

Nos. 14-13131, 14-13174, 14-13175

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

FEDERAL TRADE COMMISSION,
Plaintiff-Appellee,

v.

HI-TECH PHARMACEUTICALS, INC., *et al.*,
Defendants-Appellants,

On Appeal from the United States District Court
For the Northern District of Georgia
No. 1:04-cv-03294-CAP
Hon. Charles A. Pannell, Jr.

CORRECTED BRIEF FOR PLAINTIFF-APPELLEE
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Nos. 14-13131, 14-13174, 14-13175

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STATEMENT REGARDING ORAL ARGUMENT

The FTC believes that oral argument will assist the Court in its consideration of this appeal.

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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/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm073200.htm>..... 5

JURISDICTIONAL STATEMENT

The district court had jurisdiction to issue the underlying injunctions at issue pursuant to 28 U.S.C. §§ 1331, 1337(a), and 1345 and 15 U.S.C. § 53(b). The district court had jurisdiction to enter the contempt order under review pursuant to its inherent power to enforce compliance with its decrees. *See Spallone v. United States*, 493 U.S. 265, 276, 110 S. Ct. 625, 632 (1990); *Serra Chevrolet, Inc. v. General Motors Corp.*, 446 F.3d 1137, 1147 (11th Cir. 2006). Appellants filed a timely notice of appeal on July 11, 2014, and a timely amendment to the notice on July 14, 2014. Docs. 675, 681. This Court has jurisdiction to review the contempt judgment under 28 U.S.C. § 1291.

ISSUES PRESENTED FOR REVIEW

In 2008, the district court permanently enjoined appellants from claiming, *inter alia*, that Hi-Tech's weight-loss products lead to rapid loss of body fat and affect metabolism or appetite in the absence of "competent and reliable scientific evidence" to support those claims. The court also found, based on expert testimony, that for these types of claims competent and reliable scientific evidence requires "well-conducted, randomized, double-blind, placebo-controlled clinical trials" that are conducted on the specific product at issue or its equivalent.

Despite the permanent injunction against them, appellants continued to promote weight-loss products, again claiming that their products would lead to rapid loss of body fat and affect the users' metabolism and appetite. They made those claims even though they lacked the type of evidence the district court had determined was needed to support them. The district court held appellants in contempt and, as a compensatory sanction, ordered them to disgorge the revenue they had generated using the unlawful sales pitch. The court also imposed contempt sanctions on Hi-Tech's compensated endorser, Dr. Terrill Mark Wright, for endorsing a Hi-Tech weight-loss product without the requisite support. The questions presented are:

1. Whether the district court abused its discretion when it found that the injunction's requirement that Hi-Tech support weight-loss claims with "competent and reliable scientific evidence" called for randomized, double-blind, placebo-controlled clinical trials on the products at issue; and
2. Whether the district court relied on privileged information in determining the amount of the compensatory sanction imposed on Hi-Tech, Wheat, and Smith.

3. Whether the district court abused its discretion in holding appellant Smith in contempt.

COUNTERSTATEMENT OF THE CASE

A. Legal Framework

Section 5 of the FTC Act prohibits, and “direct[s]” the FTC “to prevent * * * deceptive acts or practices in or affecting commerce.” 15 U.S.C. § 45(a)(2).¹ In general, “an advertisement is considered deceptive if the advertiser lacks a ‘reasonable basis’ to support the claims made in it.” *Thompson Med. Co. v. FTC*, 791 F.2d 189, 193 (D.C. Cir. 1986); *see FTC v. Pantron I Corp.*, 33 F.3d 1088, 1096 (9th Cir. 1994); *Am. Home Prods. Corp. v. FTC*, 695 F.2d 681, 693 (3d Cir. 1982). A court thus assesses an FTC deceptive advertising claim by determining whether the advertiser in fact had evidentiary substantiation, sufficient under the circumstances, for making the claims in the ads. *See Thompson Med. Co.*, 791 F.2d at 193; *see also*

¹ Section 12 of the FTC Act, 15 U.S.C. § 52, is specifically directed to false advertising of foods, drugs, devices, or cosmetics. An advertisement is “false” under Section 12 (and therefore an “unfair or deceptive practice” in violation of Section 5) if it is “misleading in a material respect.” 15 U.S.C. § 55. Under Section 15, 15 U.S.C. § 55, an advertisement which is “misleading in a material respect” is “false.”

FTC v. Direct Mktg. Concepts, Inc., 624 F.3d 1, 8 (1st Cir. 2010) (when “advertisers lack adequate substantiation evidence * * * their ads are deceptive as a matter of law”). The requisite level of substantiation for a particular claim is a question of fact that is established by evidence, including the testimony of experts in the relevant field. *See, e.g., Direct Mktg. Concepts, Inc.*, 624 F.3d at 8; *Pantron I Corp.*, 33 F.3d at 1096; *Removatron Int’l Corp. v. FTC*, 884 F.2d 1489, 1497 (1st Cir. 1989).

B. Hi-Tech’s Unsubstantiated Advertisements And The District Court’s Injunction

In November 2004, the Commission sued Hi-Tech, Wheat, Smith, Wright, and others for false and deceptive advertising of two weight-loss supplements, “Thermalean” and “Lipodrene,” and an erectile performance supplement, “Spontane-ES.” The Commission alleged that appellants had violated Sections 5 and 12 of the FTC Act by making false, deceptive, and unsubstantiated claims that their dietary supplements were safe and effective treatments for weight loss and erectile dysfunction.² Doc. 1. Most pertinent here, the Commission

² Sections 5 and 12 complement the requirements of the Dietary Supplement Health and Education Act of 1994 (DSHEA), Pub. L. No. 103-417, 108 Stat. 4325. Under DSHEA, a manufacturer may state on

alleged that they lacked adequate substantiation for claims that the supplements were effective and safe and that they caused rapid and substantial weight and fat loss.

In a 99-page order issued June 4, 2008, the district court found that appellants had violated the FTC Act. Doc. 219. Regarding the appropriate level of substantiation for the challenged weight-loss claims, the district court explained that the requirement “is context specific and permits different variations on ‘competent and reliable scientific evidence’ depending on what pertinent professionals would require for the particular claim made.” *Id.* at 26. It then found, relying on uncontroverted expert testimony, that “to substantiate weight-loss

product labels that a dietary supplement has health benefits, but only if it “has substantiation that such statement is truthful and not misleading.” DSHEA § 6, 108 Stat. 4329 (21 U.S.C. § 343(r)(6)(B)). DSHEA defines substantiation to mean “competent and reliable scientific evidence.” *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* (request for extension approved to Feb. 28, 2015), available at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm073200.htm> (“FDA intends to apply a standard for the substantiation of dietary supplement claims that is consistent with the FTC approach.”).

claims for any product, including a dietary supplement,” an advertiser must have “independent, well-designed, well-conducted, randomized, double-blind, placebo-controlled clinical trials, given at the recommended dosage involving an appropriate sample population in which reliable data on appropriate end points are collected over an appropriate period of time.” *Id.* at 65.

The court also credited unchallenged expert testimony that such trials must be conducted “on the product itself,” and not on a product that uses a different combination or lower doses of a product’s active ingredients. *Id.* Thus, the court held, if advertising claims relate to a product, evidence relating only to its constituent ingredients cannot substantiate the claims. *Id.* at 64-67.

Appellants did not counter the expert testimony regarding the appropriate level of substantiation for Hi-Tech’s claims. Instead, they simply argued that the claims were not made and that their studies regarding the products’ ingredients supported their ingredient-specific claims. *Id.* at 66 & n.21. The court thus concluded that the weight-loss claims were unsubstantiated and that the specific representations that

such claims were “clinically proven” were “inherently false.” *Id.* at 67-68.

On December 16, 2008, the district court entered a Final Order and Judgment for a Permanent Injunction against Hi-Tech, Wheat, and Smith.³ Doc. 230. The court entered a separate Final Order and Judgment for a Permanent Injunction against Dr. Wright based on his unsubstantiated endorsements of weight-loss products. Doc. 229. Three provisions of the Injunctions are pertinent to this appeal:

First, Section II of the Injunctions prohibits “Unsubstantiated Claims for Weight Loss Products.” As most relevant here, it prohibits representations that weight-loss products cause a rapid or substantial loss of weight or fat, or that they affect human metabolism, appetite, or body fat, unless they are substantiated with “competent and reliable scientific evidence.” Doc. 230 at 13 (Hi-Tech); Doc. 229 at 7-8 (Wright). The Injunctions define such evidence to mean “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

³ The district court also granted the Commission’s request for monetary equitable relief.

manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.”⁴ Doc. 230 at 5 (Hi-Tech, Definition 3); Doc. 229 at 4 (Wright, Definition 3).

Second, Section VII of the Hi-Tech Injunction and Section IV of the Wright Injunction (“Other Prohibited Claims”) apply the same prohibitions and definitions to representations about “the health benefits, absolute or comparative benefits, performance, safety, or efficacy of [any covered] product or service * * *.” Doc. 230 at 16-17 (Hi-Tech); Doc. 229 at 10 (Wright). “Covered product or service” is defined to mean “any health-related service or program, weight loss product, erectile dysfunction product, dietary supplement, food, drug, or device.” Doc. 230 at 9 (Definition 11); Doc. 229 at 5 (Definition 6).

⁴ These requirements mirror longstanding FTC guidelines for advertising dietary supplements. Under those guidelines, “claims about the efficacy or safety of dietary supplements” must be supported by “competent and reliable scientific evidence.” FTC, Bureau of Consumer Protection, *Dietary Supplements: An Advertising Guide for Industry* 9 (April 2001), available at <http://business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry>. FTC guidelines define that phrase to mean “tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.” *Id.*

Third, Section VI of the Hi-Tech Injunction (“Warning of the Health Risks of Yohimbine”) requires Hi-Tech, Wheat, and Smith, to include a specific health-risk warning on any advertisement, product package, or product label that makes efficacy claims relating to products containing yohimbine, a stimulant derived from the bark of a tree indigenous to Central Africa. Doc. 230 at 15-16 .

On December 15, 2009, this Court affirmed the judgment of the district court on the basis of its “well-reasoned” decision. *FTC v. Nat’l Urological Grp., Inc.*, 356 F. App’x 358 (11th Cir. 2009), *reh’g denied*, 401 F. App’x 522 (11th Cir. 2010). The Supreme Court denied a petition for a writ of certiorari. *Nat’l Urological Grp., Inc. v. FTC*, 530 U.S. 703, 131 S. Ct. 505 (2010).

C. Hi-Tech’s Contempt Of The Permanent Injunctions

1. Hi-Tech’s New Ads Promising Weight Loss

Undeterred by the Permanent Injunction, Hi-Tech continued to promote weight-loss supplements. In September 2010, Hi-Tech launched a new nationwide promotion for four supposed weight-loss products: Fastin, Lipodrene, Stimerex-ES, and Benzedrine. The media blitz, which cost approximately \$4 million, included full-page ads in well-known national publications such as *Allure*, *Cosmopolitan*, *Flex*, *In*

Touch, Muscle & Fitness, Redbook, Star, and Whole Living.⁵ In addition, Hi-Tech created webpages for each of the products on the company's website and made claims on product packaging and labels.⁶

Hi-Tech's promotion trumpeted the same types of claims it made in the underlying action – *i.e.*, that the products would lead to rapid and dramatic weight and fat loss. For example, although the Injunctions prohibit unsubstantiated claims that products would affect metabolism, appetite, or body fat, the ads promised that Fastin “[i]ncreases the metabolic rate, promoting thermogenesis (The Burning of Stored Body Fat),” Doc. 700-42 at 3 (PX46 at 2); Doc. 700-46 at 3 (PX50 at 2), and

⁵ Doc. 701-9 at 37 (DX65 at 19) (cost); Doc. 621 at 8-9 (cost); Doc. 700-13 at 10-13, 16-19, 22-24, 27-30 (PX18 at 9-12, 15-18, 21-23, 26-29) (ad dissemination); Doc. 700-16 at 4 (PX20 at 3) (ad dissemination); Doc. 700-28 at 5-10 (PX32 at 4-9) (ad dissemination); Doc. 700-39 at 3 (PX43 at 2); Doc. 700-40 at 3 (PX44 at 2); Doc. 700-48 at 3 (PX52 at 2); Doc. 700-53 at 3 (PX57 at 2); Doc. 700-57 at 3 (PX61 at 2) (full-page ads).

⁶ Doc. 700-41 at 3 (PX45 at 2); Doc. 700-49 at 3 (PX53 at 2); Doc. 700-54 at 3 (PX58 at 2); Doc. 700-58 at 3 (PX62 at 2) (webpages); Doc. 700-13 at 12, 14-17, 20-23, 27-28, 31-32 (PX18 at 11, 13-16, 19-22, 26-27, 30-31) (web dissemination); Doc. 700-37 at 4-9, 12-14 (PX41 at 3-8, 11-13); Doc. 700-50 at 3-4 (PX54 at 2-3); Doc. 700-51 at 2-3 (PX55); Doc. 700-52 at 3 (PX56); Doc. 700-55 at 3-4 (PX59 at 2-3); Doc. 700-56 at 3-4 (PX60 at 2-3); Doc. 700-59 at 3-4 (PX63 at 2-3); Doc. 700-60 at 2 (PX64); Doc. 700-61 at 2 (PX65); Doc. 701-14 at 51 (DX101) (packaging and labels); D. 534-10 at 54-55 (Wheat Dep. at 47:21-48:2); Doc. 618 at 49-51; Doc. 619 at 92-93 (packaging and label dissemination).

that Fastin “has both immediate and delayed release profiles for appetite suppression, energy and weight loss.” Doc. 700-46 at 4 (PX50 at 3). And although the Injunctions ban ads claiming without substantiation that products cause a rapid or substantial loss of weight or fat, Hi-Tech proclaimed, for example, “WARNING! EXTREMELY POTENT DIET AID! DO NOT CONSUME UNLESS RAPID FAT AND WEIGHT LOSS ARE YOUR DESIRED RESULT.” Doc. 700-42 at 3 (PX46 at 2); Doc. 700-46 at 3 (PX50 at 2). Supposed expert endorsements for Fastin by Dr. Wright (shown wearing a white lab coat) lent an aura of medical authenticity to those grandiose claims. *See, e.g.*, Doc. 700-39 at 3 (PX43 at 2) (“As a Weight Loss Physician I am proud to join Hi-Tech Pharmaceuticals in bringing you a Truly Extraordinary Weight Loss Product. I believe Fastin® is the Gold Standard by which all Fat Burners should be judged.”).

Despite the same injunctive ban on unsubstantiated claims of rapid fat or weight loss, Hi-Tech’s ads for Lipodrene exclaimed, “LIPODRENE WILL CAUSE RAPID FAT AND WEIGHT LOSS WITH USAGE.” *See* Doc. 700-218 at 15 (PX272); Doc. 700-135 (PX148 (physical exhibit)). The ads promised consumers that Lipodrene would

“increase[] th[eir] metabolic rate, promoting thermogenesis (the burning of stored body fat),” and, by “[s]low[ing] the absorption of serotonin,” would enable them to “control[] food cravings and suppress[] the appetite.” *See, e.g.*, Doc. 700-50 at 4 (PX54 at 3); *see also* Doc. 700-51 at 2 (PX 55 at 1) (“ADVANCED APPETITE CONTROL AND METABOLIC STIMULATION”).

Similarly, Hi-Tech promoted Stimerex with express, unsubstantiated claims that the product affected body fat. *See, e.g.*, Doc. 700-57 at 3 (PX61 at 2) (“Fat Burner/Energizer”); *see also* Doc. 700-61 at 2 (PX65) (“High Performance Thermogenic Intensifier for Maximum Fat Loss”). In addition, Hi-Tech made unsubstantiated comparative benefits claims that Stimerex-ES caused the same weight-loss and metabolic effects as products containing the ephedrine alkaloids banned by the FDA in 2004. *See* Doc. 700-57 at 3 (PX61 at 2) (“The benefits of ephedra are now ‘Back in Black!’”).

To like effect, Hi-Tech touted Benzedrine as a weight-loss product designed to “annihilate the fat” (Doc. 700-53 at 3 (PX57 at 2) (full-page print ad)) with “Unmatched Anorectic Activity to Manage Caloric

Intake.” See Doc. 700-54 at 3 (PX58 at 2) (Hi-Tech website product page). “Anorectic” means lacking appetite. See Doc. 524 at 22 n.8.

Despite claiming that consumers would experience dramatic metabolic changes, appetite suppression, and weight loss, Hi-Tech admitted it lacked clinical testing of the products to substantiate its claims. Doc. 619 at 54-55; Doc. 700-39 at 3 (PX43 at 2); Doc. 700-40 at 3 (PX44 at 2); Doc. 700-48 at 3 (PX52 at 2); Doc. 700-53 at 3 (PX57 at 2); Doc. 700-57 at 3 (PX61 at 2). Hi-Tech also admitted failing to include the specific health-risk warning required by Section VI of the Hi-Tech Injunction for products containing yohimbine. Doc. 534-10 at 130-32, 160-62 (Wheat Dep. at 123-125, 153, 154-55). It instead insisted that its preferred warnings were sufficient. Doc. 478 at 123-24.

2. The Contempt Proceeding

On November 1, 2011, the Commission asked the district court to order Hi-Tech, Wheat, and Smith to show cause why they should not be held in contempt for advertising weight-loss products that, in violation of Sections II and VII of the Permanent Injunction, were not supported by “competent and reliable scientific evidence.” The FTC also asked for a show cause order with respect to Hi-Tech’s failure to issue the

prescribed warning to consumers about yohimbine. Doc. 332. The FTC separately moved to hold Dr. Wright in contempt with respect to his unsubstantiated endorsement of Fastin. Doc. 377.

Hi-Tech did not deny disseminating product-based advertising for four weight-loss products, or advertising products containing yohimbine without the mandated health warnings. Likewise, Dr. Wright did not deny he was a compensated endorser for Fastin. They contended, however, that Hi-Tech's claims were "puffery" and that the health warnings were adequate.⁷ Of particular relevance to this appeal, they also sought to reopen the factual question of what constitutes "competent and reliable scientific evidence" to support safety and efficacy claims for weight-loss products. *See* Doc. 346 at 23-24; Doc. 368 at 12-13. The district court had ruled that any weight-loss claim must be substantiated by double-blind, placebo-controlled clinical trials on the product itself (as opposed to its ingredients). Hi-Tech admitted that

⁷ "Puffing" is an expression of opinion that is not offered as a representation of fact. *See United States v. Simon*, 839 F.2d 1461, 1468 (11th Cir. 1988); *see also FTC v. Trudeau*, 579 F.3d 754, 765 (7th Cir. 2009) ("an exaggerated opinion expressed for the intent to sell something").

it had no such evidence and asked the district court to deem its claims substantiated by studies on individual ingredients in the new products.

On May 11, 2012, the district court issued an order directing appellants to show cause why they should not be held in contempt. The show cause order rejected Hi-Tech's claim that the challenged ads were non-actionable puffery. Doc. 390 at 6-9. The court also rejected Hi-Tech's contention that the substantiation standard adopted in the underlying case did not apply. "The fact question of what constitutes 'competent and reliable scientific evidence' to substantiate a weight loss claim," the court held, "is not subject to re-litigation." *Id.* at 8-9. Rather, expert testimony on that point was "broad enough to establish what constituted substantiation of weight loss claims 'for *any product*, including dietary supplements' * * *." *Id.* (emphasis added) (quoting expert report of Dr. Louis J. Aronne in underlying action). As Dr. Aronne had established without contradiction, *all* weight-loss claims must be supported by well-designed, randomized, double-blind and placebo-controlled clinical trials "on the product itself" or its duplicate. *Id.* at 9-10.

The court held that the new claims were not categorically different from the prior ones and thus did not call for a different standard. Both sets of claims asserted that the products would increase metabolism and lead to weight loss. For example, one of Hi-Tech's advertisements in the underlying case promised that "Thermalean inhibits absorption of fat, suppresses appetite, and safely increases metabolism without dangerous side effects[.]" *Id.* (citing *FTC v. Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d 1167, 1192 (N.D. Ga. 2008)). The post-injunction ads made the same type of claims. The court held further that evidence of intent was irrelevant to charges of civil contempt, but reserved ruling on the question whether such evidence could be relevant to an appropriate sanction. Doc. 390 at 10-11.

On August 7, 2012, the district court denied Hi-Tech's motion for reconsideration of its order to show cause. Doc. 422. The court rejected the claim that its definition of "competent and reliable scientific evidence" was outside the "four corners" of the injunction and therefore did not govern the alleged contempt. The court explained that the issue "was actually litigated" and "played a critical, necessary part in the grant of summary judgment." *Id.* at 16. Thus, appellants "only needed

to look to the final judgment and the conclusively determined issues” to discern the relevant standard. *Id.* at 9.

3. *The Contempt Judgment*

On August 8, 2013, the district court entered a contempt judgment, finding clear and convincing evidence that appellants had violated the Permanent Injunctions. The court reiterated its two earlier rulings that the “fact question of what constitutes ‘competent and reliable scientific evidence’ to substantiate the [revised] claims was not open to re-litigation,” noting that Hi-Tech’s advertisements and Wright’s endorsements made precisely the types of claims that require “competent and reliable scientific evidence” under the Permanent Injunctions. Doc. 524 at 4. The court determined that Hi-Tech had no such evidence to support its claims. *Id.* at 16-17.

The court also reiterated its rejection of appellants’ contention that Hi-Tech’s advertisements constituted only non-actionable “puffery.” To the contrary, many of Hi-Tech’s statements explicitly violated the injunction. *Id.* at 18-25. Even those statements arguably characterized as “puffery” still violated the Injunctions because they prohibited not only direct violations of the FTC Act, but also “any

representation, in any manner, expressly or by implication, including through the use of endorsements, that * * * [any weight-loss product] causes rapid or substantial loss of weight or fat * * * [or] affects human metabolism, appetite, or body fat.” *Id.* at 28-29.

Finally, the court held that the packaging and labeling for all four weight-loss products lacked the specific health warning required by Section VI of the Permanent Injunction. *Id.* at 23-24. Hi-Tech provided *other* warnings about dangers to consumers who are pregnant, nursing, or sensitive to caffeine, and about the possible side effects of exceeding the recommended dosage. *See, e.g.*, Doc. 700-43 at 4 (PX47 at 2); Doc. 700-50 at 3 (PX54 at 2); Doc. 700-55 at 4 (PX59 at 3); Doc. 700-61 at 2 (PX65). Section VI of the Hi-Tech injunction, however, requires a specific health risk warning for *all* consumers. Doc. 230 at 15-16 (“WARNING: This product can raise blood pressure and interfere with other drugs you may be taking. Talk to your doctor about this product.”).

Turning next to the affirmative defenses, the court held that good faith was not a defense to contempt liability, and that, in any event, “Wheat’s conclusory and self-serving assertions” did not establish that

he had made “all reasonable efforts” to comply with the injunction. Doc. 524 at 32-33. The court found instead that his assertions of good faith reliance on the advice of counsel raised an issue of fact that – at most – might mitigate coercive contempt sanctions. *Id.* at 34.

4. *Contempt Sanctions*

In January 2014, the district court heard four days of live testimony and argument relating primarily to the amount of compensatory sanctions and possible need for coercive sanctions.⁸ Doc. 618-Doc. 621. Following the hearing, the parties submitted proposed findings of fact and conclusions of law and post-trial briefs. Doc. 600, Doc. 623-Doc. 624, Doc. 629-Doc. 630, Doc. 632-Doc. 634. On May 14, 2014, the court held Hi-Tech, Wheat and Smith in contempt of Sections II and VII of the Permanent Injunction with respect to their promotion of weight-loss products without “competent and reliable scientific evidence.” Doc. 650. The court also held that Dr. Wright violated the Permanent Injunction by making unsubstantiated endorsements for

⁸ In light of his role as an expert endorser with no position of authority at Hi-Tech, the Commission did not ask the court to impose coercive sanctions against Dr. Wright. Doc. 446-1 at 27 n.19.

Fastin and articles he authored in the Hi-Tech Health & Fitness magazine promoting Hi-Tech's weight-loss products. *Id.* at 18.

The court held Hi-Tech, Wheat, and Smith jointly and severally liable for compensatory sanctions in the amount of \$40 million – *i.e.*, Hi-Tech's gross receipts for the relevant time period, less refunds and returns. Doc. 650 at 18-19, 22-23 & n.17. The court also found Dr. Wright liable for \$120,000 – the sum Hi-Tech paid him for endorsing Fastin between 2010 and 2012. Doc. 650 at 23-24 & n.19. The court rejected Hi-Tech's good faith and due diligence defenses to compensatory sanctions, holding that “the only issue [was] compliance.” *Id.* at 25 (quoting *FTC v. Leshin*, 618 F.3d 1221, 1232 (11th Cir. 2010)). The court rejected the same defenses to coercive contempt sanctions. It noted that Hi-Tech had been advised by counsel that its claims would violate the Permanent Injunction but then sought contrary advice from other counsel to use as a shield in any contempt proceedings, knowing that such advice was incorrect. Doc. 650 at 26. The court, however, did not immediately impose coercive sanctions, but instead directed Hi-Tech, Wheat, and Smith to complete a product recall and to report on those efforts within 60 days. *Id.* at 28-29.

This appeal followed, with the matter of coercive sanctions proceeding on a separate track. On September 2, 2014, after hearing evidence of delay in the product recall, the district court ordered Wheat and Smith coercively imprisoned. Doc. 726. They appealed immediately, but dismissed the appeal after this Court denied their petition for a writ of mandamus and motion for a stay pending appeal.

STANDARD OF REVIEW

This Court reviews the district court's decision to impose contempt sanctions for abuse of discretion. *See, e.g., Leshin*, 618 F.3d at 1231. The Court reviews the underlying factual findings for clear error. *United States v. Coulton*, 2014 U.S. App. LEXIS 22233 at *4 (11th Cir. Nov. 25, 2014). Review of the court's construction of an injunction is *de novo*, but "great deference" is due to the court that issued and must enforce it. *Med. Assoc. of Ga. v. Wellpoint, Inc.*, 756 F.3d 1222, 1234 (11th Cir. 2014); *see also Schering Corp. v. Illinois Antibiotics Co.*, 62 F.3d 903, 908 (7th Cir. 1995) (district court's construction entitled to "particularly heavy weight").

SUMMARY OF ARGUMENT

1. In the underlying action this Court rejected appellants' claim that the Permanent Injunctions are impermissibly vague. In this appeal, appellants forswear any renewed challenge to the validity of the injunctions. Instead, they purport to argue only that the specific meaning of the operative phrase, "competent and reliable scientific evidence," must be found within the "four corners" of the injunction. But that argument boils down to the very argument appellants insist they are *not* making – and that is precluded in any event by this Court's earlier decision.

Here's why: the Permanent Injunctions forbade appellants from making any representation about the health benefits or efficacy of *any* dietary supplement, food, drug, or device unless they had "competent and reliable scientific evidence" to support those claims. That standard is flexible and can apply differently to different claims and products, depending on the type and amount of evidence experts would deem sufficient to support an advertisement. Its application in any given instance thus is a factual matter that must be determined on the basis of evidence.

When they contend that the injunction is unenforceable against them unless it specifies within its four corners the precise type and quantum of evidence required for their weight-loss advertisements, appellants are therefore arguing that the injunction as written is too vague to be enforced. That is the very claim they have already litigated and lost, and they may not litigate it again.

In many cases, determining whether an advertisement is supported by “competent and reliable scientific evidence” (a term that appears in hundreds of injunctions in FTC cases) involves an evidentiary hearing at which the district court hears testimony to determine what level of substantiation is sufficient for the types of products and claims at issue. In this case, however, the district court resolved that question in the underlying action. There, it received uncontroverted expert evidence and found as a factual matter that experts in the field would call for *any* claim about a weight-loss product to be supported by studies of the product at issue and not just its ingredients.

That ruling is not a requirement of the injunction that must appear in its “four corners;” it is a specific application of the “competent

and reliable scientific evidence” standard that appellants concede is lawful and insist that they do not challenge. Moreover, because the district court resolved that question as to *all* weight-loss advertisements, appellants are now precluded from challenging its application to their current weight-loss advertisements.

In any event, the law requires only that persons subject to an injunction understand what the injunction requires of them. Here, there is no doubt that appellants’ understood their obligations exactly. Emails sent by Hi-Tech’s CEO acknowledged that the Permanent Injunctions require a double-blind study on the products themselves. The law requires no more.

2. Appellants are wrong that in setting the amount of the compensatory contempt sanction the district court improperly relied on communications protected by the attorney-client privilege. The court did no such thing. It calculated the sanction on the basis of revenues generated by appellants’ unlawful advertising. That information came not from any attorney communications, but from charts supplied by appellants’ own expert witness. Even if the court had relied on attorney communications, however, appellants did not object to their submission

below and they have waived any privilege argument on appeal. The documents are not privileged in any event both because they were sent using a monitored prison email system that eliminates any expectation of confidentiality and because appellants relied on an advice-of-counsel defense, which forfeits any privilege.

3. Appellant Smith separately contends that the district court improperly imputed to him conduct of others in holding him jointly and severally liable for compensatory sanctions. It did not. Smith, Hi-Tech's Senior Vice-President in charge of sales, participated directly and substantially in Hi-Tech's promotion of its weight-loss products. Because he is individually bound under the Injunction, he is obliged to ensure that the claims in the advertising he used to promote the products were supported by the standard of substantiation required by the district court. By failing to do so, he is individually culpable for contempt.

ARGUMENT

I. The District Court Properly Held Appellants in Contempt of the Permanent Injunctions

A. The Permanent Injunctions Are Valid and Enforceable Against Appellants, and Appellants Have Forfeited Any Argument to the Contrary

Federal Rule of Civil Procedure 65(d) requires that an injunction “shall be specific in terms [and] shall describe in *reasonable* detail * * * the act or acts sought to be restrained.” Fed. R. Civ. P. 65(d) (emphasis added). That Rule is intended to prevent uncertainty and confusion on the part of those faced with injunctive orders, thus avoiding the possibility of a contempt citation on a decree that is too vague to be understood. *See, e.g., Planetary Motion, Inc. v. Techsplosion, Inc.*, 261 F.3d 1188, 1203 & n.30 (11th Cir. 2001). As the word “reasonable” in the rule suggests, the relevant inquiry in assessing whether an injunction can be enforced against an alleged violator is “whether the parties subject to the injunctive order understood their obligations.” *Williams v. City of Dothan, Ala.*, 818 F.2d 755, 761 (11th Cir. 1987).

The Permanent Injunctions satisfy that standard. They require appellants to have “competent and reliable scientific evidence” supporting claims made to market their products. They define such

evidence 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.” Doc. 230 at 5; Doc. 229 at 4.

This Court has already determined in substance that the competent and reliable scientific evidence standard adopted by the district court is sufficiently clear to enforce. In an order subsequently affirmed by this Court in the underlying case, the district court rejected appellants’ argument that “competent and reliable scientific evidence” is impermissibly vague. The district court found “no reason why this definition would not give people of ordinary intelligence a reasonable opportunity to understand what evidence is required to substantiate their health related claims.” *Nat’l Urological Grp., Inc.*, 645 F. Supp. 2d at 1186. This Court then upheld that decision, finding it “well-reasoned.” 356 F. App’x 358, 359 (11th Cir. 2009).⁹

⁹ The legal standard for sufficient clarity to enforce an order provision under Rule 65(d) is essentially the same as that for enforcing a statute. *Compare Eastern Air Lines, Inc. v. Air Line Pilots Ass’n*, 920 F.2d 722, 730 (11th Cir. 1990) (holding that injunctions are enforceable where “an

Appellants insist that they are not merely repeating their argument that the standard set forth in the Permanent Injunctions is unenforceably vague. Br. 39. But their challenge to the district court’s ruling that “competent and reliable scientific evidence” requires placebo-controlled clinical trials boils down to the very attack that they disavow and that this Court previously foreclosed. The flexible “competent and reliable scientific evidence” standard requires appellants to have the type and amount of evidence required by experts in the field relevant to their claims – *i.e.* weight loss. 645 F. Supp. 2d at 1186. As the district court recognized, application of the standard will vary based on the type of claim made and type of product involved. *Id.* Indeed, the Permanent Injunctions cover products other than weight-loss products, including “any health-related service or program,” and any “dietary supplement, food, drug, or device.” Doc. 230 at 9 (Definition 11); Doc. 229 at 5 (Definition 6). Any advertising claim for

ordinary person reading the court’s order should be able to ascertain from the document itself exactly what conduct is prescribed”) *with Hill v. Colorado*, 530 U.S. 703, 732, 120 S. Ct. 2480, 2498 (2000) (holding that a statute is enforceable if it “provide[s] people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits.”).

any such products or services must be substantiated by “competent and reliable scientific evidence,” as defined by the Injunctions. The type and amount of evidence required will vary depending on the claim.

If, as appellants assert, the specific way in which the standard applies to each field must be explicitly written into the “four corners” of the injunction, the underlying “competent and reliable scientific evidence” standard – terminology used in hundreds of FTC injunctions – could never be sufficiently clear without delineating the specific scientific substantiation necessary for every conceivable covered claim. In addition, the drafting of injunctions would become an uncertain exercise in prognostication as the court and the agency could protect against future misconduct only if they successfully predict the types of claims that creative wrongdoers might use. That disruptive outcome is the direct implication of appellants’ “four corners” argument.

Appellants’ central argument thus amounts to the very vagueness challenge they have already litigated and lost before this Court (and which they insist they are not making now). *See Br. 39.*

Appellants may not renew that challenge here. “[A] contempt proceeding does not open to reconsideration the legal or factual basis of

the order alleged to have been disobeyed and thus become a retrial of the original controversy. The procedure to enforce a court's order commanding or forbidding an act should not be so inconclusive as to foster experimentation with disobedience." *CFTC v. Wellington Precious Metals, Inc.* 950 F.2d 1525, 1528-29 (11th Cir. 1992) (quoting *Maggio v. Zeitz*, 333 U.S. 56, 69, 68 S. Ct. 401, 408 (1948)).¹⁰ "It would be a disservice to the law" if the Court were to allow the contempt proceeding to "become a retrial of the original controversy." *United States v. Rylander*, 460 U.S. 752, 756, 103 S.Ct. 1548, 1552 (1983).

B. Hi-Tech May Not Relitigate The District Court's Factual Finding Defining Competent And Reliable Scientific Evidence

As shown above, the Permanent Injunctions, including the "competent and reliable scientific evidence" standard they incorporate, comply with Rule 65(d) and are enforceable against appellants, and appellants have explicitly disavowed any argument to the contrary.

¹⁰ Appellants clearly "experimented with disobedience." The Permanent Injunctions required them to have "competent and reliable scientific evidence" *prior* to making a weight-loss claim. But when the FTC filed its contempt action, appellants said in response more than a month later that they did not "have ready for the Court's review an expert declaration" on the matter and that it was their "intention to submit independent expert evidence" in the future. Doc. 346 at 20.

The principal issue before the Court therefore does *not* concern the meaning of the Injunctions themselves. The main question is whether in the contempt proceedings the district court properly precluded appellants from litigating again the question of what experts in the field would require to substantiate the types of claims appellants made for their weight loss products.¹¹

In many cases, but not this one, contempt proceedings on injunctions that require competent and reliable scientific evidence involve an evidentiary hearing at which the district court hears testimony to determine what level of substantiation is sufficient for the types of products and claims at issue. *See, e.g., FTC v. Garden of Life, Inc.*, 516 F. App'x 852 (11th Cir. 2013); *FTC v. Lane Labs-USA, Inc.*, 624 F.3d 575 (3d Cir. 2010). Here, however, the district court had already resolved that inquiry in the underlying case. Specifically, after

¹¹ Appellants contend that the cost of such substantiation could reach as much as \$600 million (Br. 38), but that assertion is untenable. To begin with, appellants rely solely on dubious cost evidence presented by a party in another case involving unrelated advertising claims, and appellants' own witness here described a clinical test costing about \$30,000. Doc. 620 at 110. The cost of such studies is irrelevant in any event. The FTC Act does not permit a marketer to use the cost of developing substantiation as a free pass to make any claim it wishes. FTC Advertising Guide at 9.

full and fair litigation on that issue, the district court ruled in its summary judgment order that experts in the field would call for all weight-loss claims to be substantiated by a randomized, controlled study conducted on the particular product at issue. Appellants may not now relitigate the matter.

What constitutes competent and reliable scientific evidence to support an advertising claim is a question of fact that is established through evidence. *See, e.g., Direct Mktg. Concepts, Inc.*, 624 F.3d at 8; *Thompson Med., Inc.*, 791 F.2d at 193; FTC, Bureau of Consumer Protection, *Dietary Supplements: An Advertising Guide for Industry* 9 (April 2001), available at <http://business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry>. In the underlying action, the FTC presented evidence that any claim that a dietary supplement will lead to weight loss must be supported by controlled trials of the specific product at issue. Hi-Tech “had a full and fair opportunity to present” its own evidence on the appropriate quantum of evidence, but it “chose not to.” Doc. 422 at 16.

On the basis of the uncontroverted evidence, the district court found that “to substantiate weight loss claims for *any* product, including

a dietary supplement,” an advertiser must have “independent well-designed, well-conducted, randomized, double-blind, placebo-controlled clinical trials, given at the recommended dosage involving an appropriate sample population in which reliable data on appropriate endpoints are collected over an appropriate period of time.” Doc. 172-25 at 30 (emphasis added). The contempt case presented that very issue. As the district court explained, “the issue of what constitutes competent and reliable scientific evidence was actually litigated,” the determination of that fact issue “played a critical, necessary part in the grant of summary judgment,” and appellants had a “full and fair opportunity” to controvert the Commission’s expert.”¹² Doc. 422 at 16.

Appellants contend, however, that “competent and reliable scientific evidence” is “context specific,” and that the standard of substantiation therefore must be determined anew for every claim made in an ad. Br. 42. The argument fails because the question presented to the district court and answered by evidence provided by the FTC was

¹² The district court’s ruling is consistent with this Court’s pronouncements on the preclusive effect of factual findings. *See, e.g., Axiom Worldwide, Inc. v. Excite Med. Corp.*, 2014 U.S. App. LEXIS 21851 at *13 (11th Cir. Nov. 17, 2014); *Miller’s Ale House v. Boynton Carolina Ale House, LLC*, 702 F.3d 1312, 1318 (11th Cir. 2012).

“the type of evidence required to substantiate weight loss claims for *any product, including a dietary supplement.*” *Nat’l Urological Grp, Inc.*, 645 F. Supp. 2d at 1202-03 (emphasis added). It therefore is immaterial that the substantiation standard is “context-specific,” because the context here is precisely the same as in the underlying case. For the types of weight-loss claims at issue here – both in the underlying case and now – the standard has been conclusively established.¹³ For that reason, appellants err in relying (Br. 41) on *CSX Transp. v. Board of Maint. of Way Employees*, 327 F.3d 1309, 1316 (11th Cir. 2003). That case involved “substantially unrelated claims.” *Id.* at 1316. And appellants’ preferred approach – under which each new product and each new claim is subject to a new determination of the substantiation standard would be untenable in practice. It would unnecessarily burden courts by forcing them to relitigate the same issue each time a defendant subject to an injunction against deceptive advertising makes

¹³ Appellants err in claiming that an FTC administrative law judge interpreted the district court’s decision differently. Br. 42. In *POM Wonderful LLC*, FTC Docket No. 9344 (FTC Jan. 10, 2013), the ALJ cited the decision in the underlying action for the general proposition that what constitutes “competent and reliable scientific evidence” is “a question of fact for expert interpretation.” *Id.* at 239 (quoting *Nat’l Urological Grp., Inc.*, 645 F. Supp. 2d at 1190).

minor changes to its ads or products without changing the underlying deception.¹⁴

Finally, appellants are wrong to contend that “not even the FTC read the injunction how the district court did.” Br. 41. The claim is that by submitting the declaration of Dr. Aronne in support of its show cause motion, the agency acknowledged its own doubt that the underlying order controlled the contempt proceeding. That is not the case. The Commission did not debate the relevant standard of substantiation. *See, e.g.*, Doc. 332-1 at 11, 21-23.

¹⁴ Appellants offered no good reason for the district court to revisit its factual finding in any event. They simply asserted once again that double-blind, placebo-controlled studies were not necessary to substantiate their claims. Doc. 346 at 20-27.

C. Appellants Understood Their Obligations Under The Permanent Injunctions

For the reasons discussed above, the Permanent Injunctions comply with Rule 65(d) and the district court's order applying the competent and reliable scientific evidence standard is no longer subject to challenge. Moreover, the record leaves no room for an argument that appellants did not understand what the Permanent Injunctions required them to do.

This Court has ruled that it will “determine the propriety of an injunctive order by inquiring into whether the parties subject thereto understand their obligations under the order.” *Planetary Motion*, 261 F.3d at 1203. So long as the subjects of an injunction understand their obligations, they may be held liable for a contempt judgment. *See Combs v. Ryan's Coal Co.*, 785 F.2d 970, 978-79 (11th Cir. 1986). Even under the more stringent standards applicable to criminal contempt, technical flaws are immaterial if “it is clear from the totality of the language in the various documents that the contemnors understood their obligations.” *United States v. Sarcona*, 457 F. App'x 806, 811 (11th Cir. 2012).

Appellants clearly understood their obligations under the Permanent Injunctions. Specifically, Jared Wheat – Hi-Tech’s sole owner, President, and CEO – understood that the Permanent Injunction required a double-blind, placebo-controlled study of the product itself to substantiate any weight-loss claim. He sent an email to a group of Hi-Tech employees describing the difficulty of getting a lawyer to sign off on Hi-Tech’s advertising if the summary judgment ruling were affirmed on appeal:

If the FTC verdict stands there is nothing we can say without doing a double-blind placebo study so nobody would sign off on that.

Doc. 700-88 at 3 (PX94 at 2) (emphasis added). He emailed appellant Smith similarly commenting that affirmance by this Court in the underlying case “will allow FTC to win *any advertising case* that a company has not done *a double-blind study on the product itself.*” Doc. 700-90 at 3 (PX96 at 2); *see* Doc. 700-94 at 3 (PX100 at 2) (“[I]f our set of facts is not good enough [in the

petition for a writ of certiorari] then a double-blind placebo study would be required.”).¹⁵

Other communications also show that Wheat understood the types of claims prohibited. In a phone call with Smith, he acknowledged that “[t]here were some things like fat loss * * * and there’s a couple of other things we’re prohibited from saying. Increasing the metabolic rate was claim one. We can’t say that,” he wrote. Doc. 700-100 at 7 (PX106 at 5:7-12); *see also id.* at 10-11 (PX106 at 8:25-9:1) (with regard to the rapid fat burner claim, “we can’t say rapid that’s part of our consent decree.”).

Not only did Hi-Tech’s owner understand the scope of the Injunction, his own lawyers advised him point blank that the

¹⁵ The FTC came into possession of a group of Wheat’s emails – which included some emails between Wheat and his attorney – because he transmitted them using a Bureau of Prisons monitored system in which a prisoner has no expectation of confidentiality. *See* p. 44-45, *infra*. The FTC had requested Wheat’s emails for a period of approximately four months in connection with its efforts to collect the judgment in the underlying action. *See* Doc. 332-6 at 79. This was well before it initiated contempt proceedings. The FTC at first made no use of the emails for any other purpose. But once it initiated contempt proceedings and Wheat and Hi-Tech invoked an advice-of-counsel defense, the district court determined that they waived any privilege that might otherwise have protected them. *See* pp. 46-47, *infra*.

Permanent Injunction required double-blind, placebo-controlled, product specific trials prior to any weight-loss claim. Specifically, four Hi-Tech attorneys, two of whom were also on the company's Board of Directors, advised Wheat that "based upon Judge Pannell's previous findings, it is reasonable to assume that he would take the position that consistent with the FTC that double-blind, clinical trials of the product were necessary to substantiate the representation. * * * [A]t present, *it is the premise upon which the FTC Injunction is based.*" Doc. 700-105 at 4 (PX117 at 3) (emphasis added). The attorneys also advised Wheat that studies would have to involve not just individual ingredients, but the products themselves. "[B]ased on Judge Pannell's and the FTC's findings," they informed their client, "it would seem unlikely that 'ingredient specific substantiation' would be considered compliant with this provision." *Id.* at 5 (PX117 at 4).¹⁶

¹⁶ Hi-Tech's recognition that its new ads would violate the Permanent Injunction may explain why it "provided inaccurate and incomplete information in compliance reports * * * and in response to [the FTC's] request for information * * *." Doc. 650 at 16. For example, Hi-Tech did not provide the Commission with complete and accurate information regarding advertisements and product packaging and labels. It also

That record leaves no doubt that Hi-Tech “understood [its] obligations” under the Injunction. *City of Dothan*, 818 F.2d at 761. That is all Rule 65(d) requires. When Hi-Tech embarked on its new advertising campaign in the face of that understanding, it “acted at [its] peril.” *McComb v. Jacksonville Paper Co.*, 336 U.S. 187, 192, 69 S. Ct. 497, 500 (1949); *Polo Fashions, Inc. v. Stock Buyers Int’l, Inc.*, 760 F.2d 698, 700 (6th Cir. 1985) (appellants acted at their own risk by failing to seek the court’s interpretation).

In sum, consistent with the intent of Rule 65(d), an injunction is enforceable when its subject understands the obligations imposed. Here, appellants understood their obligations. They cite no case reversing a contempt judgment against a party that violated a known requirement.

II. The District Court Properly Assessed Compensatory Sanctions

Having found clear and convincing evidence that appellants had violated the 2008 injunction, the district court ordered Hi-Tech, Wheat, and Smith, jointly and severally, to pay compensatory sanctions in the

failed to disclose print advertisements in a catalogue that Hi-Tech sent to retailers for their customers. *Id.* at 16-17.

amount of \$40 million.¹⁷ The court calculated that figure by totaling Hi-Tech's gross receipts, less refunds and returns, from sales of Fastin, Lipodrene, and Benzedrine for the time period Hi-Tech used its unlawful advertising. Doc. 650 at 18-19, 22-23. The sales figures came primarily from a table introduced by appellants' own damages expert at the four-day sanctions hearing. Doc. 650 at 23 n.17; Doc. 534-1 at 2-3. Separately, the court ordered Dr. Wright to pay \$120,000, the amount he received for his unlawful endorsements.¹⁸ Doc. 650 at 23. The court directed the FTC to use these funds to reimburse consumers who purchased the products at issue during the relevant time period, save for a "reasonable" portion to cover the costs of administering the fund and locating consumers. Doc. 650 at 24.

Hi-Tech now claims that the \$40 million contempt sanction must be reversed because it rested improperly on communications protected by the attorney-client privilege. The gist of Hi-Tech's claim is that "[i]n

¹⁷ Although appellant Wright adopts the arguments made in the principal Hi-Tech brief and raises no separate argument of his own, this issue does not pertain to him.

¹⁸ This sum was based on representations by Dr. Wright's counsel at the sanctions hearing. Doc. 650 at 23 n.19; Doc. 621 at 69:14-21.

imposing its \$40,000,000 contempt sanction, the district court found evidence of bad faith in * * * attorney-client communications between Mr. Wheat and his lawyers.” Br. 48-49. The allegedly privileged communications consist of emails between Wheat and Hi-Tech’s lawyers. The contention fails because the court’s compensatory sanction did not rest, and had no need to rest, on any scienter-revealing communications between Wheat and his lawyers. Even if it did, Wheat has waived any claim of privilege by failing to raise it below, and in any event, the relevant communications were not privileged to begin with.

A. The Contempt Sanction Did Not Rest On Hi-Tech’s Communications With Its Lawyers

Appellants cite nothing to suggest that the court took privileged communications into account in fashioning the compensatory remedy. To the contrary, the court ruled that “good faith is, *at best*, relevant to coercive contempt sanctions, *and not to compensatory sanctions*.” Doc. 524 at 34 (emphasis added). Indeed, in civil contempt proceedings, the “the focus of the court’s inquiry * * * is not on the subjective beliefs or intent of the alleged contemnors in complying with the order, but whether in fact their conduct complied with the order in issue.”

Howard Johnson Co. v. Khimani, 892 F.2d 1512, 1516 (11th Cir. 1990).

Thus, “substantial, diligent, or good faith efforts [to comply] are not enough; the only issue is compliance.” *Leshin*, 618 F.3d at 1232. “[I]t matters not with what intent the defendant did the prohibited act.” *McComb*, 336 U.S. at 191, 69 S. Ct. at 499.

Appellants do not dispute that \$40 million represents gross revenues, less returns and revenues, for the relevant time period. *See* Doc. 650 at 22-23 & nn.17-18. That method of calculating sanctions follows the established approach in this Court: where parties have acted in contempt of an injunction and harmed consumers as a result, gross revenues less refunds and returns is the appropriate baseline for compensatory sanctions. *See Leshin*, 618 F.3d at 1239; *accord FTC v. BlueHippo Funding*, 762 F.3d 238, 244-45 (2d Cir. 2014); *McGregor v. Chierico*, 206 F.3d 1378, 1378-79 (11th Cir. 2000); *see also FTC v. Kuykendall*, 371 F.3d 745, 765 (10th Cir. 2004) (en banc).

B. Appellants Waived Any Argument Of Privilege

Even if the contempt sanction had rested on allegedly privileged communications, appellants nevertheless waived their argument by failing to raise it below. It is black letter law that “[a]rguments not raised in the district court are waived.” *United States v. Haynes*, 764

F.3d 1304, 1308 (11th Cir. 2014) (citation omitted). Appellants did not object to the admission of any of Wheat’s communications from prison on any grounds – let alone because they were privileged.¹⁹ Compare Doc. 601 at 4-6 (FTC Exhibit List entries for PX69, 97-102, 104) with Doc. 605 (Appellants’ Objections to FTC Exhibits); Doc. 618 at 23-25 (admitting exhibits).

C. Wheat’s Emails Are Not Privileged

The district court properly held that Wheat’s emails to Hi-Tech’s lawyers were not privileged for two reasons. See Docs. 365, 433, 470. First, before a privilege can attach to a communication, the client must have a reasonable expectation of confidentiality. See, e.g., *United States v. Melvin*, 650 F.2d 641, 645 (5th Cir. 1981). No such reasonable expectation existed here. Wheat sent emails to his lawyers using TRULINCS, a prison email system, which informed its users that emails using the TRULINCS system were “subject to monitoring and interception.” Br. 50. It makes no difference that the TRULINCS

¹⁹ Not only did appellants stipulate to their admissibility, but they also offered into evidence additional “privileged” emails that were not on the FTC’s initial exhibit list. See, e.g., Doc. 701-4 at 13-15 (DX8); Doc. 701-4 at 18 (DX10); Doc. 701-4 at 19 (DX11); Doc. 701-4 at 21- 24 (DX13).

warning does not specifically use the words “attorney” and “privilege.” See Br. 49. The crucial point is that a core element of the privilege – a reasonable expectation of confidentiality – is absent when inmates use a monitored system to communicate with counsel, as Wheat did here. See *United States v. Walia*, 2014 U.S. Dist. LEXIS 102246 at *48 (E.D.N.Y. July 25, 2014). Indeed, the Second Circuit has held in the analogous context of telephone calls placed from a prison phone system that the inmate waived attorney-client privilege when he made phone calls knowing they were monitored. *United States v. Mejia*, 655 F.3d 126, 133 (2d Cir. 2011) (inmate waived privilege when he made phone calls knowing they were monitored); *United States v. Hatcher*, 323 F.3d 666, 674 (8th Cir. 2003) (presence of prison recording device destroyed attorney-client privilege).²⁰

Second, appellants waived any privilege that might otherwise have protected Wheat’s communications with his attorneys by relying

²⁰ The circumstances here are considerably different from *Al-Amin v. Smith*, 511 F.3d 1317 (11th Cir. 2008). See Br. 50. That case did not consider the privileged status of a communication made, as here, without any reasonable expectation of confidentiality. Rather, it involved a prisoner’s charges that a pattern and practice of opening sealed attorney mail outside a prisoner’s presence violated his Sixth Amendment rights.

on an advice-of-counsel defense in the contempt proceeding. The attorney-client privilege was “intended as a shield, not a sword.” *Cox v. Adm’r U.S. Steel & Carnegie*, 17 F.3d 1386, 1417 (11th Cir. 1994). A litigant that defends itself by relying on an advice-of-counsel defense thus waives any privilege that may otherwise have attached to his attorney communications. *See United States v. Jensen*, 573 F. App’x 863, 870 (11th Cir. 2014).

Moreover, by asserting an advice-of-counsel defense to the FTC’s contempt allegations, appellants waived privilege not only as to the specific attorney communications on which they rely, but also as to any other attorney-client communications documents that contained or related to advice that counsel gave Hi-Tech about the compliance of its advertising with the Permanent Injunctions. A litigant who relies on the advice-of-counsel defense may not define selectively the subject matter of the advice. *See, e.g., In re Echostar Commc’n Corp.*, 448 F.3d 1294, 1299 (Fed. Cir. 2006) (privilege waived for all attorney-client communications “including any documentary communications such as opinion letters and memoranda”) (emphasis added); *Glenmede Trust Co. v. Thompson*, 56 F.3d 476, 486 (3d Cir. 1995). That included the five-

page advice memorandum the district court required Hi-Tech to produce.²¹

Wheat protests he would not have raised an advice-of-counsel defense had he known the FTC had, and intended to use, such damaging emails. Br. 52. Wheat, of course, had no right to know in advance what evidence the FTC had in its possession. In any event, his assertion that appellants would not have raised such a defense rings hollow. Appellants knew that the FTC had received Wheat's prison communications from Jessup at the time they first raised an advice-of-counsel-defense. *See* Doc. 346 at 16 n.6, 36 n.11. Nonetheless, they

²¹ The FTC did not learn of the memorandum through Wheat's 2010 prison emails. The FTC did not learn of the memorandum until almost a year into the contempt proceedings. In June 2012, in an effort to rebut appellants' advice-of-counsel defense, the FTC served a subpoena demanding documents pertaining to any advice regarding advertising on the products at issue on appellants' counsel, Joseph Schilleci. *See* Doc. 414-1. In response to that subpoena, Mr. Schilleci identified the memorandum for the first time on his September 27, 2012, privilege log. *See* Doc. 442-2. The district court, reiterating that appellants' continuing assertion of the advice-of-counsel defense constituted a subject-matter waiver of the attorney-client privilege, granted the FTC's motion to compel production of the memorandum. *See* Doc. 470 at 14 ("[O]nce these strategies and other advice was communicated to the client, Mr. Wheat, and once Mr. Wheat chose to rely on this advice (among others) of his counsel *as part of his defense*, then the privilege is waived.") (emphasis added).

continued to press that defense even after the FTC produced the emails in discovery.

III. The District Court Did Not Abuse Its Discretion In Holding Smith In Contempt

Appellant Stephen Smith separately contends that the district court improperly imputed the actions of others to him in finding him jointly and severally liable for compensatory sanctions. Smith Br. 6. Smith is wrong.

The district court did not impute the conduct of others to Smith. *See* Smith Br. 6. It did not need to. Smith is individually bound by the Permanent Injunction and thus obliged to ensure that the claims he used to market Hi-Tech's products are substantiated. Instead, the court explained, he participated directly in Hi-Tech's unlawful promotion of the four products at issue and contributed substantially to Hi-Tech's success in doing so. The court found that "Smith [was] the senior vice-president in charge of sales of Hi-Tech products, including Fastin, Lipodrene, Benzedrine, and Stimerex-ES," Doc. 650 at 7; *see also* Doc. 700-13 at 16, 22, 26, 32, 34 (PX18 at 15, 21, 25, 31, 33). He oversaw the

sales force,²² had the authority to decide which retailers sell Hi-Tech products (including Fastin, Lipodrene, and Benzedrine)²³, and was responsible for acquiring retail accounts with food stores, drug chains, and mass merchandisers for those products. Doc 534-10 at 307-08 (Smith Dep. at 27-28); Doc. 618 at 69-70 (Trial Tr. Smith). As the court also found, Smith helped to disseminate advertising for Fastin, Lipodrene, Benzedrine, and Stimerex-ES that violates the Permanent Injunction against him. Doc. 650 at 7-8; Doc. 700-13 at 35 (PX18 at 34) (identifying Smith as responsible for placing advertisements for Fastin, Lipodrene, Benzedrine, and Stimerex-ES); Doc. 700-83 at 2 (PX89 at 2); Doc. 700-84 at 3-7 (PX90 at 2-6) (discussing placement of Fastin print ad); Doc. 534-10 at 314-16 (Smith Dep. at 34-36) (discussing negotiating prices for and placing Fastin, Lipodrene, and Stimerex-ES print ads). The court was not required to say more about these undisputed facts. *See, e.g., FTC v. Enforma Natural Prods., Inc.*, 362 F.3d 1204, 1215 (9th Cir. 2004).

²² Doc. 618 at 80 (Trial Tr. Smith); Doc. 700-9 at 3-4 (PX14 at 2-3); Doc. 534-10 at 322-23 (Smith Dep. at 42-43).

²³ Doc. 534-10 at 307-08 (Smith Dep. at 27-28).

Those findings fatally undermine Smith's attempt to portray himself as having only inconsequential responsibilities at Hi-Tech. Smith Br. 2-3. Indeed, except for Wheat, he was at the top of the chain of command for sales. Doc. 534-10 at 41-42 (Wheat Dep. at 34-35); Doc. 700-9 at 3 (PX14 at 2). As Senior Vice-President, he was in charge of sales for the products at issue.²⁴ He oversaw the sales force that marketed Hi-Tech products to retailers,²⁵ was authorized to decide which retailers would sell Hi-Tech products (including Fastin, Lipodrene, and Benzedrine),²⁶ and managed day-to-day operations while Wheat was incarcerated. Doc. 650 at 8; Doc. 700-71 at 3-5 (PX75 at 2-4). Smith attended trade shows where he made presentations to brokers using images of product labels and packaging with violative claims. Doc. 618 at 83-84 (Trial Tr. Smith). Although Smith denies drafting ad copy, he was involved in placing advertising for all four

²⁴ See Doc. 700-9 at 3 (PX14 at 2); Doc. 534-10 at 294, 323-34 (Smith Dep. at 14, 43-44); see also Doc. 700-13 at 12, 16, 22-23, 27, 33, 35 (PX18 at 11, 15, 21-22, 26, 32, 34); Doc. 700-20 at 2 (PX24).

²⁵ Doc. 700-9 at 3 (PX14 at 2); Doc. 700-13 at 12, 16, 22-23, 27, 33, 35 (PX18 at 11, 15, 21-22, 26, 32, 34); Doc. 700-20 at 2 (PX24); Doc. 534-10 at 305-08, 322, 338-39, 372 (Smith Dep. at 26-28, 42; 58-59, 92).

²⁶ Doc. 534-10 at 307-08 (Smith Dep. at 27-28); Doc. 534-10 at 41-42 (Wheat Dep. at 34-35).

products at issue. *See* Doc. 700-13 at 12, 16, 22-23, 27, 33, 35 (PX18 at 11, 15, 21-22, 26, 32, 34). This included negotiating prices, developing monthly advertising plans, and signing ad insertion orders. *See* Doc. 700-83 at 2 (PX89 at 2); Doc. 700-84 at 3-7 (PX90 at 2-6); Doc. 534-10 at 314-16 (Smith Dep. at 34-36).²⁷ Retailers and brokers contacted Smith when they had concerns about Hi-Tech’s claims, including concerns whether the weight-loss claims for Fastin were substantiated. *See, e.g.*, Doc. 700-82 at 3-7 (PX88 at 2-6); Doc. 700-170 at 2-5 (PX223); Doc. 700-171 at 2 (PX224). (describing retailer and broker concerns regarding claim substantiation). Yet Smith continued to fill retail orders and promote the products. His pay – \$375,000 in 2012 alone – reflects his stature in the company. Doc. 618 at 65.

In short, ample and uncontroverted evidence establishes that Smith played a direct role in promoting weight-loss products in violation of the Permanent Injunction. It does not matter that Smith “did not have the power to change the advertising or order double-blind,

²⁷ *See* D. 534-10 at 314-17, 349-52, 392 (Smith Dep. at 34-37, 69-72, 112); Doc. 700-13 at 12, 16, 22-23, 27, 33, 35 (PX18 at 11, 15, 21-22, 26, 32, 34); Doc. 700-20 at 2 (PX24); Doc. 700-83 at 2 (PX89 at 2); Doc. 700-84 at 3-7 (PX90 at 2-6).

placebo-controlled trials.” Smith Br. 7. Smith, who is individually under order, is prohibited from marketing and selling Hi-Tech’s products using unsubstantiated weight-loss claims, and there is no dispute that he did just that. “Where * * * parties join together to evade a judgment, they become jointly and severally liable for the amount of damages resulting from the contumacious conduct.” *Leshin*, 618 F.3d at 1236-37 (quoting *NLRB v. Laborers’ Int’l Union of N. Am.*, 882 F.2d 949, 955 (5th Cir. 1989)).

CONCLUSION

For all the foregoing reasons, the judgments should be affirmed.

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a), I certify that the foregoing Corrected Brief for Plaintiff-Appellee Federal Trade Commission complies with the volume limitations of Fed. R. App. P. 32(a)(7) because it contains 10,380 words, as created by Microsoft Word, excluding the items that may be excluded under Fed. R. App. P. 32(a)(7)(iii).

January 16, 2015

s/Leslie Rice Melman
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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing Brief for Plaintiff-Appellee Federal Trade Commission with the Clerk of the Court for the United States Court of Appeals for the Eleventh Circuit by using the appellate CM-ECF System on the 16th day of January 2015. I certify that on the same date I caused the foregoing to be served by and through the Court's CM-ECF system and by Federal Express.

s/Leslie Rice Melman
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