No. 12-12382-AA

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

FEDERAL TRADE COMMISSION,
Plaintiff-Appellant,

v.

GARDEN OF LIFE, INC. and JORDAN S. RUBIN,
Defendants-Appellants.

On Appeal from the United States District Court for the Southern District of Florida
No. 9:06-cv-80226-DMM

BRIEF FOR PLAINTIFF-APPELLANT FEDERAL TRADE COMMISSION

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CERTIFICATE OF INTERESTED PERSONS

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

Pursuant to Fed. R. App. P. 26.1 and 11th Cir. R. 26.1-1, plaintiff-appellant Federal Trade Commission hereby submits the following list of interested persons:

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Atrium Innovations Inc. (TSX: ATB) - Parent Company of Garden of Life, Inc.

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Bideau, Mark F. - Attorney for Garden of Life, Inc.

Blumenthal, William - Former General Counsel, FTC

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Federal Trade Commission - Plaintiff-Appellant

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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.*

Rubin, Jordan S. - Defendant-Appellee

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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

TABLE OF CITATIONS

CASES **PAGE**

FEDERAL STATUTES

MISCELLANEOUS

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 contempt sanctions, the Commission alleged that the advertisements for these products were again rife with the sorts of unsubstantiated health claims and misrepresentations about studies supporting those claims that were specifically

[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).

prohibited by the Stipulated Final Order. On February 27, 2012, the district court issued an order denying the contempt motion, finding that the Commission had failed to show by clear and convincing evidence that defendants violated the Stipulated Final Order. The Commission seeks review of that order.

B. Facts and Proceedings Below

1. Background

Garden of Life, Inc. ("GOL") is a marketer and supplier of "whole-food" dietary supplements. Doc. 9 - Ex. 37 at 2. Jordan S. Rubin ("Rubin") is GOL's founder and was, during the relevant time period, its CEO. *Id.*; Doc. 9 - Ex. 43 at GOL-I2-000008 (¶ 1).

In March 2006, the Commission filed an action in the United States District Court for the Southern District of Florida against GOL and Rubin, charging them with violations of Sections 5(a) and 12 of the FTC Act in connection with their marketing of dietary supplements. Doc. 1. The Complaint alleged that defendants had made unsubstantiated claims that their products could treat a range of serious diseases (including cancer, intractable immune system disorders, asthma, irritable bowel syndrome, chronic fatigue syndrom, rheumatoid arthritis, lupus, and age-related neurodegeneration), and falsely represented that there was clinical proof for these claims. Defendants settled these allegations, and on March 30, 2006, the

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 marketing materials for their calcium supplements, RAW Calcium and Grow Bone System, touted their superiority to other calcium supplements. Specifically, defendants claimed that their calcium products are better able than other calcium supplements – indeed, uniquely able – to reverse normal bone density loss by growing bone:

> 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.
>
> * * *
>
> 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.

Doc. 9 - Ex. 16 at GOL-A2-00038-39; *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. 17 at GOL-A2-00041 (AlgaeCal "is differentiated by its purity, potency and sustainability" and "sets a new standard in

the calcium market with best-in-class scientific support"); Ex. 23 ("a breakthrough bone health formula").[2] According to defendants' ads, their products' superiority is due largely to their use of algae-derived "plant-form" calcium, which (the ads claimed) is more beneficial than conventional "rock-source" calcium:

> As you will learn, there are several factors that go into actually building bone mineral density or growing bone. The source of your calcium is a key factor. Did you know that most calcium supplements are ground up rocks or oyster shells?
>
> * * *
>
> Most calcium supplements come from ground-up rock: usually limestone. The RAW Calcium in the Grow Bone system is a patented form of marine algae. . . .
>
> * * *
>
> Using plant-form calcium has huge advantages over rock-source calcium. For starters, while rock is technically a natural substance, it's not in human nature to eat rocks.

Doc. 9 - Ex. 16 at GOL-A2-00038-39. *See* Doc. 9 - Ex. 17 at GOL-A2-00042 ("[u]nlike other sources of calcium from limestone or animal bones").

Defendants bolstered these superiority claims with assurances that Grow Bone System has been clinically studied to stimulate bone growth, increase bone strength, and increase bone mineral density, and that "[i]t is the only supplement that can truly make this claim." Doc. 9 - Ex. 27 at GOL-A2-00078.[3] Many of

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[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 Studies = Confidence."); Ex. 22 (clinical research gives "unprecedented confidence in the product's efficacy").

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

> In just six months, participants experienced a significant average INCREASE in bone mineral density of 2.8% . . . [and] participants who 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.

Defendants retained a consultant (Dr. Steven Weisman, a clinical pharmacologist) to evaluate the scientific support for certain of their product claims. *See* Doc. 44-1 at 1-4. They did not, however, ask Dr. Weisman to evaluate whether competent and reliable scientific evidence substantiates their calcium superiority claims. *Id.* at 39-40. In fact, no such substantiation exists.

Defendants also made baseless claims about the health benefits of Oceans Kids, their cod liver oil supplement. Defendants claimed that because Oceans Kids contains omega-3 fatty acids – docosahexaenoic acid ("DHA") and eicosapentaenoic acid ("EPA") – it has "brain boosting" powers and other benefits for children "ages 2 and older," including that it:

- supports "Brain Development"
- supports "Cognitive Function"
- supports "Mental Focus"
- supports "Positive Mood & Behavior"

- is "Important for Brain & Eye Development"

Doc. 9 - Ex. 1, Attach. H at FTC-CONTEMPT-0000067; Ex. 1, Attach. J at FTC-CONTEMPT-0000083-84; Ex. 12 at GOL-A2-00008; Ex. 14 at GOL-A2-00007.[4]

Defendants also retained Dr. Weisman to review these claims. But Dr. Weisman lacked any expertise in this field of science, and the scientific literature that he identified – which related almost exclusively to distinct test populations (*e.g.*, fetuses, infants, children with diagnosed medical or behavioral disorders) – did not establish the benefits of omega-3 supplementation for generally healthy children ages two and older (the Oceans Kids target population). Indeed, Dr. Weisman himself cautioned that some of these studies "might be taken with caveats toward applicability in a healthy population of children." Doc. 65-1 at 6. Defendants did not opt for caution, and made these extravagant claims of benefits anyway.

2. The Civil Contempt Proceedings

In August 2011, the Commission filed a motion in the district court to show cause why the defendants should not be found in contempt for violating the Stipulated Final Order by making unsubstantiated claims that RAW Calcium and

[4] After the Commission asked defendants to provide substantiation for these claims, and after learning that the Commission intended to challenge similar product claims made by other companies, defendants removed these claims from the Oceans Kids labels. Doc. 9 - Ex. 36 at 2.

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 of which could not be generalized to the Oceans Kids target population of generally healthy kids ages two and up. Although defendants' consultant was of the view that these studies supported defendants' claims, he had no expertise in the relevant field of cognitive or behavioral development that would qualify him to evaluate whether this research could be generalized to the Oceans Kids target population. Defendants thus failed to rebut the Commission's expert testimony, because they failed to present evidence "based on the expertise of professionals in the relevant area," as the Stipulated Final Order requires. (Part II, *infra*.)

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

benefit claims for which defendants must have competent and reliable scientific evidence. Indeed, the district court's interpretation effectively reads out the prohibition of unsubstantiated claims about a product's "comparative health benefits" altogether.

The district court's ruling is also at odds with the case law, in particular a recent decision by the Third Circuit in *FTC v. Lane Labs-USA, Inc.*, 624 F.3d 575 (3d Cir. 2010). In that case, as here, marketers of dietary supplements agreed to a stipulated permanent injunction prohibiting them from making unsubstantiated claims about the health benefits of their products.[8] There, as here, the Commission alleged that the defendants had violated the stipulated order by making unsubstantiated claims that their calcium supplement was superior to other calcium supplements and unique in its ability to build bone. The district court denied the contempt motion, citing evidence that the defendants' product was a beneficial source of calcium, but the Third Circuit reversed because the court below failed to consider the superiority claims challenged by the Commission. The court found

[8] The relevant stipulated order provision in *Lane Labs* did not specifically reference "comparative" claims, but generally prohibited unsubstantiated claims about the "health benefits" of a product. Specifically, it enjoined the defendants from making any representation "about the effect of [a] product on any disease or disorder, or the effect of such product on the structure or function of the human body, *or about any other health benefits of such product*." 624 F.3d at 578 (emphasis added).

that the defendants lacked substantiation, and thus violated the consent order, when they claimed that their calcium supplement was unique in its ability increase bone density, and when they claimed that their calcium supplement was comparable or superior to osteoporosis drugs. *Id*. at 583-84, 586-87.[9] The Third Circuit thus recognized that a prohibition against making unsubstantiated claims about a product's health benefits applies to unsubstantiated superiority claims. Given that the Stipulated Final Order entered in this case explicitly prohibits unsubstantiated claims about "comparative health benefits" of defendants products, it is all the more apparent that the Order applies to the calcium superiority claims challenged here.

Indeed, courts have long recognized that advertisers violate the Federal Trade Commission Act when they make baseless claims that a product confers superior health benefits to competing products. *See, e.g.*, *Sterling Drug Inc. v. FTC*, 741 F.2d 1146 (9th Cir. 1984) (manufacturer found to have violated the FTC

[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 limited their marketing to individuals at risk for achlorhydria or, instead, marketed their calcium to the general population. *Lane Labs*, 624 F.3d at 585-86.

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 "comparative health benefits" of a product as prohibiting unsubstantiated superiority claims would transform this provision into an unenforceable "obey the law" injunction. Doc. 77 at 11-12 (citing *Hughey v. JMS Developmental Corp.*, 78 F.3d 1523 (11th Cir. 1996)). Interestingly, the court

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

[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

"cannot be required to confine its road block to the narrow lane the transgressor has traveled; it must be allowed effectively to close all roads to the prohibited goal, so that its order may not be by-passed with impunity").

It is worth noting, moreover, that defendants agreed to this injunction. It is far too late for them to argue, as they did below, that an order they bargained for in 2006 is too broad or the obligations it imposes are insufficiently clear. As was the case in *Combs v. Ryan's Coal Co., Inc.*:

> [A]t no time before the trial court did appellants ever complain about the adequacy of the consent decree . . . . They made no attempt to request more specific language; they chose not to exercise their right to the usual remedy for inadequacies of this sort: a motion for clarification or modification of the consent decree. . . . At this point any possible objection they might have to the decree is stale.

785 F.2d 970, 979 (11th Cir. 1986); *see NLRB v. Alterman Transp. Lines, Inc.*, 587 F.2d 212, 216 (5th Cir. 1979) (if the terms of a consent decree "read more broadly than respondent intended that they should, the time and manner of avoiding that breadth was by objections to the decree before its entry and not by disobedience of it afterwards").

The Stipulated Final Order gives defendants ample "notice of what conduct will risk contempt," *Hughey*, 78 F.3d at 1531, and thus is not an unenforceable "obey-the-law" injunction. The district court's conclusion to the contrary was error.

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

[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

[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 of their products, they are implicitly representing that the study in question is reliable – or, stated another way, that it is valid. If it is not, defendants have violated the Order's prohibition against misrepresentations of the validity of studies. Thus, the district court erred in this respect, as well.

II. THE DISTRICT COURT ABUSED ITS DISCRETION IN DENYING THE COMMISSION'S MOTION TO HOLD DEFENDANTS IN CONTEMPT FOR MAKING UNSUBSTANTIATED CLAIMS ABOUT THE BENEFITS OF OCEANS KIDS.

The district court viewed the question whether defendants had substantiation for their claims that Oceans Kids provides benefits for "brain and eye development," "cognitive function," "mental focus," and "positive mood and behavior" in children "ages 2 and older" as a dispute between experts, and credited the opinion of defendants' consultant, Dr. Weisman, that studies adequately substantiated these claims. Doc. 77 at 9-10. That characterization was incorrect, however, because defendants adduced *no* competent evidence to support the proposition that the studies in question supported the claims defendants made for Oceans Kids. Even assuming that Dr. Weisman qualified as an "expert" in the

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 it is scientifically sound to make such extrapolations." *Dietary Supplements* at 17 (Doc. 55-4 at 22). Furthermore, "the extent to which studies support an unqualified claim will depend largely on what experts in the relevant field would consider to be adequate support." *Id.* at 8 (Doc. 55-4 at 13).

Here again, the Third Circuit's *Lane Labs* decision is instructive. The defendants there claimed that their calcium supplement was three to four times more absorbable than calcium carbonate, citing a study that found calcium carbonate to be poorly absorbed by elderly women suffering from achlorhydria (an inability to produce stomach acid). Recognizing the principle that an advertiser's substantiation must match its claims, the Third Circuit observed that "[t]he problem with this argument is its failure to account for the actual language of the challenged representations," which "did not include phraseology limiting its claims to elderly females suffering conditions of achlorhydria." 624 F.3d at 585. Moreover, the district court neglected to "address the incongruity between the Lane defendants' argument and the actual language of the marketing claims identified by the FTC." *Id*. at 586. Notably, it was the expertise provided by the parties' calcium experts, who explained the differences in calcium absorption in these different populations, that was central to the Third Circuit's understanding of the mismatch between defendants' proffered substantiation and their claims of benefits

for the general population. *See id.* at 585 (discussing the expert testimony).[17]

This is precisely the problem with defendants' Oceans Kids claims: the studies do not match their claims. Virtually all of the studies upon which defendants relied dealt with distinct test populations, such as fetuses, infants, and children with diagnosed medical or behavioral disorders. Doc. 9 - Ex. 3 at 6-7. Yet Ocean Kids was being marketed to a general population of healthy kids, ages two and up. *See, e.g.*, Doc. 9 - Ex. 12. In the absence of evidence based on expertise in child development issues, there is no basis whatever for defendants' contention that the studies they relied on supported the claims they made. Dr. Weisman, on whom the district court relied, did not even pretend to have this expertise.

The Commission, by contrast, adduced evidence establishing – without any effective refutation – that the studies in question provided no support for GOL's advertising claims. The Commission retained Dr. David. C. Bellinger, Professor of Neurology at Harvard Medical School, and an expert in children's cognitive and

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[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 adequate substantiation. *FTC v. Lane Labs-USA, Inc.*, No. 00-cv-3174, 2011 U.S. Dist. LEXIS 133144, at *9-15 (D.N.J. Nov. 18, 2011).

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. *See* Doc 65-8 at 10 ("it is currently too premature to either accept or dismiss a benefit of DHA on cognitive performance in school-children"); Doc. 66-3 at 12 (findings merely "suggest a possible association"

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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.

court with instructions to enter an order granting the Commission's motion to find defendants in civil contempt of the Stipulate Final Order, and to conduct further proceedings on the issue of remedy.

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. 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.

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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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