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

REPLY BRIEF FOR PLAINTIFF-APPELLANT FEDERAL TRADE COMMISSION

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Defendants would have this Court believe that this case is about whether the FTC can hold their marketing of dietary supplements to the FDA's standards for new drug approvals; whether the FTC can require them to have placebo-controlled, double-blind studies to substantiate all health-related claims about their products; whether they can be required to have uncontroverted evidence before making claims about their products' health effects. But these are just straw man arguments: the FTC never said that an FDA drug standard applies; that the Stipulated Final Order necessarily requires placebo-controlled, double-blind studies; or that defendants' substantiation evidence needs to be uncontroverted. Nor, as defendants suggest, is this case about whether their products at issue here – calcium and omega-3 supplements – are safe, beneficial products. Instead, this case is about defendants' blatant claims that their algae-derived calcium supplements are superior to conventional calcium supplements, when defendants had no "competent and reliable scientific evidence," as that standard is defined in the Stipulated Final Order and was interpreted by both sides' experts, to substantiate these superiority claims. This case is about defendants' claims that their omega-3 supplement provides particular developmental and behavioral benefits for a particular population – healthy children ages 2 and up – when defendants had no "competent and reliable scientific evidence," as defined in the

Stipulated Final Order, that substantiates these specific claims.

As shown in our opening brief, the district court committed numerous reversible errors in denying the Commission's motion to hold defendants in contempt of the Stipulated Final Order. Among other things, the court misconstrued the Order's prohibition of unsubstantiated claims about the "comparative health benefits" of defendants' products, failed to apply the correct legal standard concerning the construction of advertising claims, and ignored undisputed evidence that clearly and convincingly establishes that defendants failed to substantiate their product claims and misrepresented study results. Although defendants seek to justify the decision below, their arguments cannot obscure the district court's significant legal errors.

I. THE DISTRICT COURT ABUSED ITS DISCRETION IN DENYING THE COMMISSION'S CONTEMPT MOTION WITH RESPECT TO DEFENDANTS' CALCIUM CLAIMS.

The Stipulated Final Order that defendants agreed to in 2006 prohibits them from making specified claims, unless such claims are substantiated by competent and reliable scientific evidence. In particular, it prohibits them from making unsubstantiated claims about "the absolute or *comparative health benefits*, efficacy, performance, safety, or side effects" of their dietary supplements. Doc. 8 at 5 (emphasis added). The court below failed to give effect to this provision of the

Order, in two remarkable ways. First, it failed to recognize that claims touting the superiority of the advertised products to other products fall squarely within the prohibition of unsubstantiated claims about "comparative health benefits." Second, it refused to believe that defendants made superiority claims in the first place, ignoring evidence of their explicit claims of superior and unique bone benefits. Once these errors are recognized, the defendants' violations of the Order are undeniable, in light of their undisputed lack of substantiation for their superiority claims, and their misrepresentations of the clinical support they relied on.

A. The District Court Erred in Ruling that the Prohibition of Unsubstantiated Claims About the "Comparative Health Benefits" of a Product Does Not Apply to Superiority Claims.

Defendants ask this Court to adopt an interpretation of the Stipulated Final Order that effectively reads out the requirement that they have substantiation for advertising claims about the "comparative health benefits" of the products they sell. Defendants argue that this provision (which they dismissively refer to as a "catch-all" provision) should be read to prohibit only the types of claims alleged in the initial complaint – *i.e.*, baseless claims that their products treat or cure certain health conditions. Under this reading, so long as defendants' dietary supplements generally provide some health benefits, they are on safe ground; if they deceive

consumers by making baseless claims that their supplements provide superior or unique health benefits in comparison to other products, that is no concern under the Stipulated Final Order. According to defendants, the Court should defer to this – the district court's – interpretation of the Stipulated Final Order, because that court approved the consent decree jointly proposed by the parties, and thus (defendants argue) is in a better position than this Court to comprehend the meaning of the consent decree. None of these arguments withstands scrutiny.

At the outset, defendants err in asserting that the district court's interpretation of the Stipulated Final Order is owed deference. GOL Br. at 28-29, 35. The rule in this Circuit is clear: "[c]onstruction of a consent judgment is . . . a question of law subject to *de novo* review." *Turner v. Orr*, 759 F.2d 817, 821 (11th Cir. 1985). Although some circuits have adopted a hybrid "deferential de novo" standard of review in interpreting a consent decree that the district court oversaw and approved, this Court is not one of them. *See Thomas v. Blue Cross & Blue Shield Ass'n*, 594 F.3d 814, 822 (11th Cir. 2010) (holding that district court's interpretation of an injunction entered by it pursuant to the parties' settlement was inconsistent with the "broad language" of the injunction and thus was an abuse of discretion); *see also Holland v. N.J. Dep't of Corrections*, 246 F.3d 267, 270 (3d Cir. 2001) (rejecting "oxymoronic standard" of "deferential de novo" review in

favor of "straightforward de novo review").[1]

There is likewise no merit to defendants' argument that, because the Order does not specifically mention "superiority" claims, the district court's restrictive interpretation of the prohibition of unsubstantiated "comparative" claims is warranted. This argument ignores that the plain, unambiguous meaning of "comparative" encompasses superiority claims – *i.e.*, claims that a product has superior health benefits as *compared to* another product. Additionally, because this provision unambiguously applies to superiority claims, the maxim of *ejusdem generis* does not, as defendants contend, apply here. *See United States v. Veal*, 153 F.3d 1233, 1246 (11th Cir. 1998) ("[t]he rule of *ejusdem generis* . . . comes into play only when there is some uncertainty as to the meaning of" the provision at issue). That defendants urge a contrary interpretation of this provision does not create ambiguity. *Id.* (noting that "[b]y insisting that the [provision] be read in the most restrictive way, [defendants] have attempted to create an uncertainty in the [provision] where none exists").

There is also no validity to defendants' further argument that, because the underlying action did not involve superiority claims, the district court's restrictive

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[1] The sole Eleventh Circuit case cited by defendants in support of this proposition, *Cave v. Singletary*, 84 F.3d 1350 (11th Cir. 1996), did not involve a consent decree and is inapposite.

interpretation of the Stipulated Final Order is justified. Glaringly absent from defendants' brief is any discussion explaining how this proposition – that an injunction in an FTC consumer protection enforcement action is appropriately limited to the specific practices alleged in the complaint – could possibly comport with the well-established legal principle (which defendants simply ignore) that the FTC "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. Colgate-Palmolive Co.*, 380 U.S. 374, 395, 85 S. Ct. 1035, 1048 (1965); *see FTC v. Gem Merch. Corp.*, 87 F.3d 466, 469 (11th Cir. 1996) (because the public interest is involved, a district court's equitable powers to grant relief under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), "assume an even broader and more flexible character than when only a private controversy is at stake") (quoting *Porter v. Warner Holding Co.*, 328 U.S. 395, 398, 66 S.Ct. 1086, 1089 (1946)).[2]

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[2] Defendants' passing suggestion that a broader interpretation of this provision would impinge on their free speech rights is patently without merit. This provision prohibits only deceptive (because unsubstantiated) advertising claims. As such, it does not raise First Amendment concerns. *See Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557, 566, 100 S. Ct. 2343, 2351 (1980) (commercial speech "must . . . not be misleading" to qualify for First Amendment protection); *In re R.M.J.*, 455 U.S. 191, 200, 102 S. Ct. 929, 936 (1982) ("[f]alse, deceptive, or misleading advertising remains subject to restraint"); *cf. FTC v. Direct Mktg. Concepts, Inc.*, 624 F.3d 1, 8 (1st Cir. 2010) ("Where the advertisers lack adequate substantiation evidence, they necessarily lack any reasonable basis for their claims. And where the advertisers so lack a reasonable

Indeed, defendants' argument that construing this prohibition as applying to superiority claims "would swallow Sections 5(a) and 12 of the FTC Act whole," GOL Br. at 39, is absurd. Superiority claims are a well-defined category of claims employed by advertisers – including advertisers of health-related products – to persuade consumers to choose their product over competing products. Indeed, superiority claims (when lacking substantiation) have long been the subject of FTC litigation,[3] including in the *Lane Labs* contempt action, which involved calcium claims nearly identical to the ones challenged here.[4] It thus strains credulity to suggest that the Order's prohibition of claims about the "comparative health benefits" of their products leaves defendants in the dark as to the type of claims they must take care to substantiate or risk a contempt action.[5] Contrary to what the

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basis, their ads are deceptive as a matter of law.") (internal citation omitted).

[3] *See*, *e.g.*, *Sterling Drug Inc. v. FTC*, 741 F.2d 1146 (9th Cir. 1984); *American Home Prods. Corp. v. FTC*, 695 F.2d 681 (3d Cir. 1982).

[4] *See* note 7, *infra* (comparing defendants' claims here to those at issue in *FTC v. Lane Labs-USA, Inc.*, 624 F.3d 575 (3d Cir. 2010)).

[5] *Cf. Colgate-Palmolive,* 380 U.S. at 393, 85 S. Ct. at 1047 ("If respondents in their subsequent commercials attempt to come as close to the line of misrepresentation as the Commission's order permits, they may without specifically intending to do so cross into the area proscribed by this order. However, it does not seem unfair to require that one who deliberately goes perilously close to an area of proscribed conduct shall take the risk that he may cross the line.") (internal quotation marks omitted).

district court believed, and the defendants here argue, this is not an injunction that merely orders defendants to "obey the law," but rather an injunction that, though perhaps "broad in terms of the scope of the conduct captured," gives defendants "fair notice of what conduct will risk contempt." *SEC v. Goble*, 682 F.3d 934, 951 (11th Cir. 2012) (internal quotation marks omitted).[6]

The arguments that defendants make here are no more convincing than the ones that the defendants in another FTC contempt action recently made, and the Ninth Circuit readily rejected, in *FTC v. EDebitPay, LLC*, __ F.3d __, 2012 WL 3667396 (9th Cir. Aug. 28, 2012). The court rejected the defendants' contention that the provisions of the consent decree were limited to the defendants' marketing of debit cards, credit cards, and prepaid cards – *i.e.*, the products and services at issue in the underlying action – because the plain language clearly and explicitly enjoined misrepresentations of, and failure to disclose, material information about

[6] Defendants cite several additional decisions of this Court on "obey-the-law" injunctions, but none of them involved injunctions remotely resembling the one at issue here. *See Fla. Ass'n of Rehab. Facilities, Inc. v. Fla. Dep't of Health & Rehab. Servs.*, 225 F.3d 1208, 1223 (11th Cir. 2000) (injunction ordered defendants to "compl[y] with the substantive requirements of" the Medicare Act), *Burton v. City of Belle Glade*, 178 F.3d 1175, 1201 (11th Cir. 1999) (discussing injunction ordering city not to discriminate in future annexation decisions); *Payne v. Travenol Labs., Inc*. 565 F.2d 895, 897(5th Cir. 1978) (order enjoined defendants from "[d]iscriminating on the basis of color, race, or sex in employment practices or conditions of employment").

"any product or service" offered by the defendants. 2012 WL 3667396, at *3-4 (also finding the maxim of *ejusdem generis* inapplicable). The court also rejected the defendants' contention that such a construction would transform the consent decree into an unenforceable "obey-the-law" injunction. The court held that, because defendants had stipulated to entry of the order, such a challenge was an impermissible collateral attack; moreover, the defendants' argument "proves only that the Final Order is broad, not vague." *Id.* at *4.

The same is true here. The plain and ordinary meaning of the Order's prohibition of unsubstantiated claims about "comparative health benefits" applies to the calcium superiority claims challenged here. Defendants stipulated to this injunction, broad as it may be. It is far too late for them to raise objections to the scope of this Order, now that the FTC seeks to enforce it. And, though the Order may be broad, if is not vague. The district court thus erred as a matter of law in ruling that the Stipulated Final Order does not apply to defendants' calcium superiority claims.

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

1. The District Court Erred in Ruling that Defendants Did Not Make Superiority Claims.

Defendants' advertisements do not, as they argue here, simply make truthful

statements about their calcium products' beneficial effects and describe how their products' added vitamins and minerals make them different from other supplements that lack those added nutrients. Instead, defendants' advertisements blatantly claim that their algae-derived calcium supplements have superior and unique bone benefits that "rock-source" calcium supplements categorically do not provide – that other calcium supplements can only slow down bone loss, while their calcium supplements actually stimulate bone growth. Defendants make these claims not just in their "article" on bone health (the only advertisement that the district court considered), but in many other ads and their product packaging. Defendants claim, for example:

- "The Grow Bone System . . . ha[s] been clinically studied to increase bone mineral density, increase bone strength and stimulate bone density growth! It is the only supplement that can truly make this claim – backed by human clinical studies." Doc. 9 - Ex. 27 at GOL-A2-00078.
- "Until now, Calcium supplementation, at best, helped to slow down the rate of bone loss." Doc. 9 - Ex. 1, Attach. O at FTC -CONTEMPT-0000101.
- "The best that can be said is that calcium supplementation helps slow down or stop bone loss. . . . There is good news on the horizon, however. . . . 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 FTC Br. at 6-7.

These claims are not, as defendant suggests, mere "impressionistic" suggestions, but instead are explicit representations that their calcium supplements provide bone-building benefits that other calcium supplements do not provide. The further message conveyed by defendants' ads as to why this is purportedly so is equally clear: their products contain plant-form calcium, which supposedly provides superior bone benefits than the rock-source calcium found in other calcium supplements. *See*, *e.g.*, Doc. 9 - Ex. 16 at GOL-A2-00038-39 ("The source of your calcium is a key factor. . . . Using plant-form calcium has huge advantages over rock-source calcium. . . . [O]ur bodies thrive on the nutrition that plants provide. The same will never be said of rocks."). Contrary to defendants' contention, no extrinsic evidence is necessary to ascertain the clear meaning of these advertisements: our plant-form calcium supplements are better for bone health than rock-source calcium supplements. *See Kraft, Inc. v. FTC*, 970 F.2d 311, 318-20 (7th Cir. 1992) (rejecting the "faulty premise that implied claims are inescapably subjective and unpredictable," and holding that extrinsic evidence is

not needed to construe express claims or claims "that are implied, yet conspicuous"); *accord FTC v. Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d 1167, 1189 (N.D. Ga. 2008), *aff'd*, 356 Fed. Appx. 358 (11th Cir. 2009); *FTC v. Bronson Partners, LLC*, 564 F. Supp. 2d 119, 125-26 (D. Conn. 2008).

Nor are defendants' claims about their calcium supplements' superior and unique bone benefits mere "puffery," as defendants contend. GOL Br. at 45. They are not "mere exaggeration" of the qualities of defendants' products, but instead are specific, factual assertions that can be – and, under the Stipulated Final Order are required to be – scientifically ascertained. *See United States v. Simon*, 839 F.2d 1461, 1468 (11th Cir. 1988) (holding that an advertiser who "'created' advantages by placing otherwise general assertions about the value [of his product] into a concrete, factual setting," created representations that were either true or false, and "not mere puffery"); *FTC v. Direct Mktg. Concepts, Inc.*, 624 F.3d 1, 11-12 (1st Cir. 2010) ("specific and measurable" health claims are not mere puffery).

Defendants' protestations to the contrary, their calcium superiority claims are nearly identical to claims of unique bone-building benefits that the Third Circuit in *Lane Labs* found were in violation of a consent decree that required the defendants to have competent and reliable scientific evidence for claims about their products' health benefits. *FTC v. Lane Labs-USA, Inc.*, 624 F.3d 575, 583-84 (3d

Cir. 2010).[7] The same conclusion is warranted here.

Although defendants argued, and the district court found, that the Commission took various statements in defendants' "article" out of context when it pointed to separate representations and examined them together to identify the message conveyed by this ads, in fact this is precisely what the law requires: that the net impression created by an advertisement be considered. *See, e.g.*, *Thompson Medical Co., Inc. v. FTC*, 791 F.2d 189, 197 (D.C. Cir. 1984); *American Home Prods. Corp. v. FTC*, 695 F.2d 681, 687 (3d Cir. 1982). It was the district court that erred, by ignoring evidence of defendants' express claims of superiority, and confining its analysis to isolated statements in this "article" apart from their context, without considering the overall impact of the ad. *See* FTC Br. at 27-31.

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[7] *Compare* GOL's claim that "[u]ntil now" – *i.e.*, introduction of the Grow Bone System – "[c]alcium supplementation, at best, helped to slow down the rate of bone loss" (Doc. 9 - Ex. 1, Attach. O at FTC -CONTEMPT-0000101), *with* Lane Labs' claim that: "Up until then, calcium supplements, at best, could only PREVENT bone loss. AdvaCal was different. AdvaCal demonstrated in multiple clinical studies that it could actually BUILD bone density quickly, naturally and safely." *Lane Labs*, 624 F.3d at 583. *Also compare* GOL's claim that "[t]he Grow Bone System . . . ha[s] 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" (Doc. 9 - Ex. 27 at GOL-A2-00078), *with* Lane Labs' claim that its calcium is "the one calcium clinically shown to build bone density in multiple human clinical studies. No other calcium can make that claim." *Lane Labs*, 624 F.3d at 583.

2. Undisputed Evidence Shows that Defendants Lacked Competent and Reliable Scientific Evidence for Their Calcium Superiority Claims.

Contrary to defendants' contention, the parties and their experts did not dispute the meaning of "competent and reliable scientific evidence" that is required to substantiate superiority claims. *See* GOL Br. at 48. Both the Commission's and defendants' expert agreed that competent and reliable scientific evidence that one calcium product provides superior bone benefits than another requires a clinical trial comparing one product against another. They also agreed that, to the best of their knowledge, no such studies comparing defendants' calcium supplements to other products had ever been done. Doc. 9 - Ex. 4 at 6, 11-12; Doc. 44-1 at 39-40. Indeed, defendants asserted below that they are entitled to rely on studies of generic calcium to substantiate their claims about their calcium products' bone benefits, "because 'nearly all calcium supplements produce a measurable increase in bone density.'" Doc. 40 at 9 (quoting the testimony of the Commission's calcium expert in *Lane Labs*). Thus, it was undisputed that defendants lacked competent and reliable scientific evidence to substantiate their calcium superiority claims.

Defendants now suggest that their claims about their calcium supplements' superior bone benefits compared to other calcium supplements are truthful and

substantiated, because their products have added vitamins and minerals that calcium-only supplements lack, and calcium enhanced with other nutrients (in particular, vitamin D) has been shown to provide greater bone benefits than calcium alone. GOL Br. at 18, 47. But this argument ignores their actual claims. Defendants' ads do not claim superiority to calcium-only products devoid of additional nutrients; they claim categorical superiority to all rock-source calcium supplements, regardless of whether such supplements also contain added nutrients shown to improve bone health. In fact, most other calcium supplements in the market *do* contain added nutrients, such as vitamin D, shown to enhance bone formation. Doc. 57-3 at 6 ("Many of the commercially available [calcium] products also contain vitamin D, magnesium, potassium, and other minerals.");[8] *see* Doc. 44-1 at 12 (¶ 20) (Dr. Weisman reported that studies using other sources of calcium "substantiated the use of calcium and calcium in combination with other nutrients and minerals . . . in supporting bone density and overall bone health"). Thus, defendants' contention is unequivocally contradicted by the record.

In a last-ditch effort to obscure the complete lack of *any* scientific support for their claims of superior and unique bone-health benefits, defendants accuse the

[8] Defendants' assertion that most other calcium supplements are calcium-only products, GOL Br. at 44, lacks any record support.

FTC of judging their compliance with the Stipulated Final Order against an FDA drug-approval standard,[9] rather than the Order's "flexible" "competent and reliable scientific evidence" standard.[10] GOL Br. at 48-52. This accusation is wholly unfounded. Defendants' calcium superiority claims are contumacious because defendants do not have, as the Order's "competent and reliable scientific evidence"

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[9] Defendants insinuate that their dietary supplement claims comport with the FDA's standards under the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Pub. L. No. 103-417, 108 Stat. 4325 (1994) (codified as amended in scattered sections of 21 and 42 U.S.C.). GOL Br. at 5-6. But under DSHEA, advertising claims for dietary supplements are permitted only if the manufacturer "has substantiation that such statement is truthful and not misleading," 21 U.S.C. § 343(r)(6)(B) – which the FDA has stated requires "competent and reliable scientific evidence," applying the same definition that is in Stipulated Final Order. *See* Food and Drug Administration, *Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act*, available at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm073200.htm (last visited September 20, 2012) ("FDA intends to apply a standard for the substantiation of dietary supplements that is consistent with the FTC approach.").

[10] The FTC has indeed, as defendants emphasize, described this standard as a flexible one. Flexibility means that the evidence needed to substantiate a claim will depend on the nature of the claim; it does not mean that any evidence a defendant offers, no matter how unreliable or inapplicable to the claim made, must be accepted as adequate substantiation. *See* Federal Trade Commission, *Dietary Supplements: An Advertising Guide for Industry* 10 (2001) ("[T]he evidence needed depends on the nature of the claim. A guiding principle for determining 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."), in the record as Doc 55-4 at 15.

standard requires, the type of evidence that experts in this field – what *both sides' experts* – agreed is needed to substantiate calcium superiority claims. The FTC required no more.[11]

C. Undisputed Evidence Shows that Defendants Misrepresented the Clinical Support for Their Calcium Products.

As shown in our opening brief, defendants compounded their contempt by misrepresenting the clinical study that they advanced in ostensible support for their calcium products. Before this Court, defendants admit that their claims that participants in a study of the ingredients in the Grow Bone System experienced an increase in bone mineral density in six-months ranging from 2.8% to "an amazing" 3.7% was a misrepresentation – that, in fact, study participants experienced bone mineral density increases that were only half that. GOL Br. at 52-53. Defendants argue, however, that this misrepresentation should be excused because they were merely relying on their expert, who confused annualized data reported in the study

[11] Defendants' lengthy argument about the FTC's motion to modify the Stipulated Final Order to impose a more detailed standard of substantiation going forward is irrelevant to the question whether defendants had "competent and reliable scientific evidence," as that standard is defined in the existing Stipulated Final Order, to support the claims at issue here. As the discussion above shows, they had none at all. The Commission proposed modifications to the Order to better protect consumers in light of defendants' contumacious conduct; the district court denied the motion; and the Commission has not appealed that ruling. Accordingly, the issue whether these proposed modifications are warranted is not before this Court.

for the actual six-month results, and, in any event, they ceased making that claim. Neither of these arguments withstands scrutiny.

This Court has made clear that "the absence of willfulness is not a defense to a charge of civil contempt. . . . [T]he only issue is compliance." *FTC v. Leshin*, 618 F.3d 1221, 1232 (11th Cir. 2010) (citing *McComb v. Jacksonville Paper Co.*, 336 U.S. 187, 191, 69 S. Ct. 497, 499 (1949)). By defendants' own admission, they misrepresented the results this study. They are, therefore, in violation of the Stipulated Final Order's prohibition of misrepresentations of the result of studies. Whether they did so purposefully or inadvertently, as a result of their and their expert's carelessness in ascertaining the accuracy of their representations, is irrelevant.[12]

Moreover, there is good reason to doubt defendants' claim that they did not realize that the "amazing" study results they boasted about in their ads were annualized data, not the actual study results. A GOL press release announcing the

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[12] The district court appears to have accepted defendants' arguments on this point, at least to a degree, concluding, for example, that a claim could be "substantiated" by virtue of their consultant's approval. Doc. 77 at 15. Any such conclusion is flatly erroneous; hiring a consultant does not comply with the Stipulated Final Order's requirement that defendants have scientific support for their product claims when – as is the case with defendants' calcium superiority claims – they never asked the consultant to evaluate whether those particular claims were substantiated (and the consultant testified that no studies substantiate defendants' superiority claims).

results of this study shows unequivocally that defendants understood from the outset the distinction between the results actually experienced by study participants and the annualized data. Doc. 9 - Ex. 22 at GOL-A2-00059 (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%").[13]

Furthermore, contrary to defendants' contention, the fact that, at some point, they stopped making this representation does not moot the Commission's contempt claim for this violation. Although cessation of contumacious conduct might obviate the need for coercive sanctions to bring defendants into compliance, it does not moot the Commission's action for compensatory contempt sanctions to remedy the harm to consumers who purchased defendants' products in reliance on their deceptive ads.[14] *See Jim Walter Res., Inc. v. Int'l Union, United Mine Workers of Amer.*, 609 F.2d 165, 170 (5th Cir. 1980) (holding that it was not improper to assess a fine for civil contempt to compensate for losses caused by contumacious

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[13] Although the press release is undated, there is little question that it demonstrates defendants' knowledge at a time when they were disseminating ads that contained this misrepresention: both the press release and the ads announce an upcoming product giveaway on October 10 at 10:00 a.m. Doc. 9 - Ex. 18 at GOL-A2-00030; Ex. 22 at GOL-A2-00058; Ex. 23.

[14] The case that defendants cite in support of their mootness argument, *United States v. McCorkle*, 321 F.3d 1292 (11th Cir. 2003), did not involve compensatory contempt sanctions.

conduct, even though the contempt had ended); *cf. Mar-Jac Poultry, Inc. v. United States*, 153 Fed. Appx. 562, 565 (11th Cir. 2005) (though termination of underlying action out of which contempt proceeding arose moots a coercive civil contempt proceeding, it does not moot a civil contempt proceeding for compensatory relief).[15]

Because the district court ignored this undisputed evidence demonstrating that defendants misrepresented the results of this study, the court erred in ruling that Commission failed to present clear and convincing evidence that defendants were in contempt of the Stipulated Final Order's prohibition of the misrepresentation of studies.

II. THE DISTRICT COURT ABUSED ITS DISCRETION IN DENYING THE COMMISSION'S CONTEMPT MOTION WITH RESPECT TO DEFENDANTS' OCEANS KIDS CLAIMS.

Defendants assert that there is a "wealth" of evidence demonstrating the benefits of omega-3 supplementation. GOL Br. at 54. But the existence of studies showing that omega-3 supplementation provides certain health benefits in certain study populations (fetuses, infants, and individuals with certain medical

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[15] For this same reason, there is also no merit to defendants' argument of mootness with respect to the Commission's contempt action regarding their Oceans Kids claims (discussed in Part II, *infra*), on the ground that they stopped making those claims after the Commission challenged them. *See* GOL Br. at 54.

conditions) does not answer the critical question here: whether these studies substantiate defendants' particular claims of cognitive and behavioral benefits to a distinct population not examined in these studies: normal, healthy children ages 2 and older. Unless the findings of these studies can be generalized to the Oceans Kids target population, they do not serve – however numerous they may be – to substantiate defendants' claims. Defendants do not dispute this, but argue that their expert, though entirely lacking education or professional experience in cognitive and behavioral development, nonetheless is sufficiently qualified to assess the applicability of these studies.[16] They are wrong.

Although defendants cite Dr. Weisman's experience in assessing "generalized health claims for natural, benign products," GOL Br. at 55, they fail to demonstrate any link between their expert's knowledge and the specific subject at issue here: claims of benefits to brain development, cognitive function, mental focus, and positive mood and behavior in children ages 2 and older. The Stipulated Final Order expressly requires that "competent and reliable scientific evidence" be "based on the expertise of professionals in the relevant area" – here, cognitive and

[16] Though defendants repeatedly refer to a "team of scientists" working for Dr. Weisman, they have not suggested, and nothing in the record shows, that any member of this team has education or professional experience in cognitive and behavioral development.

behavioral development. Doc. 8 at 3. Defendants respond that this requirement merely refers to the expertise needed by those who conduct the primary research. Acceptance of this argument would reduce the Order's substantiation requirement to a shell game, allowing defendants to rely on any properly-conducted scientific study, regardless of its lack of any connection to the claims being asserted. The Order's further express requirement that the evidence in question must be "evaluated in an objective manner by persons qualified to do so," *id.*, refers to an evaluation that the research actually supports the claims made. This was not done by any "person qualified to do so."

Dr. Bellinger, the Commission's expert in children's cognitive and behavioral development, confirmed that substantive expertise in this field is critically important to assessing whether results from one study population translate to a different population. He explained, for example, that differences in brain development *in utero* and in early infancy versus in older children make findings about a substance's effects on brain development *in utero* and in infancy inapplicable to older children. Doc. 67-2 at 3-4. He also explained that the findings of studies regarding the effects of omega-3 supplementation in subjects with existing cognitive or behavioral disorders do not translate to children without such cognitive or behavioral disorders (*i.e.*, the Oceans Kids target population of

healthy kids). Doc. 9 - Ex. 3 at 6.[17] For his part, Dr. Weisman – lacking any expertise in this field – did not venture to explain how omega-3 studies concerning children at earlier developmental stages or with cognitive or behavioral disorders can be generalized to healthy children over the age of two. Thus, the evidence on this issue was entirely one-sided.

Contrary to defendants' argument, the Commission never suggested that substantiation under the Stipulated Final Order requires undisputed proof. Nor did the Commission (or its expert) judge defendants' substantiation against any standard other that the "competent and reliable scientific evidence" standard set forth in the Stipulated Final Order. Rather, defendants' substantiation fails because defendants adduced *no* evidence of the kind specifically required by the Stipulated Final Order to substantiate their specific claims of benefits for healthy children ages 2 and older. 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.

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[17] Defendants note that Dr. Bellinger found the hypothesis that some level of omega-3 supplementation is beneficial to healthy children to be "plausible." But the Stipulated Final Order requires actual substantiation of health claims, not mere plausibility.

CONCLUSION

For the reasons stated above and in its opening brief, the Commission requests that this Court reverse the district court's order denying its contempt motion, and remand this case for further proceedings on the issue of remedy.

Respectfully Submitted,

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Dated: September 21, 2012

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 5,569 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 September 21, 2012, a copy of the foregoing Reply Brief for Plaintiff-Appellant Federal Trade Commission was served by first class U.S. mail upon the counsel for defendants-appellees Garden of Life, Inc. and Jordan S. Rubin listed below:

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