated.

[21] Even if this Court were to view the dispute in such a manner, and addressed the issue at hand as a purely factual issue under the "clearly erroneous" standard, the Commission must still prevail because the record made below so one-sidedly favors its position, for the reasons discussed in this section.

CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitation set forth in Fed. R. App. 32 (a)(7)(B), in that it contains 9,913 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and 11th Cir. R 32-4.

s/Michele Arington
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CERTIFICATE OF SERVICE

I hereby certify that, in addition to service accomplished by the CM/ECF system, on July 3, 2012, a copy of the foregoing Brief for Plaintiff-Appellant Federal Trade Commission was served by overnight courier upon counsel for defendants-appellees Garden of Life, Inc. and Jordan S. Rubin as follows:

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