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UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 17-15695

FEDERAL TRADE COMMISSION,

Plaintiff-Counter Defendant-Appellee,

CERTUSBANK, N.A.,

Plaintiff,

v.

NATIONAL UROLOGICAL GROUP, INC., d.b.a. Warner Laboratories, et al.,

Defendants-Counter Claimants,

HI-TECH PHARMACEUTICALS, INC., corporations, JARED WHEAT, individually and as officers of the corporations, STEPHEN SMITH, individually and as officers of National Urological Group, Inc., and National Institute for Clinical Weight Loss, Inc.,

Defendants-Appellants,

THOMASZ HOLDA, individually and as officers of the corporations, et al.,

Defendants.

Appeal from the United States District Court
for the Northern District of Georgia
No. 1:04-cv-03294-CAP

Filed September 18, 2019
[DO NOT PUBLISH]

MEMORANDUM

Before MARTIN, ROSENBAUM, Circuit Judges, and MARTINEZ,* District Judge.

PER CURIAM:

The defendants in this case were enjoined from making certain claims about health products without "competent and reliable scientific evidence" to substantiate those claims. The Federal Trade Commission ("FTC") alleged that they violated the injunction when they publicized the weight- and fat-loss benefits of the four products at issue in this case. After a bench trial, the district court agreed with the FTC and found the defendant in civil contempt. The district court consequently imposed approximately $40 million in sanctions.

Upon review, we conclude that the defendants have waived their challenge to the facial clarity of the injunction and that the district court committed no

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* Honorable Jose Martinez, United States District Judge for the Southern District of Florida, sitting by designation.

abuse of discretion. Accordingly, we affirm the district court's order of contempt and entry of sanctions.

I. BACKGROUND

A. Initial Entry of the Injunction at Issue

Hi-Tech Pharmaceuticals, its chief executive officer ("CEO"), Jared Wheat, and its head of sales, Stephen Smith (collectively, "the defendants"), sold dietary supplements that advertised weight- and fat-loss benefits. They promised that one of their products, Thermalean, would help consumers lose "as much as 30 pounds in two months," and that another product, Lipodrene, was "clinically proven to enable users to lose up to 42% of total body fat." In 2004, the FTC charged the defendants with falsely advertising those products, in violation of Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

The district court granted summary judgment for the FTC. *F.T.C. v. Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d 1167, 1215 (N.D. Ga. 2008), *aff'd*, 356 F. App'x 358 (11th Cir. 2009). Claims about the safety and efficacy of dietary supplements, the district court noted, "must be substantiated with competent and reliable scientific evidence." *Id.* at 1202. The FTC's guide for advertisers defined "competent and reliable scientific evidence" as "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.* at 1190 (citation and quotation marks omitted).

The district court agreed with the FTC's expert, Dr. Louis Aronne, that to satisfy the FTC's definition of "competent and reliable scientific evidence" supporting weight- and fat-loss claims regarding any product, randomized clinical trials ("RCTs") on the advertised products are necessary. *See id.* at 1202. As the defendants had not conducted any RCTs on Thermalean or Lipodrene, the district court concluded that the defendants' weight- and fat-loss claims about those products were unfounded.

In its motion for summary judgment, the FTC had attached the proposed text of a permanent injunction against the appellants. Sections II and VII of the proposed injunction banned the defendants from making unsubstantiated claims, meaning they were to refrain from making any representation about the safety, efficacy, or health or weight-loss benefits of dietary supplements unless, "at the time the representation is made, [they] possess and rely upon *competent and reliable scientific evidence* that substantiates the representation." (emphasis added). The proposed injunction adopted the definition for "competent and reliable scientific evidence" from the FTC's advertising guide.

Complaining of "space limitations," the defendants indicated that they would not object to the proposed injunction in their opposition to summary judgment. They instead requested "that they be given further opportunity" to voice their objections later. The district court granted the defendants' request. *Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d at 1215.

And the defendants took advantage of their second chance. They objected to several provisions in

the proposed injunction, including the definition of several terms, like "[c]overed product or service," "drug," or "manufacturing." Notably, though, they did not object to the use of the phrase "competent and reliable scientific evidence."

After overruling the defendants' objections, the district court entered a permanent injunction against them. Just as the proposed injunction had, Sections II and VII of the final injunction prohibited the defendants from making fat- and weight-loss claims about covered products unless, at the time of the representation, the defendants relied on "competent and reliable scientific evidence that substantiates the representation." That phrase was defined by reference to the FTC's advertising guide, as it had been during the litigation.

The defendants appealed to this Court, raising a host of arguments. But again, significantly, they did not argue that the phrase "competent and reliable scientific evidence" was unclear. A different panel of this Court rejected the defendants' arguments and affirmed the district court. *F.T.C. v. Nat'l Urological Grp., Inc.*, 356 F. App'x 358, 359 (11th Cir. 2009).

B. Contempt

The ink had hardly dried on filings from the first injunction case when the defendants started a new marketing campaign in 2009. This time, they touted the fat- and weight-loss benefits of four products—a reformulated version of Lipodrene, Fastin, Benzedrine, and Stimerex-ES. For example, advertisements for Lipodrene warned users not to consume the product unless "fat loss and weight loss are your intended result"; advertisements for Fastin

boasted that it was an "Extreme Fat Burner"; those for Benzedrine claimed that it would "annihilate . . . fat"; and advertisements for Stimerex-ES told users that this was a product "for those who want their fat-burner to light them up all day as their pounds melt away."

The FTC moved for an order to show cause why the defendants should not be held in contempt for marketing those four products without proper substantiation, in violation of their injunction. *F.T.C. v. Nat'l Urological Grp., Inc.*, 785 F.3d 477, 479-80 (11th Cir. 2015). In response, the defendants argued that they had fully complied with the injunction. *Id.* at 481. Contending that RCTs on the products at issue were not required, the defendants offered *other* types of evidence that they claimed were competent and reliable scientific evidence to support their claims.

The FTC disagreed and pointed to several communications that revealed the defendants' knowledge that the injunction could require them to conduct RCTs on the advertised products.[1] In one email, Hi-Tech's attorneys informed Wheat that "competent and reliable scientific evidence," as used in the injunction, meant RCTs on the marked product:

> [I]t is safe to say that Judge Pannell did not then and would not now find this form of ingredient specific substantiation to be consistent with the express language in the

[1] Wheat was incarcerated from March 16, 2009, to September 15, 2010. The FTC acquired communications sent between Wheat and other parties while he was in jail. The district court ruled that those communications were admissible, and the defendants do not challenge their admissibility on appeal.

> FTC Injunction requiring "competent and reliable scientific evidence." Rather, based upon Judge Pannell's previous findings, it is reasonable to assume that he would take a position consistent with the FTC that double-blind, clinical trials of the products were necessary to substantiate the representation. Although we certainly have not and do not now agree with this position, at present, it is the premise upon which the FTC Injunction is based.

Wheat certainly heard his attorneys' advice, telling another Hi-Tech employee that "[his attorney's] opinion is anything short of a double-blind study on each product leaves [Hi-Tech] open to exposure to FTC." But, Wheat said, "[he] s[i]mply [could] not quit advertising."

The district court agreed with the FTC. Observing that the issue of what constituted "competent and reliable scientific evidence" in this context had already been determined to be RCTs on the products themselves, the district court held that, under the doctrine of collateral estoppel, only RCTs on the marketed products could count. Thus, the district court refused to consider the defendants' proffered evidence and granted the FTC's motion to show cause. *Nat'l Urological Grp., Inc.*, 785 F.3d 481.

After the defendants could not produce RCTs to support their claims, the district court found them in contempt for violating the injunction. *Id.* It consequently held the defendants jointly and severally liable for about $40 million of sanctions, which reflected the defendants' total gross receipts from the

sales of Fastin, Lipodrene, Benzedrine, and Stimerex-ES. *Id.*

The defendants then appealed to this Court, arguing that nothing within the four corners of the injunction automatically equated "competent and reliable scientific evidence" with RCTs. They clarified that they were not arguing that the "competent and reliable scientific evidence" standard was so facially unclear as to render the injunction unenforceable. Rather, they disputed only the notion that "competent and reliable scientific evidence" had to mean RCTs:

> [T]he Contempt Defendants do not argue that the substantiation standard is, in and of itself, impermissibly vague. They do contend, however, that it is not sufficiently specific—without resort to documents beyond the four corners of the injunction—to require Contempt Defendants to produce double-blind, placebo-controlled clinical trials of their products to substantiate all future weight-loss claims.

Brief of Appellants at 39, *F.T.C. v. Nat'l Urological Grp., Inc.*, 785 F.3d 477 (11th Cir. 2015) (No. 14-13131).[2]

And when the FTC nonetheless pointed out that any challenge to the facial clarity of the injunction had been waived, the defendants criticized the FTC for missing the point. The defendants repeated that they were not challenging the facial validity of the

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[2] Smith adopted Wheat and Hi-Tech's arguments here. Opening Brief for Appellant Smith at 5, *F.T.C. v. Nat'l Urological Grp., Inc.*, 785 F.3d 477 (11th Cir. 2015) (No. 14-13131).

injunction, only the notion that "competent and reliable scientific evidence," without any discussion, had to mean RCTs:

> [T]he FTC opens its brief by arguing that the injunction contains "reasonable detail" and that the competent-and-reliable-scientific-evidence standard "is sufficiently clear to enforce" and impose the unwritten randomized-clinical-trials requirement on Contempt Defendants. Contempt Defendants, the FTC says, have "already litigated and lost" a challenge to the vagueness of the injunction.
>
> That argument is beside the point. The Contempt Defendants, as they explained in their opening brief (at 39), are not arguing that the "the 'context specific' substantiation standard may create unreasonable ambiguity on the face of the injunction." Instead, they argue that the FTC cannot carry its burden to show that the competent-and-reliable-scientific-evidence standard clearly and unambiguously requires them to have randomized, double-blind, placebo-controlled clinical studies to substantiate their claims.

Reply Brief of Appellants at 7, *F.T.C. v. Nat'l Urological Grp., Inc.*, 785 F.3d 477 (11th Cir. 2015) (No. 14-13131) (citations omitted).

We determined that the district court had erred when it applied the doctrine of collateral estoppel to hold that the "competent and reliable scientific evidence" standard automatically required RCTs. *Nat'l Urological Grp., Inc.*, 785 F.3d at 482. We

remanded to the district court with instructions to "make findings about whether any evidence of substantiation, if admissible, satisfies the standard of the injunctions for 'competent and reliable scientific evidence.'" *Id.* at 483. Before concluding, we emphasized that our holding was "only that the district court misapplied collateral estoppel when it barred [the defendants] from presenting evidence to prove their compliance with the injunctions." *Id.*

C. Bench Trial on Remand

After conducting a bench trial, the district court determined that the FTC had shown by clear and convincing evidence that the defendants lacked competent and reliable scientific evidence to substantiate their claims. The district court consequently found the defendants in contempt and re-imposed the sanction of approximately $40 million on the defendants.

The defendants appealed. Wheat and Hi-Tech filed their own appeal, primarily to challenge the facial validity of the injunction. Alternatively, Wheat and Hi-Tech argue that the district court's finding that they lacked competent and reliable scientific evidence was clearly erroneous. Smith filed a separate appeal, adopting Wheat and Hi-Tech's arguments but also arguing that he lacked the ability to comply with the injunction.

We hold that the defendants have waived their challenge to the clarity of the injunction. We also conclude that the district court did not abuse its discretion in finding that the defendants lacked competent and reliable scientific evidence to substantiate the relevant claims and in imposing the

order of contempt. Accordingly, we affirm the district court.

II. STANDARD OF REVIEW

We must affirm the district court's judgment of civil contempt unless we find that the court abused its discretion. *Howard Johnson Co. v. Khimani*, 892 F.2d 1512, 1516 (11th Cir. 1990). We review any underlying factual findings for clear error, *Jove Eng'g, Inc. v. I.R.S.*, 92 F.3d 1539, 1545 (11th Cir. 1996), and we review any legal rulings *de novo*, *Ala. v. Ctrs. For Medicare & Medicaid Servs.*, 674 F.3d 1241, 1244 n.2 (11th Cir. 2012).

III. DISCUSSION

The petitioning party has the initial burden in a civil-contempt case to clearly and convincingly show the district court that (1) the injunction was valid and lawful; (2) the order was clear, definite, and unambiguous; and (3) the contempt defendant had the ability to comply with the order (but did not do so). *McGregor v. Chierico*, 206 F.3d 1378, 1383 (11th Cir. 2000). Once this prima facie showing is made in the district court, the burden shifts to the defendants to explain their noncompliance. *See F.T.C. v. Leshin*, 618 F.3d 1221, 1232 (11th Cir. 2010). In the civil-contempt context, "substantial, diligent, or good faith efforts are not enough; the only issue is compliance." *Id.*

With these principles in mind, we examine the defendants' arguments that the district court abused its discretion by holding them in contempt.

A. The defendants have waived any objection to the clarity of the injunction.

The defendants' chief argument on appeal is that the injunction is too ambiguous to be enforced. They contend that that the "competent and reliable scientific evidence" standard and its accompanying definition are unclear, in violation of Fed. R. Civ. P. 65(d), which states that an injunction should "describe in reasonable detail" what is required without referring to another document. Fed. R. Civ. P. 65. Their argument, however, has been squarely foreclosed by *McComb v. Jacksonville Paper Co.*, 336 U.S. 187 (1949), where the Supreme Court illustrated the common-sense lesson that a defendant cannot defeat an injunction by employing the following formula: (1) staying silent about purported ambiguities; (2) deliberately engaging in activities that risk violating the injunction; and (3) pleading ignorance after those risky activities are indeed found to violate the injunction.

McComb was a civil-contempt case. *McComb*, 336 U.S. at 189. In 1943, the district court entered a decree ordering the defendants there to comply with the Fair Labor Standards Act ("FLSA") by (1) paying certain employees a minimum wage, (2) paying overtime compensation to certain employees, and (3) keeping certain records about hours worked and wages paid. *Id.* The contempt defendants did not appeal from the district court's order. *Id.*

Three years after the district court entered its order, the government instituted contempt proceedings against the defendants, and the district court found that the defendants had violated the

decree. *Id.* at 189–90. Among other things, the defendants had set up a "false and fictitious" method of calculating compensation, provided employees wage increases in the guise of bonuses to reduce the amount of overtime pay they had to give, and misclassified some employees. *Id.* Despite these findings, however, the district court did not hold the defendants in contempt, and the court of appeals upheld that decision. *Id.* According to the court of appeals, there was no "willful contempt" because "neither the [FLSA] nor the injunction *specifically* referred to or condemned the [defendants'] practices." *Id.* at 191 (emphasis added).

The Supreme Court reversed, and its discussion applies forcefully in this case. First, the Court explained that "[t]he absence of wil[l]fulness does not relieve from civil contempt." *Id.* This is because "the purpose [of civil contempt] is remedial, [so] it matters not with what intent the defendant did the prohibited act." *Id.* The Supreme Court went on to explain that injunctions of some generality "are often necessary to prevent further violations where a proclivity for unlawful conduct has been shown." *Id.* at 192.

Significantly, the Court continued, if the contempt defendants had a problem with the injunction, they could have done a number of things, like appeal or ask the district court for "a modification, clarification[,] or construction of the order." *Id.* But the defendants did none of those things, opting instead to "make their own determination of what the decree meant." *Id.* Thus, the Court explained, the defendants "knew they acted at their peril." *Id.*

To excuse the defendants years later, after they already took the questionable actions, the Court explained, would basically render the injunction useless and "give tremendous impetus to the program of experimentation with disobedience of the law":

> The instant case is an excellent illustration of how it could operate to prevent accountability for persistent contumacy. Civil contempt is avoided today by showing that the specific plan adopted by respondents was not enjoined. Hence a new decree is entered enjoining that particular plan. Thereafter the defendants work out a plan that was not specifically enjoined. Immunity is once more obtained because the new plan was not specifically enjoined. And so a whole series of wrongs is perpetrated and a decree of enforcement goes for naught.

Id. at 192–93. The Supreme Court refused to allow this never-ending cycle of violations, ruling that the defendants "knew full well the risk of crossing the forbidden line" and "took a calculated risk when under the threat of contempt they adopted measures designed to avoid the legal consequences of the [FLSA]." *Id.* at 193. They were not, the Supreme Court said, "unwitting victims of the law" and could not escape punishment now. *Id.*

The *McComb* Court might as well have been talking about this case. The defendants here were likewise not "unwitting victims of the law" but were instead calculating actors who stayed silent concerning the purported ambiguity about which they now complain. Then they deliberately engaged in self-

serving activities they knew seriously risked violating the injunction.

As we have recounted, during the original injunction proceedings, at the defendants' request, the district court gave the defendants an opportunity to object to a draft version of the injunction that was ultimately entered. The defendants did not object that the phrase "competent and reliable scientific evidence" or its accompanying definition were unduly ambiguous. The district court then entered the injunction. The defendants also did not make a Rule 65 objection to the clarity of the injunction when they appealed to this Court (and even if they had, this Court affirmed the entry of the injunction).

They had, after all, just litigated what that phrase meant in the context of dietary supplements that touted weight- and fat-loss benefits, and the district court had explained that only RCTs on the products themselves would suffice. So they likely understood that, in the future, to make claims about weight- and fat-loss benefits for dietary supplements, they would need RCTs. And even if they didn't, the defendants' attorneys expressly advised them on multiple occasions that only RCTs would satisfy the standard.

Wheat understood what his attorneys were telling him, as he conceded in an email to other Hi-Tech employees: "If the FTC verdict stands there is nothing we can say without doing a double-blind placebo study . . . ." But as Wheat expressed repeatedly, the RCT requirement put a heavy strain on his business. So knowing the risk, the defendants made a choice to continue to market products, relying largely on supporting evidentiary material the district court

previously rejected and their own attorneys repeatedly advised Wheat was insufficient.

As *McComb* explained, injunctions sometimes need to be phrased with some generality, to give flexibility to cover the endless derivations of a specific kind of prohibited conduct. *McComb*, 336 U.S. at 192. And although Rule 65 specifies that the injunction should be self-contained, it is also impossible to spell out every imaginable detail. So those subject to an injunction can timely ask questions, seek modification or clarification, or object. That way, if some detail needs to be articulated more specifically, it will be. But a person facing an injunction cannot stay silent, take actions he has reason to believe are prohibited, and then complain about alleged "ambiguity" later.

Here, though, the defendants did precisely that. They stayed silent about the supposed ambiguity of which they now complain, were repeatedly informed by counsel that they risked contempt for using anything other than RCTs to substantiate their claims, knowingly proceeded anyway in the face of that risk—and reaped $40 million in gross receipts—and now plead ignorance after being held in contempt. Injunctions are not so easily circumvented.

The defendants offer some theories about why they have not waived their ambiguity argument. We dismiss each in turn.

First, the defendants point out that the FTC bears the initial burden of making a prima facie showing that an injunction is valid and clear before the Hi-Tech defendants can be held in contempt. To the extent that the defendants make this argument to suggest that ambiguity objections can *never* be waived, we find that

contention to be meritless. *See McComb*, 336 U.S. at 191–94. As for the injunction's definition of "competent and reliable scientific evidence"—"tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that ha[ve] 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"—that appears on its face to be reasonable, particularly when we consider that the defendants did not object to the phrase, despite conceding it was the "operative command" in the substantiation requirement. In short, we are satisfied that the FTC has carried its prima facie burden of showing the clarity of the injunction.

Next, the defendants note that in rejecting their claim that the injunction was not sufficiently clear, the district court discussed the defendants' assertions that the injunction was ambiguous and that it did no more than require them to obey the law.[3] Because the district court addressed these arguments, the defendants contend, they had a right to address those grounds on appeal. We don't disagree. But nothing

[3] We have explained that an injunction that simply tells a defendant to obey the law can be too ambiguous to be enforced. But aside from concerns about clarity, there is nothing inherently wrong with an injunction that instructs a party to comply with a specific law. *S.E.C. v. Goble*, 682 F.3d 934, 950–51 (11th Cir. 2012) (explaining that obey-the-law injunctions often suffer from lack of specificity, but that "an injunction that orders a defendant to comply with a statute may be appropriate" when the enjoined activity remains clear). Thus, the defendants' complaint that the injunction tells them only to obey the law is just another way of voicing their ambiguity argument.

about the district court's discussion of those issues absolves the defendants' waiver problem.

District courts can offer multiple rationales, sometimes in the alternative, for their decisions, and we can affirm on any basis. Here, before discussing the defendants' ambiguity arguments, the district court expressed doubt that those arguments were properly before it. Indeed, the court said that "the defendants were given an opportunity to object to the scope of the injunctions before they were entered, but they did not object to any of the provisions they *ostensibly* challenge now." (emphasis added). So there can be no doubt that the district court in fact concluded that the defendants had waived their ambiguity arguments.

Finally, the defendants contend that they did not have a fair opportunity to object to the "competent and reliable evidence" standard, since, according to them, they "could not reasonably have been expected to know in 2008 that the FTC would later seek to hold them in contempt for failing to substantiate *different* advertising claims with a product-specific RCTs standard not in the injunction." We agree generally that, in some instances, a person subject to an injunction cannot fairly be expected to object to an ambiguity that becomes apparent only when, for example, a court evinces an unexpected interpretation of certain terms. But that's not the case here, since the defendants' attorneys literally told them that "it is *reasonable to assume*" that competent and reliable scientific evidence means RCTs on the marketed products. (emphasis added.) At the very least, then, the defendants were on notice that RCTs were likely to be required, and they were not permitted to assume

the risk without accepting the consequences. *See McComb*, 336 U.S. at 192 ("They undertook to make their own determination of what the decree meant. They knew they acted at their peril.").

B. The defendants cannot show that the district court clearly erred when it found that they lacked competent and reliable scientific evidence to substantiate the claims at issue.

As explained, we remanded to the district court with instructions to determine whether any admissible evidence presented by the defendants constituted "competent and reliable scientific evidence." *Nat'l Urological Grp., Inc.*, 785 F.3d at 483. On remand, the district court conducted a bench trial, after which it determined that the defendants did not have competent and reliable scientific evidence that substantiated the claims at issue.[4] The defendants allege that the district court clearly erred in making this finding. We disagree.

The district court's finding that the defendants' evidence did not amount to competent and reliable scientific evidence to substantiate the relevant claims is a factual determination, which we review for clear error. *Jove*, 92 F.3d at 1545. On clear-error review, "[i]f the district court's account of the evidence is plausible in light of the record viewed in its entirety, the court of appeals may not reverse it even though convinced that had it been sitting as the trier of fact, it would

[4] The district court clarified that even if what the defendants presented could be "competent and reliable scientific evidence" that would suffice in other contexts, it was not "competent and reliable scientific evidence" that could substantiate the claims at issue here.

have weighed the evidence differently." *Anderson v. City of Bessemer City, N.C.*, 470 U.S. 564, 573–74 (1985). And when a district judge's factual finding "is based on his decision to credit the testimony of one of two or more witnesses, each of whom has told a coherent and facially plausible story that is not contradicted by extrinsic evidence, that finding, if not internally inconsistent, can virtually never be clear error." *Id.* at 575.

Here, the district court detailed its extensive reasoning as to why the defendants' evidence was inadequate and why protections offered by tests like RCTs would be necessary for the claims at issue. The district court considered the qualifications of the FTC's experts, Dr. Aronne and Dr. Richard van Breemen, who urged that protections offered by RCTs were necessary. It considered all the beneficial characteristics of RCTs that are run on humans and on the specific products: they factor in the unique biochemical properties of humans; there are placebo controls and double blinding;[5] there is randomization;[6] the studies would be large enough to produce reliable results; the studies would be long enough to produce reliable results; the products and dosages tested would be the ones about which the company makes claims; the studies would measure the endpoints the company makes claims about; and the results would

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[5] A double-blind test is one where the test subjects do not know whether they are in the placebo group (first blind), and the researchers do not know which group is the placebo one, either (second blind).

[6] Randomization is the process by which test subjects are randomly assigned to either the treatment or the placebo group.

be statistically significant, so there is less of a chance that the outcome is a fluke.

The district court also explained why *not* having those beneficial properties would cause a study to be less reliable: results in animals or results in vitro would have to be extrapolated to humans (but certain biochemical reactions that occur outside the human body may not repeat in the same way inside the body); there would be no way to know whether any placebo effect contributed to the results; it would have to be assumed that different ingredients in other products did not affect the outcome; it would have to be assumed that different dosages of the ingredients in other products did not affect the outcome; and there would be no way to determine whether selection bias had occurred. Notably, many of the defendants' experts agreed with the district court's points here. And the district court noted that the defendants' evidence, which primarily consisted of studies on *ingredients* in the marketed products—as opposed to studies on the marketed products themselves—and RCTs of *other products*—as opposed to RCTs on the marketed products—lacked many of the safeguards of reliability mentioned above.

The district court also considered the credentials of the defendants' experts and found them lacking in many cases. Worse yet, the district court illuminated disturbing facts about the credibility of some of the defendants' experts. For example, one of their experts, Dr. Wright, was repeatedly reprimanded by the Georgia Composite Medical Board and, in a 2003 civil case, may have lied to the district court in the Northern District of Georgia when he said that Wheat

was in Belize to recuperate from an illness when Wheat was actually there to illegally further a conspiracy to manufacture, import, and distribute drugs in the United States. Another of the defendants' experts, Dr. Jacobs, admitted that he broke the blind[7] and re-administered dosages when one of the RCTs he was conducting on another Hi-Tech product was not turning out the way he expected—that is, he deliberately influenced the experiment's results.

It should come as no surprise, then, that in the end, the district court concluded that the FTC had shown, by clear and convincing evidence, that the defendants' collection of ingredient-specific studies and RCTs of other products (some of which were run by Dr. Jacobs) did not constitute competent and reliable scientific evidence to substantiate their claims. Far from clear error, the district court's findings were supported by the evidence.

The defendants' attempts to show that the district court committed clear error all fall flat. First, the defendants allege that the district court's "cursory analysis never explains what standard the Hi-Tech defendants somehow failed to meet in the alternative" if RCTs were not required. In this respect, the defendants argue, "Having failed to identify precisely what substantiation standard it would apply in the alternative," "the court surely could not objectively evaluate substantiation under that unarticulated standard." But the district court did not necessarily need to articulate a standard to recognize that what

[7] To break the blind is to uncover the placebo group in an experiment.

the defendants presented did not amount to competent or reliable scientific evidence. Moreover, it should be clear from the district court's analysis that it used as the standard the level of reliability and competency afforded by RCTs on the advertised products. Put differently, what evidence the defendants presented had to be as reliable and as competent as results derived from RCTs on the marketed products.

Second, the defendants argue that "the district court impermissibly shifted the burden to [them] to *disprove* contempt in the first instance by proving that their product claims were substantiated." Not so. The FTC met its prima facie burden of clearly and convincingly showing that the injunction was violated, when it pointed out that the defendants were again making weight- and fat-loss claims about products without having RCTs on the products themselves, even though the court had held that only RCTs on the products themselves could be "competent and reliable scientific evidence" the last time. So the burden shifted to the defendants to explain why RCTs were not necessary and why they had evidence that carried the same reliability and competency as the RCTs that were required the first time. *Howard*, 892 F.2d at 1516. Then at the bench trial, the FTC demonstrated by clear and convincing evidence that the evidence the defendants presented was not as reliable or as competent as RCTs on the marketed products would have been.

Finally, the defendants argue that "when experts reasonably disagree over whether representations are supported by competent and reliable scientific evidence, as they did here, the FTC has not carried its

burden to establish contempt by clear and convincing evidence." This argument does not save the day for the defendants for two reasons. First, we have already explained the problems the district court found with the defendants' experts—problems the district court reasonably could rely on to discount those experts' views. And second, even setting aside the defendants' experts' deficiencies, a battle of the experts does not necessarily paralyze the district court and exonerate the defendant. Rather, a district court can decide for one side or the other even when both present plausible stories. *Anderson*, 470 U.S. at 573–74 ("If the district court's account of the evidence is plausible in light of the record viewed in its entirety, the court of appeals may not reverse it even though convinced that had it been sitting as the trier of fact, it would have weighed the evidence differently.").

The mere fact that a battle of experts exists goes more directly to the potential good faith of the defendant in attempting to comply with the injunction than to the defendant's actual compliance. But as we have noted, good faith—even when it is demonstrated—is not enough, in and of itself, to escape civil contempt. *Leshin*, 618 F.3d at 1232 (explaining that in a civil contempt proceeding, "substantial, diligent, or good faith efforts are not enough; the only issue is compliance.").

C. Smith had the ability to comply with the injunction.

Smith adopted the arguments we have already discussed, but he also made a separate argument: that he did not have the ability to comply with the injunction. Smith claims he was merely "a salesman

for Hi-Tech" who "never held a position with decision-making authority over Hi-Tech's advertising, its product labels, or its testing of products." According to Smith, "[t]he district court's finding with respect to [him] is based on the actions of others . . . and must be reversed." Specifically, "[r]ather than consider him individually, the district court effectively imputed the actions of Hi-Tech and Mr. Wheat to Mr. Smith." We disagree.

The district court did not have to rely on imputing others' actions to Smith. In laying out the findings that supported holding him in contempt, the district court explained why *Smith* took actions that were integral to Hi-Tech's violation of the injunction. Smith was the senior vice president in charge of sales at Hi-Tech, as well as the head of the "Food, Drug, and Mass" division there. In that capacity, he was responsible for landing retail accounts, including advertising and promoting Hi-Tech products at trade shows. The district court found that Smith "oversaw the sales force that marketed Hi-Tech products to retailers and had the authority to decide which retailers sold their products."

Smith protests that it was Wheat who designed the advertisements and that he had no power to order RCTs. "There was simply nothing [he] could have done to effect compliance," he said, "because he did not have the power to change the advertising or the labels or to order double-blind, placebo-controlled clinical trials." But Smith's liability did not arise from his failure to order RCTs or design compliant advertisements. His liability stemmed instead from his decisions to continue marketing and selling Hi-Tech's products

without regard to his responsibility to ensure that those products did not carry unsubstantiated claims. Smith could have complied with the injunction simply by not participating in the infringing activities. That he chose to continue facilitating those prohibited activities sufficiently supported the district court's conclusion finding him liable.

IV. CONCLUSION

For the foregoing reasons, we affirm the district court.

AFFIRMED.

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 14-13131

FEDERAL TRADE COMMISSION,

Plaintiff-Appellee,

CERTUSBANK, N.A.,

Plaintiff,

v.

NATIONAL UROLOGICAL GROUP, INC.,
d.b.a. Warner Laboratories, et al.,

Defendants,

HI-TECH PHARMACEUTICALS, INC., Corporation,
JARED WHEAT, individually and as officer of the corporation, STEPHEN SMITH, individually and as officer of National Urological Group, Inc. and National Institute for Clinical Weight Loss, Inc.,
M.D. TERRILL MARK WRIGHT, individually

Defendants-Appellants.

Appeals from the United States District Court
for the Northern District of Georgia
No. 1:04-cv-03294-CAP

Filed May 5, 2015
[PUBLISH]

MEMORANDUM

Before TJOFLAT, WILLIAM PRYOR, and BARKSDALE,* Circuit Judges.

WILLIAM PRYOR, Circuit Judge:

In this appeal, we must decide whether the district court abused its discretion when it held Hi-Tech Pharmaceuticals, Inc., Jared Wheat, Stephen Smith, and Dr. Terrill Mark Wright in contempt for violating injunctions that prohibit them from making any representation about weight-loss products unless they "possess[] and rel[y] upon competent and reliable scientific evidence that substantiates the representation." Hi-Tech, Wheat, Smith, and Wright submitted evidence to support the challenged representations and an expert declaration that the representations were substantiated by "competent and reliable scientific evidence." But the district court refused to consider the evidence. The district court ruled that because it had required Hi-Tech, Wheat, Smith, and Wright to produce clinical trials to substantiate different representations about different weight-loss products in an earlier stage of this litigation, they were collaterally estopped from presenting new kinds of evidence to satisfy the standard of "competent and reliable scientific evidence" and instead had to produce clinical trials to substantiate the challenged representations. After Hi-Tech, Wheat, Smith, and Wright failed to produce clinical trials to substantiate their representations, the district court held them in contempt. Because the

* Honorable Rhesa H. Barksdale, United States Circuit Judge for the Fifth Circuit, sitting by designation.

district court misapplied the doctrine of collateral estoppel, we vacate and remand.

I. BACKGROUND

We divide our discussion of the background in two parts. First, we discuss the initial litigation between the Federal Trade Commission and Hi-Tech, Wheat, Smith, and Wright. Second, we discuss the contempt proceedings that gave rise to this appeal.

A. Initial Litigation.

In 2004, the Commission filed a complaint against Hi-Tech, Hi-Tech's Chief Executive Officer, Wheat, Hi-Tech's Senior Vice President, Smith, and Wright for violations of sections 5 and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45(a), 52. The Commission alleged that the defendants made unsubstantiated representations about two weight-loss products, "Thermalean" and "Lipodrene." The Commission alleged that the defendants lacked adequate substantiation for their representations that Thermalean "is an effective treatment for obesity," "is equivalent or superior to the prescription weight loss drugs Xenical, Meridia, and Fastin in providing weight loss benefits," "causes rapid and substantial weight loss, including as much as 30 pounds in 2 months," and "causes users to lose 19% of total body weight, lose 20–35% of abdominal fat, reduce their overall fat by 40–70%, [and] decrease their stored fat by 300%," and that Lipodrene "causes substantial weight loss, including as much as 125 pounds" and "enables users to lose up to 42% of total body fat and 19% of total body weight, and to increase their metabolic rate by up to 50%."

In 2008, the district court granted summary judgment in favor of the Commission. The district court concluded that the defendants had violated the Trade Commission Act because they had not substantiated their representations with clinical trials of the weight-loss products instead of ingredients in the products. The district court entered a final judgment and permanent injunction against Hi-Tech, Wheat, and Smith, and a separate final judgment and permanent injunction against Wright based on his unsubstantiated endorsements of the products.

The injunctions prohibited the defendants from making any representation that a weight-loss product "causes rapid or substantial loss of weight or fat" or "affects human metabolism, appetite, or body fat," unless the defendants "possess[] and rel[y] upon competent and reliable scientific evidence that substantiates the representation." The injunctions defined "competent and reliable scientific 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 manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." The injunctions did not mention any requirement to produce clinical trials to substantiate weight-loss representations.

B. Contempt Proceedings.

After Hi-Tech, Wheat, Smith, and Wright continued to promote weight-loss products, the Commission moved the district court in 2011 to order Hi-Tech, Wheat, and Smith to show cause why they should not be held in contempt for making

unsubstantiated representations about four products, "Fastin," "Stimerex-ES," "Benzedrine," and a reformulated version of "Lipodrene." The Commission alleged that Hi-Tech, Wheat, and Smith lacked adequate substantiation for the following representations:

> The "World's Most Advanced Weight Loss Aid Ever Developed!" . . . (Fastin print ad);
>
> "[A] Truly Extraordinary Weight Loss Product . . . Fastin is unlike anything you have ever tried before and will help you lose weight." . . . (Fastin print ad);
>
> A "Revolutionary Diet Aid Taking the Market by Storm!" . . . (Fastin product page, www.hitechpharma.com);
>
> "[A] pharmaceutical-grade dietary supplement indicated for weight loss in extremely overweight individuals." . . . (Fastin product packaging); . . .
>
> An "EXTREMELY POTENT DIET AID! DO NOT CONSUME UNLESS RAPID . . . WEIGHT LOSS [IS] YOUR DESIRED RESULT." . . . (Fastin product packaging) . . .
>
> "[I]s a revolutionary weight loss formula scientifically engineered to help people lose weight and feel great!" . . . (Lipodrene print ad);
>
> Is "the benchmark standard for the weight loss industry." . . . (Lipodrene product page, www.hitechpharma.com);

"[I]s the Gold Standard in the weight loss industry for one simple Reason . . . It Works!" . . . ;

"[W]ill cause rapid . . . weight loss with usage." . . . (Lipodrene product packaging); . . .

"The World's Most Advanced Weight Loss Aid Ever Developed!" [Lipodrene product packaging] . . .

Is an "Extreme Fat Burner." . . . (Fastin print ad);

Is a "Novel Fat Burner." . . . [Fastin print ad];

"[I]s the Gold Standard by which all Fat Burners should be judged." . . . [Fastin print ad];

Is a "Rapid Fat Burner." . . . (Fastin product packaging); . . .

Is a "Rapid Fat Loss Catalyst." . . . (Fastin product packaging) . . .

A "Novel Fat Burner that Helps Melt Away Pounds." . . . (Lipodrene print ad);

"[A] Fat Assassin unlike any other 'Fat Burner.'" . . . [Lipodrene print ad];

"[T]he best fat-burner [sic] in existence." . . . [Lipodrene print ad];

"[T]he 'Gold Standard' by which all fat loss products are judged." . . . (Print ad for multiple Hi-Tech products including Lipodrene);

"Hi-Tech's Flagship Fat Loss Product with 25 mg Ephedra Extract – Annihilate Fat." . . .

(Lipodrene product page, www.hitech pharma.com) . . .

"[T]he right move to strip away fat." . . . [Lipodrene product page]; . . .

"The Strongest Fat Burner/Energizer Ever Produced." . . . (Benzedrine print ad); . . .

"[T]he most potent Fat Burner/Energizer known to man." [Benzedrine print ad] . . .

Has "Unmatched Anorectic Activity to Manage Caloric Intake." . . . (Benzedrine product page, www.hitechpharma.com); . . .

Is "the first anorectic supplement ever produced." . . . (Benzedrine product packaging) . . .

"[U]ndeniably the most powerful, fat loss . . . formula ever created." . . . (Print ad for multiple Hi-Tech products including Stimerex-ES);

"[T]he Strongest Fat Burner/Energizer to ever hit the market!" . . . (Stimerex-ES print ad); . . .

"The Ultimate Fat Burner Ever Created." . . . (Stimerex-ES product page, www.hitech pharma.com) . . .

"Curbs the Appetite!" . . . [Fastin ad] . . .

"Increases the metabolic rate, promoting thermogenesis (The Burning of Stored Body Fat)." . . . [Fastin ad]; . . .

"[H]as both immediate and delayed release profiles for appetite suppression, energy and weight loss." [Fastin ad] . . .

> Has "Unmatched Anorectic Activity to Manage Caloric Intake." . . . (Benzedrine product page, www.hitechpharma.com); and
>
> Is "the first anorectic supplement ever produced." . . . (Benzedrine product packaging).

The Commission also moved to hold Wright in contempt for his endorsement of Fastin.

In response, the defendants submitted evidence to support their representations and an expert's declaration that the representations were substantiated by "competent and reliable scientific evidence," but the district court refused to consider the defendants' evidence. The district court explained, based on the "law of the case," that "[t]he only evidence that will be relevant to show whether the defendants 'possess[ed] and rel[ied] upon competent and reliable scientific evidence' to substantiate any representation is the kind of evidence . . . previously adopted by the court." In an earlier stage of the litigation, the district court ruled that "some form of clinical trial must have been conducted on the product itself or an exact duplicate of the product to substantiate the defendants' claims regarding the overall product." Because the defendants had not produced clinical trials on the four products at issue in the contempt proceedings, the district court granted the motion to show cause. The district court later clarified that it based its ruling that only clinical trials could establish "competent and reliable scientific evidence" on the doctrine of collateral estoppel, instead of the "law of the case."

After Hi-Tech, Wheat, Smith, and Wright failed to produce clinical trials on the weight-loss products, the district court held them in contempt for violating the injunctions. The district court held Hi-Tech, Wheat, and Smith jointly and severally liable for approximately $40 million in sanctions, which equaled Hi-Tech's gross receipts for the four products during the relevant time period. The district court also held Wright liable for $120,000, which reflected the sum Hi-Tech paid him for endorsing Fastin during the relevant time period.

II. STANDARD OF REVIEW

We review a sanction for civil contempt for abuse of discretion. *McGregor v. Chierico*, 206 F.3d 1378, 1383 (11th Cir. 2000). "A district court abuses its discretion if it applies an incorrect legal standard, applies the law in an unreasonable or incorrect manner, follows improper procedures in making a determination, or makes findings of fact that are clearly erroneous." *Citizens for Police Accountability Political Comm. v. Browning*, 572 F.3d 1213, 1216–17 (11th Cir. 2009).

III. DISCUSSION

The district court abused its discretion when it held the defendants in contempt. The district court misapplied the doctrine of collateral estoppel when it refused to consider the defendants' evidence of substantiation. Collateral estoppel "bars successive litigation of an issue of fact or law actually litigated and resolved in a valid court determination essential to the prior judgment, even if the issue recurs in the context of a different claim." *Taylor v. Sturgell*, 553 U.S. 880, 892, 128 S. Ct. 2161, 2171 (2008) (internal

quotation marks and citation omitted). We apply collateral estoppel only when four criteria are satisfied:

> (1) the issue at stake is identical to the one involved in the prior litigation; (2) the issue was actually litigated in the prior suit; (3) the determination of the issue in the prior litigation was a critical and necessary part of the judgment in that action; and (4) the party against whom the earlier decision is asserted had a full and fair opportunity to litigate the issue in the earlier proceeding.

Miller's Ale House, Inc. v. Boynton Carolina Ale House, LLC, 702 F.3d 1312, 1318 (11th Cir. 2012). To establish that an issue is not identical to one resolved in previous litigation, a party "need only point to one material differentiating fact that would alter the legal inquiry," *CSX Transp., Inc. v. Bhd. of Maint. of Way Emps.*, 327 F.3d 1309, 1317 (11th Cir. 2003). The defendants can easily do so because the level of substantiation the injunctions require for the representations at issue in the contempt proceedings is not "identical" to any issue the district court decided in the earlier litigation.

The issue decided in the earlier litigation involved different representations, different products, and the interpretation of a different legal standard from the issue the district court prevented Hi-Tech, Wheat, Smith, and Wright from litigating in the contempt proceedings. The district court previously ruled that Hi-Tech, Wheat, Smith, and Wright needed to produce clinical trials that substantiated their representations about Thermalean and an older version of Lipodrene

under the Trade Commission Act. In the contempt proceedings, by contrast, the district court held that Hi-Tech, Wheat, Smith, and Wright were collaterally estopped from litigating the level of substantiation the injunctions require for different representations about Fastin, Stimerex-ES, Benzedrine, and the reformulated Lipodrene.

The differences between the issue decided in the previous litigation and the issue the defendants were prevented from litigating in the contempt proceedings "point to" at least "one material differentiating fact that would alter the legal inquiry," *id.* at 1317. The district court explained in the previous litigation that the "competent and reliable scientific evidence" standard imposed by the injunctions is "context specific" and "permits different variations . . . depending on what pertinent professionals would require for the particular claim made." The district court further explained that "the size, duration or protocol of a scientific study, the number or type of scientific studies required to substantiate a claim, and the proper mechanism for extrapolating results from studies will obviously vary from circumstance to circumstance depending upon the expert evidence presented." That the representations at issue in the previous litigation involved different products, referenced other weight-loss products by name, and were far more specific than those at issue in the contempt proceedings accordingly "alter[s] the legal inquiry," *id*. The issue decided in the previous litigation is not "identical," *Miller's Ale House, Inc.*, 702 F.3d at 1318, to the issue the district court prevented the defendants from litigating in the

contempt proceedings. The district court erred when it applied the doctrine of collateral estoppel.

Hi-Tech, Wheat, Smith, and Wright also argue that the district court erred by adopting a stricter standard for substantiation than the injunctions require and by relying on evidence of privileged communications, but those questions are premature. On remand, the district court must exercise its discretion to determine the admissibility of any evidence offered by the Commission and by the contempt defendants and make findings about whether any evidence of substantiation, if admissible, satisfies the standard of the injunctions for "competent and reliable scientific evidence." We hold only that the district court misapplied collateral estoppel when it barred Hi-Tech, Wheat, Smith, and Wright from presenting evidence to prove their compliance with the injunctions.

IV. CONCLUSION

We VACATE the order holding Hi-Tech, Wheat, Smith, and Wright in contempt and REMAND for further proceedings consistent with this opinion.

Appendix B

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

Civil Action No. 1:04-CV-3294-CAP

FEDERAL TRADE COMMISSION,
Plaintiff,

v.

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

Filed December 20, 2017
ECF Document 978

ORDER

This matter is before the court on the defendants' motion to stay execution of judgment pending appeal without posting a supersedeas bond in full [Doc. No. 970], and the defendants' motion for leave to file matters under seal [Doc. No. 972].

I. Relevant Background

On October 10, 2017, the court found the defendants jointly and severally liable for $40,000,950 in compensatory sanctions to redress the defendants' numerous violations of injunctions the court had entered earlier in this case [Doc. No. 966]. The Clerk of Court entered final judgment on the court's

contempt order on October 31, 2017, stating that the FTC can recover from the defendants the compensatory sanction amount plus post-judgment interest at the rate of 1.42% per annum [Doc. No. 969]. The defendants have expressed their intention to appeal the court's contempt order, though no appeal has been filed as of the date of this order. In the interim, the defendants' request that the court stay the FTC's execution of the final judgment without the requirement of posting a full supersedeas bond. The defendants have proposed that the court impose an alternative form of security: offering their assurance not to dispose of or liquidate any of their substantial assets during the pendency of the appeal and to submit quarterly financial reports to the court. The FTC has opposed the defendants' motion.

II. Discussion

Federal Rule of Civil Procedure 62(d) governs the stay of proceedings to enforce a judgment. It states in pertinent part,

> If an appeal is taken, the appellant may obtain a stay by supersedeas bond . . . The bond may be given upon or after filing the notice of appeal or after obtaining the order allowing the appeal. The stay takes effect when the court approves the bond.

An appellant complying with Rule 62(d) is entitled to a stay of a money judgment as a matter of right. *American Manufacturers Mutual Insurance Co. v. American Broadcasting-Paramount Theatres*, 87 S. Ct. 1, 3 (1966). Although Rule 62(d) requires the appellant to post a supersedeas bond, the district court may substitute some form of guaranty of judgment

responsibility for the supersedeas bond "[i]f a judgment debtor objectively demonstrates a present financial ability to facilely respond to a money judgment and presents to the court a financially secure plan for maintaining that same degree of solvency during the period of an appeal." *Poplar Grove Planting & Refining Co. v. Bache Halsey Stuart, Inc.*, 600 F.2d 1189, 1191 (5th Cir. 1979).

> Contrariwise, if the judgment debtor's present financial condition is such that the posting of full bond would impose an undue financial burden, the court similarly is free to exercise a discretion to fashion some other arrangement for substitute security through an appropriate restraint on the judgment debtor's financial dealings, which would furnish equal protection to the judgment creditor.

Id. Thus, "[i]t is within the court's discretion to fashion a security arrangement that protects the rights of both the judgment creditor and the judgment debtor." *Prudential Insurance Co. v. Boyd*, 781 F.2d 1494, 1498 (11th Cir. 1986). The burden is on the moving party "to objectively demonstrate the reasons for such a departure" from the bond requirement set forth in Rule 62(d). *Poplar Grove*, 600 F.2d at 1191.

Pretermitting whether the defendants have shown that Hi-Tech Pharmaceuticals, Inc. ("Hi-Tech") will suffer an undue financial burden by posting a supersedeas bond, they have failed to show that the individual defendants, Jared Wheat and Stephen Smith, would suffer a financial burden, despite the fact that they are jointly and severally liable for the

judgment. *Cf. C. Albert Sauter Co. v. Richard Sauter Co.*, 368 F. Supp. 501, 520 (S.D.N.Y. 1973) (noting that "the defendants, *severally and jointly*, are without sufficient assets to satisfy the judgment and are unable to obtain a bond in the amount of the verdict plus counsel fees and costs") (emphasis added). The record contains evidence that Wheat has previously dissipated assets from Hi-Tech and had other forms of liquidity, so the absence of documents pertaining to his finances leaves doubt as to the defendants' collective ability to meet the bond requirement of Rule 62. With respect to the financial documents Hi-Tech submitted, the court finds them similarly lacking because they are unaudited and from 2016, so they do nothing to evidence Hi-Tech's current financial condition. *See, e.g., IA Labs CA, LLC v. Nintendo Co., Ltd.*, 946 F. Supp. 2d 429, 431 (D. Md. 2013) (holding that financial statements were not enough to establish an undue financial burden because they provided an incomplete picture of the defendant's financial resources) (citing *Poplar Grove*, *supra*).

The court also finds that Hi-Tech's proposal for a substitute security—promising not to dispose of or liquidate any of its "substantial assets" in lieu of posting a supersedeas bond—fails to protect the rights of the FTC. *See Poplar Grove*, 600 F.2d at 1190; *see also MGM Well Servs., Inc. v. Mega Lift Sys., LLC*, Civil Action No. H-05-1634, 2007 WL 2021609, at *1 (S.D. Tex. July 10, 2007) (rejecting the defendants' offer to maintain its current assets); *but see*, *Sauter*, 368 F. Supp. at 520–21 (waiving the supersedeas bond requirement but requiring the defendants to place "in escrow subject to a security agreement to be approved by the [c]ourt," substantial assets in the form of stock,

securities, and cash, in addition to posting a partial bond). Accordingly, the court will not waive the requirement of Rule 62(d) insofar as it requires the defendants to post a supersedeas bond pending appeal; their motion [Doc. No. 970] is DENIED.

The defendants have, however, demonstrated good cause to seal the financial information they submitted in support of their motion to stay. For good cause shown, the defendants' motion for leave to file Exhibit A to the declaration of Jared Wheat submitted in support of their motion to stay [Doc. No. 972] is GRANTED. The FTC's corresponding motion to seal its response to the defendants' motion to stay [Doc. No. 974], which references the defendants' financial information contained in Exhibit A, is also GRANTED. The clerk is DIRECTED to seal Doc. Nos. 971 and 974 which have been provisionally sealed on the docket.

SO ORDERED this 20th day of December, 2017.

/s/ Charles A. Pannell, Jr.
CHARLES A. PANNELL, JR.
United States District Judge

Appendix C

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 17-15695-AA

FEDERAL TRADE COMMISSION,

Plaintiff-Counter Defendant-Appellee,

CERTUSBANK, N.A.,

Plaintiff,

v.

NATIONAL UROLOGICAL GROUP, INC., d.b.a. Warner Laboratories, et al.,

Defendants-Counter Claimants,

HI-TECH PHARMACEUTICALS, INC., corporations, JARED WHEAT, individually and as officers of the corporations, STEPHEN SMITH, individually and as officers of National Urological Group, Inc., and National Institute for Clinical Weight Loss, Inc.,

Defendants-Appellants,

THOMASZ HOLDA, individually and as officers of the corporations, et al.,

Defendants.

Appeal from the United States District Court
for the Northern District of Georgia
No. 1:04-cv-03294-CAP

Filed March 5, 2020

CORRECTED ORDER

The motion of Appellants, Hi-Tech Pharmaceuticals, Inc., Stephen Smith and Jared Wheat, for stay of the issuance of the mandate pending petition for writ of certiorari is DENIED.

DAVID J. SMITH
Clerk of the United States Court of
Appeals for the Eleventh Circuit

ENTERED FOR THE COURT – BY DIRECTION

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 17-15695-AA

FEDERAL TRADE COMMISSION,

Plaintiff-Counter Defendant-Appellee,

CERTUSBANK, N.A.,

Plaintiff,

v.

NATIONAL UROLOGICAL GROUP, INC., d.b.a. Warner Laboratories, et al.,

Defendants-Counter Claimants,

HI-TECH PHARMACEUTICALS, INC., corporations, JARED WHEAT, individually and as officers of the corporations, STEPHEN SMITH, individually and as officers of National Urological Group, Inc., and National Institute for Clinical Weight Loss, Inc.,

Defendants-Appellants,

THOMASZ HOLDA, individually and as officers of the corporations, et al.,

Defendants.

Appeal from the United States District Court
for the Northern District of Georgia
No. 1:04-cv-03294-CAP

Filed January 29, 2020

ON PETITION(S) FOR REHEARING AND PETITION(S) FOR REHEARING EN BANC

BEFORE: MARTIN, ROSENBAUM, Circuit Judges, and MARTINEZ,* District Judge.

PER CURIAM:

The Petition for Rehearing En Banc is DENIED, no judge in regular active service on the Court having requested that the Court be polled on rehearing en banc. (FRAP 35) The Petition for Panel Rehearing is also denied. (FRAP 40)

* Honorable Jose Martinez, United States District Judge for the Southern District of Florida, sitting by designation.

Appendix D

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

Civil Action No. 1:04-CV-3294-CAP

FEDERAL TRADE COMMISSION,
Plaintiff,

v.

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

Filed October 10, 2017
ECF Document 966

ORDER

This matter is before the court to determine whether defendants Hi-Tech Pharmaceuticals, Inc. ("Hi-Tech"), Jared Wheat, Stephen Smith, and Dr. Terrill Mark Wright are in contempt for violating certain provisions of the court's permanent injunctions, and, if so, what sanctions are appropriate to redress any violation(s) [Doc. No. 880, ¶ 17]. Although both the court and parties are familiar with the procedural posture of the case, the court believes that a brief recitation of the facts will be helpful.

I. Case Overview

A. The Initial Proceedings

This civil action began over thirteen years ago when the Federal Trade Commission ("FTC") filed a complaint against Hi-Tech; Hi-Tech's Chief Executive Officer, Wheat; Hi-Tech's Senior Vice President, Smith; and Wright (among others) for violations of sections 5 and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45(a), 52. The FTC alleged that the defendants had made certain unsubstantiated representations about two weight-loss products, Thermalean and Lipodrene. The FTC moved for summary judgment, and the court found as a matter of law that the defendants had violated the Trade Commission Act because they had not substantiated the representations about the products with clinical trials of the products themselves. *See F.T.C. v. Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d 1167 (N.D. Ga. 2008), aff'd, 356 Fed. App'x 358 (11th Cir. 2009) ("2008 summary judgment order").

With respect to the issue of substantiation, the undisputed record at that time established that the defendants had "not countered the testimonies of the FTC's experts regarding what level of substantiation is required for the claims made in this case. Accordingly, the court conclude[d] that there [was] no issue of fact regarding the requisite levels of substantiation . . .", so the court relied upon the standard articulated by the FTC's expert, Dr. Louis Aronne. *Id.* at 1202. According to Dr. Aronne, the type of evidence required to substantiate efficacy claims for weight-loss dietary supplements is

> 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 . . . conducted on the product itself.

Id. (hereinafter "RCTs"). Notably, when adopting Dr. Aronne's RCT standard of substantiation, the court rejected the ingredient studies the defendants had referenced in opposing summary judgment [*see, e.g.*, Doc. No. 196, p. 56] to support their purported "ingredient-specific claims," finding those arguments were "unavailing." *Id.* at 1203 n.21.

After granting summary judgment in favor of the FTC, the court determined that Hi-Tech, Wheat, and Smith were jointly and severally liable for consumer redress in the amount of $15,882,436.00 and that Wright was liable for disgorgement of ill-gotten gains in the amount of $15,454.00 for his participation in the deceptive marketing of the products. *Id.* at 1214. The court also held that the FTC was entitled to a permanent injunction against Hi-Tech, Wheat, and Smith based on the evidence that demonstrated the corporate defendants' previous and ongoing violations of the FTC Act "were numerous and grave." *Id.* at 1209. The court found that the FTC was entitled to injunctive relief as to Wright as well because his violations of the FTC Act were also significant. *Id.* at 1214.

After giving the defendants an opportunity to object to the FTC's proposed injunctions, on December

16, 2008, the court entered a permanent injunction against Hi-Tech, Wheat, and Smith [Doc. No. 230] ("Hi-Tech injunction"), and a separate injunction against Wright [Doc. No. 229] ("Wright injunction").

The defendants appealed the 2008 summary judgment order. While the defendants' notice of appeal states that they also appealed the final judgments and permanent injunctions, their briefing to the Eleventh Circuit revolves almost exclusively around the summary judgment order and not the scope of, or really anything related to, the injunctions themselves [*See* Brief of Appellants, *Federal Trade Commission v. National Urological Group, Inc.*, (No. 09-10617), 2009 WL 5408404 (11th Cir.) ("Appeal Brief"); *see also* Reply Brief of Appellants, *Federal Trade Commission v. National Urological Group, Inc.*, (No. 09-10617), 2009 WL 5408406 (11th Cir.)]. The Eleventh Circuit affirmed this court's decision. *F.T.C. v. Nat'l Urological Grp., Inc.*, 356 Fed. App'x 358 (11th Cir. 2009) (per curiam).

B. The Initial Contempt Proceedings

Almost two years later, on November 1, 2011, the FTC filed a motion for an order directing Hi-Tech, Wheat, and Smith (hereinafter "the Hi-Tech defendants") to show cause why they should not be held in contempt for violating the Hi-Tech injunction [Doc. No. 332]. According to the FTC, the Hi-Tech defendants continued to make representations through a national advertising campaign about four weight-loss products—Fastin, Stimerex-ES, Benzedrine, and a reformulated version of Lipodrene—that lacked adequate substantiation in violation of Sections II and VII of the Hi-Tech

injunction. The FTC also alleged that the Hi-Tech defendants had failed to include the required yohimbine warning on each of the four products in violation of Section VI of the injunction. On March 21, 2012, the FTC filed a separate motion for an order to show cause why Wright should not be held in contempt for violating Section II of the Wright injunction by endorsing Fastin with unsubstantiated claims [Doc. No. 377].

On May 11, 2012, the court granted both motions and scheduled a status conference to address scheduling and discovery [Doc. No. 390] ("the May 11 Order"). In the May 11 Order, the court observed that, in their briefs in opposition to the motion for a show cause order, the defendants had argued that the claims surrounding the four products were substantiated by "competent and reliable scientific evidence," in accordance with the injunctions. The court disagreed, finding that what constitutes "competent and reliable scientific evidence" for purposes of this case had already been established during the 2008 summary judgment proceedings because the defendants had failed to counter Dr. Aronne's opinion that RCTs were necessary to substantiate efficacy claims. Consequently, the court held that what constitutes "competent and reliable scientific evidence" for purposes of meeting the substantiation requirement of the injunctions was law of the case and was not subject to re-litigation. *Id.* at 7–10. The court later expounded upon its rationale, finding the doctrine of collateral estoppel barred re-litigation of the substantiation standard, as opposed to merely being the law of the case [Doc. No. 422].

After completing the remaining contempt proceedings prescribed in the May 11 Order, the court entered an order on August 8, 2013, finding that the FTC had presented clear and convincing evidence that the injunctions were valid and lawful, the terms of the injunctions were clear and unambiguous, and the defendants had the ability to comply but did not when they made unsubstantiated statements about the four products at issue [Doc. No. 524]. Consequently, the court found that the defendants were liable for contempt and proceeded with a determination regarding the appropriate sanctions. After a fairly expansive, four-day sanctions hearing, the court entered an order on May 14, 2014, holding the Hi-Tech defendants jointly and severally liable for compensatory sanctions in the amount of $40,000,950.00, and ordered Wright to pay compensatory sanctions in the amount of $120,000.00 [Doc. No. 650] ("contempt order").[1] The court detailed in the contempt order previous and ongoing contumacious conduct, noting, among other things, that such conduct was "troubling." [*Id.*].

C. The Defendants' Second Appeal

On July 11, 2014, the defendants appealed the contempt order. The defendants articulated two primary arguments in their appeal: (1) that this court erred by holding the defendants to the RCT substantiation standard because that "cannot be

[1] The sum total compensatory sanctions equaled the gross receipts for the sale of the four products—Fastin, Lipodrene, Benzedrine, and Stimerex-ES—during the time period in which the court found the defendants had engaged in contumacious conduct.

found within the four corners of the injunction and was, instead, implicitly incorporated by reference from a prior ruling in the same case," and (2) this court erred by relying on the defendants' "attorney-client privileged communications and protected work product to support its sanctions award." Brief of Appellants, *Federal Trade Commission v. Hi-Tech Pharmaceuticals, Inc.*, (No. 14-13131), 2014 WL 5793778, *2 (11th Cir.).[2] According to the defendants, "[t]he central issue on appeal [was] whether [this court] erred by applying a substantiation standard that does not appear within the four corners of the injunction." *Id.* at *11. The defendants recognized in their briefing that they "did not appeal the contempt finding as to Section VI of the injunction, which required a specific warning on products that contained yohimbine." [Doc. No. 829-7, p. 40].

The Eleventh Circuit held that both primary grounds for appeal—the scope of the substantiation standard and the court's reliance on attorney-client communications—were "premature." *F.T.C. v. Nat'l Urological Grp., Inc.*, 785 F.3d 477, 483 (11th Cir. 2015). Instead, the appellate court held "only that [this court] misapplied collateral estoppel when it barred Hi-Tech, Wheat, Smith, and Wright from presenting evidence to prove their compliance with the injunctions." *Id.* at 483. The appellate court vacated the contempt order and remanded the case, instructing this court to "exercise its discretion to determine the admissibility of any evidence offered by the Commission and by the contempt defendants and

[2] Wright and Smith simply adopted these two primary arguments raised by Hi-Tech in their respective appellate briefs.

make findings about whether any evidence of substantiation, if admissible, satisfies the standard of the injunctions for 'competent and reliable scientific evidence.'" *Id.*

D. The Proceedings Following Remand

After the case was remanded, the parties submitted a proposed scheduling order to complete the contempt proceedings in a manner consistent with the Eleventh Circuit's instructions [Doc. No. 828]. In the ensuing two years, the court provided both parties a full and complete opportunity to identify and depose expert witnesses, who offered opinions relative to the issue of whether the defendants' claims were substantiated. The parties also conducted expert discovery surrounding the alleged violation of Section VI of the injunction regarding the yohimbine warning, notwithstanding the fact that the defendants had already conceded that they did not challenge the court's finding that they violated Section VI[3] when the case was appealed to the Eleventh Circuit. At the conclusion of the expert discovery, the parties filed

[3] *See* Doc. No. 524, pp. 23–24 (holding that "there is no genuine dispute of material fact that the advertisements do not contain the yohimbine warning required by Section VI of the Hi-Tech Order. . . . The defendants contend that there is a genuine issue of material fact as to whether they complied with the yohimbine-warning requirement. Wheat argues, '[I]t is not undisputed that [he] has taken no steps to include this warning in Hi-Tech's advertising or labels,' and that it was 'an apparent oversight' that 'is in the process of being corrected.' The injunction did not require Wheat to 'take steps' to include the warning; the order required the warning to be made. There is no question that the Hi-Tech defendants' conduct violated the injunction.") (citations omitted).

several motions to exclude opposing experts.[4] Since the court is in the unique position of being both the gatekeeper for purposes of *Daubert*[5] and also the fact finder, it reserved ruling on the motions to exclude but will do so now that the court has had an opportunity to hear each witness testify in court. Also pending is the defendants' motion for summary judgment seeking an order denying the FTC's application for an order of contempt [Doc. No. 876]. For the reasons discussed in detail below, that motion is DENIED.

With this procedural history in mind, the court turns its attention to the two-week bench trial following remand, which commenced on March 27, 2017 and concluded on April 7, 2017. Given the totality of the proceedings and the entirety of the record before the court, it makes the following findings of fact and conclusions of law based on the clear and convincing evidence presented by the parties or otherwise stipulated.[6]

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[4] The FTC seeks to exclude the testimony of defense experts Gerald M. Goldhaber, Ph.D. [Doc. No. 855] and Linda Gilbert [Doc. No. 875]. The defendants filed motions to exclude the following FTC expert witnesses, Susan Blalock [Doc. No. 858], Richard van Breeman [Doc. No. 865], and Louis J. Aronne, M.D. [Doc. No. 866].

[5] *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

[6] The court reiterates here that the Eleventh Circuit opinion vacating and remanding the case held "only that [this court] misapplied the doctrine of collateral estoppel", and the limited issue on remand is whether "any evidence of substantiation, if admissible, satisfies the standard of the injunctions for '"competent and reliable scientific evidence."' *F.T.C.*, 785 F.3d at 483. Therefore, the court's findings in the contempt order that are unrelated to the issue of substantiation (e.g., the defendants'

II. Findings of Fact

A. Hi-Tech's Operations

Hi-Tech is a Georgia corporation that manufactures and distributes a variety of its own branded dietary supplements (also referred to as nutraceuticals), including the four products that are at issue in these proceedings—Fastin, Lipodrene, Benzedrine, and Stimerex-ES. Each of the four products is marketed as a dietary weight-loss supplement. Hi-Tech sells these products directly to consumers, as well as through distributors and retailers nationwide.

Wheat is the sole owner, President, Chief Executive Officer, Secretary, and Treasurer of Hi-Tech. He held these positions from January 1, 2009 through the present, except for the period from November 2009 through April 2010, a portion of the time in which he was incarcerated in federal prison after having pled guilty to criminal charges in an unrelated case for conspiracy to commit mail and wire

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control over Hi-Tech's marketing, the alleged violative advertising claims, etc.) were never disturbed on appeal. Nevertheless, since the court's entire contempt order was vacated, it will again recount these other findings of fact for purposes of this order as they become pertinent. The court notes further that neither party presented any evidence during the bench trial to contradict the court's earlier findings of fact that were unrelated to whether the defendants had satisfied the competent and reliable scientific evidence standard. Indeed, the defendants' proposed findings of facts and conclusions of law do not mention Hi-Tech's operations or even the purported violative advertising claims but rather cite almost exclusively to facts relative to the substantiation and yohimbine issues [*See generally* Doc. No. 903].

fraud and to introduce and deliver unapproved new and adulterated drugs into interstate commerce, in violation of 18 U.S.C. §§ 1341, 1343, and 371, and 21 U.S.C. §§ 331(a) and (d), 333(a)(2), 351 and 355(a). *See United States of America v. Jared Robert Wheat*, 1:06-cr-382 (N.D. Ga. 2009) [Doc. No. 685]. In total, Wheat was incarcerated for those criminal charges from March 16, 2009 to September 15, 2010. While in prison, Wheat still communicated with Hi-Tech employees, including details about the contents of the company's print and web advertising, product packaging, and labels for the four products.

With respect to the labeling and promoting of Fastin, Lipodrene, Benzedrine, and Stimerex-ES, Wheat admits that he is ultimately responsible for the creation of the ad content and product labeling [Doc. No. 700-13, pp. 12, 17, 23, 28]. He also oversees the manufacturing of the products, and he designed the formulations. The defendants consider Wheat "essential to the operations of Hi-Tech." [Doc. No. 903, ¶ 4]. Thus, Wheat was responsible for and had the authority to give final approval of the claims at issue.

Smith contends he was "merely a salesman" in his post-trial briefing and, as such, did not have the requisite control over Hi-Tech and its advertising necessary to be subject to contempt. His arguments are unavailing. Relative to the time many of the alleged violative advertising claims were made, Smith was the senior vice-president in charge of sales of Hi-Tech products, including the four products at issue. In this role, Smith oversaw the sales force that marketed Hi-Tech products to retailers and had the authority to decide which retailers sold their products. Smith was

also responsible for landing retail accounts with food stores, drug chains, and mass merchandisers. He also marketed and promoted Hi-Tech products to retailers and distributors through brokers, who were not employed by Hi-Tech and were crucial to Hi-Tech's product placement. Smith made presentations to brokers about Hi-Tech products and pitched the products using the labels and packaging. Although Smith contends that Wheat was responsible for adding retailers who sold Hi-Tech products at the bottom of the print ads, Wheat obviously could not add those retailers to the ads without Smith first obtaining the account and then telling Wheat which account he had landed.

Moreover, while Wheat was in prison, Smith oversaw the day-to-day operations and his job was to "hold down the fort" at Hi-Tech. As of May 24, 2010, Wheat specifically instructed Smith, "At this time you [Smith] are the senior officer of HT [Hi-Tech] running day-to-day operations . . . ." [Doc. No. 700-71, p. 3]. Even outside the time of Wheat's incarceration, Smith helped to secure Fastin, Lipodrene, Benzedrine, and Stimerex-ES advertising on Hi-Tech's behalf with various publications and advertising agencies. To this day, Hi-Tech's website claims Smith has "expertise in Hi-Tech operations and marketing," which make him a valuable asset.[7] Accordingly, the court finds that Smith played an integral part in Hi-Tech's marketing

[7] http://hitechpharmaceuticals.com/about_corporate.php (last viewed August 3, 2017).

and advertising practices, as well as product procurement and placement.[8]

Dr. Wright is a physician with a primary specialty in internal medicine, and he has a subspecialty in bariatric medicine. Wright considers himself a "weight loss physician," who provides expert endorsements for Hi-Tech's Fastin product. From 2009 through 2011, Wright received compensation from Hi-Tech for his work assisting Wheat in advertising and endorsing Hi-Tech products.

B. The Pertinent Sections of the Injunctions

The portions of the Hi-Tech injunction that the FTC contends the Hi-Tech defendants violated are Sections II, VI, and VII. Section II prohibits the Hi-Tech defendants from making representations that any product is an effective treatment for obesity, causes rapid or substantial loss of weight or fat, causes a specified loss of weight or fat, affects human metabolism, appetite, or body fat, is safe, has virtually no side effects, or is equivalent or superior to any drug that the Food and Drug Administration has approved for sale in the United States for the purpose of treating obesity or causing weight loss, *unless*

> the representation, including any such representation made through the use of endorsements, is true and non-misleading, and, at the time the representation is made,

[8] The court also notes that Smith did not submit any evidence during the 2017 bench trial to cause the court to depart from its earlier findings in 2014 regarding Smith's control and ability to comply with the injunction. Indeed, the court does not recall Smith ever attending the 2017 bench trial, and he certainly did not testify during it.

> Defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation.

[Doc. No. 230]. The phrase "competent and reliable scientific evidence" is defined in the "Definitions" section of the injunction as:

> tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

[*Id.*]. Section VI of the Hi-Tech injunction requires that, "in any advertisement, promotional material, or product label for any covered product or program containing yohimbine that contains any representation about the efficacy, benefits, performance, safety, or side effects of such product," the Hi-Tech defendants make clearly and prominently, the following disclosure:

> **WARNING:** This product can raise blood pressure and interfere with other drugs you may be taking. Talk to your doctor about this product.

[Doc. No. 230 (bold in original)].

Finally, Section VII mirrors Section II in that it prohibits the Hi-Tech defendants from making representations about "the health benefits, absolute or comparative benefits, performance, safety, or efficacy" of their products, unless "at the time the

representation is made, Defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation." [*Id.*]

C. The Alleged Unsubstantiated Representations

The FTC contends that the defendants made the following representations, which violate the aforementioned sections of the injunctions. The defendants do not materially dispute that the representations were made nor do they dispute the medium through which they were presented to consumers. The representations, as well as the time period in which they were made, are as follows:

1. Fastin

The claims relative to the Fastin product include the following:

> "EXTREME WEIGHT LOSS GUARANTEED!" (Fastin product packaging);
>
> The "World's Most Advanced Weight Loss Aid Ever Developed!" (Fastin print ad);
>
> "[A] Truly Extraordinary Weight Loss Product . . . Fastin is unlike anything you have ever tried before and will help you lose weight." (Fastin print ad);
>
> A "Revolutionary Diet Aid Taking the Market by Storm!" (Fastin product page, www.hitechpharma.com);
>
> "Fastin® is a pharmaceutical-grade dietary supplement indicated for weight loss in extremely overweight individuals." (Fastin product packaging);

> "WARNING: EXTREMELY POTENT DIET AID! DO NOT CONSUME UNLESS RAPID FAT AND WEIGHT LOSS ARE YOUR DESIRED RESULT." (Fastin product packaging)
>
> Is an "Extreme Fat Burner." (Fastin print ad);
>
> Is a "Novel Fat Burner." (Fastin print ad);
>
> [I]s the Gold Standard by which all Fat Burners should be judged." (Fastin print ad);
>
> Is a "Rapid Fat Burner." (Fastin product packaging);
>
> Is a "Rapid Fat Loss Catalyst." (Fastin product packaging);
>
> "Curbs the Appetite!" . . . (Fastin ad);
>
> "Increases the metabolic rate, promoting thermogenesis (The Burning of Stored Body Fat)." . . . (Fastin ad); and
>
> "[H]as both immediate and delayed release profiles for appetite suppression, energy and weight loss." (Fastin ad).

From at least October 2010 through at least December 14, 2012, the Hi-Tech defendants disseminated print advertisements for Fastin containing the representations identified above through national magazines such as *Allure*, *Cosmopolitan*, *First*, *Fitness*, *Flex*, *Globe*, *In Touch*, *Life & Style*, *Martha Stewart Weddings*, *Muscle & Fitness*, *MuscleMag International*, *Muscular Development*, *National Enquirer*, *OK*, *Redbook*, *Self*, *Star*, *US Weekly*, *USA Today Women's Health Guide*,

Whole Living, *Women's Day*, and *Women's World*. In addition to magazine advertisements, the Hi-Tech defendants disseminated Fastin print advertisements through their company website, www.hitech pharma.com, through early January 2014. Since January 1, 2009, the Hi-Tech defendants also advertised Fastin through product packaging and labels that also contained the representations above, through and including the contempt sanctions hearing the court held, beginning on January 21, 2014. From 2010 to 2011 Hi-Tech roughly tripled its advertising budget from $1.3 million to $3.9 million, which enabled it to acquire more retail accounts. According to Wheat, the sale of Fastin increased the most during this time as a result of the increased advertising budget.

2. Lipodrene

The claims for the reformulated Lipodrene product include:

> "Join the millions of American's [sic] who have consumed over 1 Billion dosages of Lipodrene® . . . And watch the pounds Melt Away!" (Lipodrene print ad);
>
> "Try Lipodrene® and watch the inches melt away." (Lipodrene print ad);
>
> "LIPODRENE WILL CAUSE RAPID FAT AND WEIGHT LOSS WITH USAGE" (Lipodrene product packaging);
>
> "DO NOT CONSUME UNLESS FAT LOSS AND WEIGHT LOSS ARE YOUR INTENDED RESULT" (Lipodrene product packaging);

> "[I]s the Gold Standard in the weight loss industry for one simple reason . . . It Works!" . . . (Lipodrene product page, www.hitech pharma.com);
>
> A "Novel Fat Burner that Helps Melt Away Pounds." . . . (Lipodrene print ad);
>
> "[A] Fat Assassin unlike any other 'Fat Burner.'" (Lipodrene print ad);
>
> "Hi-Tech's Flagship Fat Loss Product with 25 mg Ephedra Extract—Annihilate Fat." . . . (Lipodrene product page, www.hitech pharma.com); and
>
> "[T]he right move to strip away fat.". . . (Lipodrene product page).

From October 2010 through at least December 14, 2012, the Hi-Tech defendants advertised Lipodrene through print ads containing the above-claims in national magazines such as *Flex*, *Muscle & Fitness*, and *MuscleMag International*. In addition, they disseminated Lipodrene print advertisements through the company website through early January 2014. From September 17, 2010 through January 21, 2014, the Hi-Tech defendants advertised and offered Lipodrene for sale on the company website using these claims. Since January 1, 2009 through at least November 10, 2014, the Hi-Tech defendants advertised Lipodrene through product packaging and labels.

3. Benzedrine

The representations for the Benzedrine product include:

> "ANNIHILATE THE FAT WHILE FIRING UP YOUR ENERGY!" (Benzedrine print ad);
>
> "Benzedrine™ simply blows fat away!" (Benzedrine product page, www.hitech pharma.com);
>
> "The Strongest Fat Burner/Energizer Ever Produced." . . . (Benzedrine print ad);
>
> "[T]he most potent Fat Burner/Energizer known to man." (Benzedrine print ad);
>
> Has "Unmatched Anorectic Activity to Manage Caloric Intake." . . . (Benzedrine product page, www.hitechpharma.com); and
>
> Is "the first anorectic supplement ever produced." . . . (Benzedrine product packaging).

The Hi-Tech defendants disseminated Benzedrine print advertisements containing these representations from September 2010 through at least November 2011 in national magazines such as *Flex*, *Muscle & Fitness*, *MuscleMag International*, and *Muscular Development*. They also disseminated the print advertisements on the Hi-Tech company website through early January 2014 and offered the product for sale on the company website using these representations through January 21, 2014. Since January 1, 2009, the Hi-Tech defendants advertised Benzedrine through product packaging and labels that also contain these representations.

4. Stimerex-ES

The claims for Stimerex-ES are as follows:

"Stimerex-ES® is hardcore stimulant action for those who want their fat-burner to light them up all day as their pounds melt away!" (Stimerex-ES print ad);

"[U]ndeniably the most powerful, fat loss . . . formula ever created." . . . (Print ad for multiple Hi-Tech products including Stimerex-ES);

"[T]he Strongest Fat Burner/Energizer to ever hit the market!" (Stimerex-ES print ad);

. . .

"Stimerex-ES® is designed as the ultimate fat burner/energizer." (Stimerex-ES product page, www.hitechpharma.com); and

"The Ultimate Fat Burner Ever Created!" (Stimerex-ES product page, www.hitech pharma.com).

The FTC also presented evidence of an advertisement containing a cartoon drawing that depicts an overweight woman walking through "The Lean Machine aka: Stimerex-ES®," a device that looks like a metal detector attached to a bottle of Stimerex-ES, and emerges shapely and toned.

The FTC further contends that the defendants made unsubstantiated representations that Stimerex-ES has comparable efficacy to ephedrine-containing dietary supplements in violation of Section VII of the injunction through the following statements:

> "The benefits of ephedra are now 'Back in Black!'" (Stimerex-ES print ad); and
>
> "Don't be fooled by the rumors, Hi-Tech's Thermo-Z™ Brand Ephedra Extract does not violate any federal or state ban on ephedrine-containing dietary supplements. We can still provide you with 25mg ephedra you've always enjoyed." (Stimerex-ES print ad).

From October 2010 through at least December 14, 2012, the Hi-Tech defendants disseminated print ads for Stimerex-ES that contained the representations above in national magazines such as *Flex*, *Muscle & Fitness*, *MuscleMag International*, and *Muscular Development*. They also disseminated print advertisements using the company website through January 21, 2014. Like the other products, since September 17, 2010, the Hi-Tech defendants advertised and offered Stimerex-ES for sale on the company website and this continued through January 21, 2014. From January 1, 2009 until November 10, 2014, the Hi-Tech defendants advertised Stimerex-ES through product packaging and labels that contain these representations.

5. Dr. Wright's Endorsement

The alleged unsubstantiated endorsement made by Wright appeared in a Fastin print ad:

> "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. Fastin® is unlike anything you have ever tried before and will help you lose weight!"

Dr. Mark Wright—Bariatric (Weight Loss Physician).

The dates for the endorsement are the same as those relative to the Hi-Tech defendants' advertising of Fastin, discussed above. Wheat testified that Wright had reviewed the Fastin print ad containing the endorsement, Wright knew that he had appeared in it, and Wright had approved it. In addition to providing the Fastin endorsement, Wright authored articles printed in the *Hi-Tech Health & Fitness* magazine promoting Hi-Tech products.

For the sake of brevity, the court will discuss its remaining findings of facts in conjunction with its analysis of whether the FTC has proven the defendants' contempt by clear and convincing evidence.

III. Discussion

A. Civil Contempt Framework

The parties agree that a finding of civil contempt must be supported by clear and convincing evidence that (1) the allegedly violated order was valid and lawful, (2) the order was clear and unambiguous, and (3) the alleged violator had the ability to comply with the order but did not. *F.T.C. v. Leshin*, 618 F.3d 1221, 1232 (11th Cir. 2010).[9] The clear and convincing

[9] The court notes that it uses the past tense when referring to the injunctions because the court is addressing whether the defendants' past conduct violated the injunctions. The court's use of the past tense when referring to the injunctions and the alleged violations in this order should not be interpreted to mean the injunctions are no longer in effect. To the contrary, both injunctions are still binding, and the parties are reminded of their continuing obligations thereunder.

standard "is more exacting than the 'preponderance of the evidence' standard but, unlike criminal contempt, does not require proof beyond a reasonable doubt." *Jordan v. Wilson*, 851 F.2d 1290, 1292 (11th Cir. 1988).

"Once this prima facie showing of a violation is made, the burden then shifts to the alleged contemnor to produce evidence explaining his noncompliance at a 'show cause' hearing." *Chairs v. Burgess*, 143 F.3d 1432, 1436 (11th Cir. 1998) (internal quotation marks omitted). "[T]he contemnor is 'allowed to show either that he did not violate the court order or that he was excused from complying.'" *Id.* (citing *Mercer v. Mitchell*, 908 F.2d 763, 768 (11th Cir. 1990) (explaining a "typical (although by no means exclusive) contempt proceeding" process)). "At the end of the day, the court determines whether the defendant has complied with the injunctive provision at issue and, if not, the sanction(s) necessary to ensure compliance." *Reynolds v. Roberts*, 207 F.3d 1288, 1298 (11th Cir. 2000).

B. Section II and Section VII Violations

Applying this framework to the case *sub judice*, and specifically the defendants' arguments surrounding the alleged violations of Sections II and VII,[10] they posit two primary arguments: the FTC

[10] The court focuses here on Sections II and VII because the Hi-Tech defendants concede that they did not place the yohimbine warning on the four products, as required by Section VI of the Hi-Tech injunction. Thus, the defendants do not contest that they violated Section VI. They instead take issue with the appropriateness of sanctioning their noncompliance of that section, which the court will discuss further below.

failed to carry its burden of establishing contempt because the injunction is not clear and unambiguous, and the FTC has not proved that the defendants violated the injunction because there is a reasonable "battle of the experts" regarding whether the defendants possessed adequate substantiation. These two arguments, as the defendants recognize in their briefing, are premised upon "many of the same reasons." [Doc. No. 961, pp. 36–37]. Thus, the defendants conflate their arguments regarding the validity/enforceability of the injunction with the defendants' explanation of their alleged noncompliance. While the arguments are somewhat intertwined, the court will proceed through the civil contempt framework discussed above, while addressing each of the defendants' defenses thereto.

1. Valid and Lawful

Within a footnote in their post-trial briefing, the defendants incorporate by reference an earlier argument that the injunction is "not valid and enforceable" because it "incorporates a substantiation standard outside of its four corners . . . and . . . because it is an impermissible obey-the-law injunction" [Doc. No. 961, p. 31 n.14 (citing Doc. Nos. 879, 861-1)].[11]

[11] The court notes that the defendants have not properly incorporated by reference their earlier arguments. The two docket entries they cite to support their "obey-the-law" argument are Doc. Nos. 879 and 861-1. Doc. No. 879 is the FTC's brief in opposition to the defendants' motion for summary judgment, which cites to contra authority from the defendants' position. Doc. No. 861-1 is a certificate of service for the FTC's reply in support of its motion to exclude the testimony of one of the defendants' experts. The court will assume the defendants'

While the defendants couch these two arguments in terms of "valid and enforceable," thus appearing to challenge the first element on these grounds, both their "four corners" argument and "obey-the-law" argument are really challenges to element two: whether the injunctions are clear and unambiguous. Indeed, the cases the defendants cite to support their four corners and obey-the-law arguments discuss those defenses in the context of the specificity requirement of Fed. R. Civ. P. 65(d). *See, e.g.*, *S.E.C. v. Smyth*, 420 F.3d 1225, 1233 n.14 (11th Cir. 2005) (collecting cases). And, the Supreme Court has interpreted Rule 65(d) in terms of the clear and unambiguous inquiry. *See Int'l Longshoremen's Ass'n v. Phila. Marine Trade Ass'n*, 389 U.S. 64, 76 (1967); *see also Drywall Tapers & Pointers of Greater New York, Local 1974 of I.B.P.A.T. AFL-CIO v. Local 530 of Operative Plasterers & Cement Masons Int'l Ass'n*, 889 F.2d 389, 400 (2d Cir. 1989) (Mahoney, J., concurring in part and dissenting in part) ("The . . . element . . . requiring that an injunction be 'clear and unambiguous,' builds upon the requirements of Fed. R. Civ. P. 65(d)."). Therefore, the court will address both arguments below when addressing whether the injunctions are clear and unambiguous. After properly framing the defendants' arguments, the court concludes that they largely do not contest the first element. Nevertheless, the court will examine whether the injunctions are valid and lawful since the defendants have invoked—albeit tenuously—a challenge that the injunctions are "not valid."

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intended to incorporate the arguments from Doc. No. 876-1, their motion for summary judgment.

In 2008, after granting summary judgment in favor of the FTC, the court found that Hi-Tech's previous and ongoing "violations of the FTC Act were numerous and grave." *Nat'l Urological Grp.*, 645 F. Supp. 2d at 1209. The court noted further that a risk of recurrent violations "could cause significant harm to consumers," thus warranting the imposition of permanent injunctions against the defendants. *Id.* at 1209–1210 (addressing Hi-Tech, Wheat, and Smith); *id.* at 1214 (addressing Wright). The court thoroughly discussed both the reasons why the FTC had the authority to seek injunctive relief[12] and why injunctive relief was appropriate in this case. *Id.*

Before entering the injunctions, however, the court gave the defendants an opportunity "in the interest of justice" to file objections to the FTC's proposed injunctions that had been filed contemporaneously with its motion for summary judgment. While the defendants did file objections, they did not object to the FTC's ability to seek injunctive relief, as noted in the Preamble, nor did they object to any of the "Findings" noted in the order that authorized injunctive relief [Doc. Nos. 220–221]. Moreover, when the defendants filed their appeal, they never challenged the imposition of injunctive relief. Thus, even assuming arguendo that the defendants impliedly challenged the appropriateness of the injunctions by appealing the 2008 summary judgment order, the Eleventh Circuit disposed of that challenge when it affirmed this court's final judgment and order. *See F.T.C. v. Nat'l Urological Grp., Inc.*, 356

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[12] *See* 15 U.S.C. § 53(b); *FTC v. Evans Products Co.*, 775 F.2d 1084, 1086 (9th Cir. 1985).

Fed. App'x 358 (11th Cir. 2009). In sum, the record is clear that the imposition of injunctive relief and the injunctions themselves were valid and lawful orders of the court. *Cf. S.E.C. v. Pension Fund of Am., L.C.*, 396 Fed. App'x 577, 581 (11th Cir. 2010) (finding an injunction was not valid and lawful because the threshold requirements of entering injunctive relief had not been met).

2. Clear and Unambiguous

Virtually the entire thrust of the defendants' arguments surrounding the alleged violations of Sections II and VII of the injunctions focuses on this element. As noted above, they contend the FTC has failed to meet its burden of proving by clear and convincing evidence that the four corners of the injunctions were clear and unambiguous and the injunctions are impermissible "obey-the-law" injunctions. The court will address each argument in turn.

a. The Hi-Tech Defendants' Understanding of the Injunction

The defendants have been correct throughout the entirety of these contempt proceedings that, for an injunction to be sufficiently clear and unambiguous to support a finding of contempt, Fed. R. Civ. P. 65(d) requires the injunction to "state its terms specifically; and . . . describe in reasonable detail—and not by referring to the complaint or other document—the act or acts restrained or required." The FTC, as the moving party, shoulders the burden of proving the injunction is clear and unambiguous.

The specificity requirement of Rule 65(d) and the "four corners" rule the defendants reference are

functionally the same thing: "[a] person enjoined by court order should only be required to look within the four corners of the injunction to determine what he must do or refrain from doing." *S.E.C. v. Goble*, 682 F.3d 934, 952 (11th Cir. 2012) (citing *Hughey v. JMS Dev. Corp.*, 78 F.3d 1523, 1532 n.12 (11th Cir. 1996)).

The problem with the premise of the defendants' Rule 65(d) argument, however, is that they omit what follows the "[b]ut" in *Goble*, where the Eleventh Circuit continues the specificity requirement analysis: "But, we will not apply Rule 65(d) 'rigidly,' and we 'determine the propriety of an injunctive order by inquiring into whether the parties subject thereto understand their obligations under the order." *Goble*, 682 F.3d at 952 (citing *Planetary Motion, Inc. v. Techsplosion, Inc.*, 261 F.3d 1188, 1203 (11th Cir. 2001)); *see also United States v. Goehring*, 742 F.2d 1323, 1324 (11th Cir. 1984) (*per curiam*) (upholding a contempt order where the district court found the defendant had violated an order that had incorporated findings of an earlier order because the record contained "sufficient findings of fact and conclusions of law for [the appellate court] to perform its proper function and for the appellant to clearly understand the basis for the contempt order," though Rule 65(d) was not specifically invoked); *cf. Int'l Longshoremen's Ass'n*, Local 1291, 389 U.S. 64 (finding the district court's decree was invalid under Rule 65(d), but noted, "We do not deal here with a violation of a court order by one who fully understands its meaning but chooses to ignore its mandate.").

Stated another way, "while the preference is to enforce the requirements of Rule 65(d) 'scrupulously,'

failure to abide by the precise terms of the Rule does not compel finding [the district court's contempt judgment] void." *United States v. Sarcona*, 457 Fed. App'x 806, 811–12 (11th Cir. 2012) (citing *Combs v. Ryan's Coal Co.*, 785 F.2d 970, 978 (11th Cir. 1986). Thus, the clear and unambiguous inquiry can be satisfied "if it is clear from the totality of the language in the various documents that the contemnors understood their obligations under the injunction." *Combs*, 785 F.2d at 978; *see also S.C. Johnson & Son, Inc. v. Clorox Co.*, 241 F.3d 232, 241 (2d Cir. 2001) (finding an injunction was not impermissibly vague because the district court's prohibition was "sufficiently specific when read in the context" with another order the court previously had entered).

The notion that an injunction may still be enforceable—notwithstanding a purported Rule 65(d) defect—if there is evidence the contemnors understood their obligations under the injunction makes sense because, as the defendants point out, the purpose of Rule 65(d) is to provide a putative contemnor with "fair notice" of exactly what is required of him. *Hughey*, 78 F.3d at 1531. Accordingly, the crux of the clear and unambiguous inquiry is whether the record contains clear and convincing evidence that the defendants understood their obligations under the injunctions.

Each of the Hi-Tech defendants received a copy of the Hi-Tech injunction on December 16, 2008. The FTC has put forth voluminous documentary evidence demonstrating that, after the injunctions had been entered and throughout the time period in which the alleged contemptuous advertising claims were made,

both Wheat and Smith understood that in order for their advertising claims to be substantiated by "competent and reliable scientific evidence," the injunction required RCTs of the products. A bulk of the evidence includes communications to and from Wheat and Smith while Wheat was incarcerated. The court will divide the communications into two separate categories—those among Hi-Tech employees and those that include Hi-Tech's attorneys.

i. Hi-Tech Defendants' Communications

The record contains numerous emails Wheat authored while he was incarcerated showing an express understanding of what the injunction's substantiation standard entailed. In a March 16, 2010, email Wheat sent to Hi-Tech employees Jeff Jones, Brandon Schopp, and Mike Smith using the prison email system, Wheat stated in pertinent part:

> With the FTC's verdict in essence saying 'ingredient-specific advertising' is excluded from 'valid and scientific substantiation,' which is the FTC standard . . . . *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. No. 700-88, p. 3 (emphasis added)].[13] Several days later, on March 22, 2010, in an email he wrote

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[13] The "verdict" Wheat was referring to could only mean the 2008 summary judgment order [Doc. No. 219], which adopted Dr. Aronne's RCT substantiation standard, because the defendants' appeal of that order was still pending at the time Wheat sent the March 16, 2010, email. Although the Eleventh Circuit had entered its judgment on December 15, 2009 affirming the summary judgment order, the defendants requested a rehearing,

from prison to just Smith, Wheat stated "I talked to Vic [Kelley] for a minute about the need for us to advertise in order to build Fastin more and he wants to see if he can get an opinion letter out of Jody [Schilleci] and Tim [Fulmer] as I think he wants to stay on a little longer. We will see what happens as I don't see any of our attorneys agreeing on advertising especially in light of the FTC's current position." [Doc. No. 700-89, p. 4]. The following day, on March 23, 2010, Wheat emailed Smith again, saying ". . . I believe if we are going to advertise we will need to make a change as Jody [Schilleci] will never sign off on those product pages nor the ads as the way the FTC verdict stands it would be false advertising as well." [Doc. No. 700-89, p. 3]. On March 28, 2010, Wheat sent Smith another email saying, ". . . Ullman and Shapiro are not aware of the recent ruling in the 11th circuit against us because if the verdict stands it will allow FTC to win any advertisement case that a company has not done a double-blind placebo study on the product itself." [Doc. No. 700-90].

On July 20, 2010, during a telephone call made while Wheat was incarcerated, he spoke with Smith about a draft Fastin ad [Doc. No. 700-100]. Wheat stated that, after having looked at the injunction, "[t]here were some things like fat loss . . . and there's a couple other things that we're prohibited from saying. Increasing the metabolic rate was claim one. We can't say that." [*Id.* at 5:2–12]. During the same call, Wheat and Smith discussed Hi-Tech attorney Ed Novotny's suggestion to do away with the claim

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which was denied, and the appellate court's mandate was not issued to this court until May 4, 2010 [Doc. No. 277].

"warning, extremely potent diet aid, do not consume." [*Id.* at 5:14–6:9]. Wheat stated during the call, "[R]apid fat loss catalyst . . . would be a claim that [the] FTC would have an issue on" and that with regard to the "rapid fat burner" claim, "we can't say rapid, that's part of our consent decree." [*Id.* at 7:6–14; 8:19–9:1].

At the outset of the 2017 contempt proceedings, the Hi-Tech defendants renewed an objection to the admissibility of correspondence sent to and from Wheat during his incarceration based on the attorney-client privilege. The court overruled the objection at the beginning of the proceedings, and, later, while the proceedings were still ongoing, the court entered an order providing in more detail the court's rationale for overruling the renewed objection [Doc. No. 935]. When the defendants renewed their objection, however, they asserted a blanket objection and did not indicate specifically which communications they claim were cloaked under the privilege. Although the court has already deemed all the communications to be admissible [*see id.*], it finds that the privilege may not even be implicated with respect to the emails identified above and the telephone call between Smith and Wheat.

Even if portions of some of the emails reference Hi-Tech's attorneys, the court finds that "the communication was not 'for the purpose of securing legal advice or assistance.' The communications were, rather, for the purpose of maximizing the business value of [Hi-Tech] and [its marketing]." *Capital Sec. Sys., Inc. v. NCR Corp.*, 1:14-CV-1516-WSD, 2016 WL 4191028, at *3 (N.D. Ga. May 26, 2016). Thus, "legal

advice does not predominate in many of the emails," meaning the communications among the Hi-Tech employees are not privileged in the first place. *Id.* Furthermore, in light of the defendants' failure to specifically identify which email communications they contend are privileged, the defendants have also failed to carry their burden of showing which communications were "for the purpose of obtaining legal advice, not business advice" among employees. *Id.*

Accordingly, when looking at these emails and the telephone call in isolation, the court finds that they clearly and convincingly demonstrate that Wheat and Smith knew that the only way for Hi-Tech to substantiate advertising claims under the injunction was to do RCTs on the products.

ii. Hi-Tech Defendants' Communications with Counsel

In addition to the communications identified above, the record contains additional correspondence among the Hi-Tech defendants and their counsel, which might ordinarily fall under the attorney-client privilege. For the reasons discussed in the court's April 5, 2017, order, however, the court reaffirms its findings that the attorney-client privilege objection is unfounded [Doc. No. 935]. These communications are even more telling of the Hi-Tech defendants' understanding of the substantiation requirement under the injunction.

On April 27, 2010, in an email he wrote from prison to Arthur Leach, Tim Fulmer, and Victor Kelley, Wheat stated: "Over the past few months, I have brought up the subject of advertising with Vic

and he said he was not opposed to it. But the truth remains there is NO lawyer who could render an opinion that an ad is Kosher with the 11th circuit ruling" [Doc. No. 700-92, p. 3 (emphasis original)]. On July 7, 2010, in connection with Hi-Tech's motion for a writ of certiorari to the Supreme Court, after the Eleventh Circuit had affirmed this court's 2008 summary judgment order and injunctions, Wheat authored an email from prison to Arthur Leach and Joseph Schilleci, stating: "[I]f our set of facts is not good enough then a double-blind placebo study would be required." [Doc. No. 700-94, p. 3]. Two days later, on July 9, 2010, Wheat stated in a prison email to Victor Kelley, "I agree with you about the website and have stayed on Jody [Schilleci] about the site. His opinion is anything short of a double-blind study on each product leaves HT [Hi-Tech] open to exposure to the FTC. I somply [sic] can not [sic] quit advertising" [Doc. No. 700-95, p. 3].

Perhaps most telling of Wheat's and his attorneys' understanding of the Hi-Tech injunction's substantiation requirement is a letter Hi-Tech's attorneys provided to Wheat while he was incarcerated. In a memorandum dated June 4, 2010, four Hi-Tech attorneys wrote to Wheat specifically warning him that several proposed Fastin advertising claims would run afoul of the injunction [Doc. No. 700-105, pp. 2–6] ("June 4, 2010 Memo").[14] Victor Kelley testified in the 2014 proceedings that his concern

[14] The court previously determined that the June 4, 2010 Memo is admissible for the reasons discussed in its January 20, 2012, September 18, 2012, and again in its April 5, 2017, orders [Doc. Nos. 365, 433, 935].

about the very real potential for contempt sanctions predicated his role in drafting the June 4, 2010 Memo to Wheat.

Specifically, Hi-Tech's attorneys stated in the letter that they had reviewed several of the proposed Fastin claims in conjunction with the Hi-Tech injunction. Their assessment included a review of the following claims: "***Rapid Fat Loss*** Catalyst, ***Rapid Fat Loss*** Thermogenic Intensifier, ***Increases the Metabolic Rate***, Promoting Thermogenesis (The ***Burning of Stored Body Fat***), Increases the Release of Norepinephrine and Dopamine for ***Dramatic Weight Loss***, Rapid Fat Burner, DO NOT CONSUME UNLESS ***RAPID FAT AND WEIGHT LOSS*** ARE YOUR DESIRED RESULT" *Id.* at p. 3 (bold and italics in original). Each of these claims is included within the totality of claims the FTC alleges violated the injunctions, identified in full above [*See* Part II(B), *supra.*].

In their 2010 review of the claims, Hi-Tech's attorneys noted that these representations "were based upon prior scientific studies on the ingredients in the product, rather than the product itself", which the attorneys believed ordinarily would be compliant with "FTC law" [Doc. No. 700-105, p. 3]. But, the attorneys went on to state that this court's findings "in the FTC Injunction" meant that an ingredient specific argument would be "extraordinarily difficult to make at this time" *Id.* In fact, counsel specifically cautioned Wheat, "[I]t would seem unlikely that 'ingredient specific substantiation' would be considered compliant with [the competent and reliable scientific evidence] provision." *Id.* at 5. Further, Hi-Tech's attorneys

specifically addressed the competent and reliable scientific evidence provision found in Section II of the injunction. Under that standard, counsel again warned Wheat,

> [I]t is safe to say that Judge Pannell did not then and would not now find this form of ingredient specific substantiation to be consistent with the express language in the FTC Injunction requiring "competent and reliable scientific evidence." Rather, based upon Judge Pannell's previous findings, **it is reasonable to assume that he would take a position consistent with the FTC that double-blind, clinical trials of the products were necessary to substantiate the representation.** Although we certainly have not and do not now agree with this position, **at present, *it is the premise upon which the FTC Injunction is based***.

Id. at 4 (emphasis added). Thus, Hi-Tech counsel stated a clear recognition that the Hi-Tech injunction required RCTs to substantiate efficacy claims. Counsel, therefore, expressed that it was "unlikely that in its current form [the proposed Fastin advertisements] would satisfy the prohibitions of the FTC Injunction" *Id.* at 4. Wheat's counsel cautioned him further in the letter saying, "[I]t is our belief that if challenged by the FTC, the Fastin® advertisement, as presently drafted, would be found to be in violation of the FTC Injunction" *Id.* at 5. Consequently, they concluded that "the very real potential for such serious consequences [such as civil and/or criminal penalties] should dictate [Wheat's] decision to withhold the

publication of the Fastin® advertisement as currently printed." *Id.*

These communications provide even more evidence that the Hi-Tech defendants understood the injunction to require RCTs of the products in order to substantiate efficacy claims. In fact, Hi-Tech's counsel specifically cautioned Wheat that, if he continued forward with the Fastin advertisements, he could end up in the very situation he now finds himself.

iii. The Hi-Tech Defendants' Inactions

In addition to the Hi-Tech defendant's *actions*, the record contains evidence of their *inactions* that further demonstrate the Hi-Tech defendants understood their obligations under the injunction. *See, e.g., Combs*, 785 F.2d at 979 (upholding contempt of injunction, noting *inter alia* that "at no time before the trial court did [contemnors] ever complain about the adequacy of the consent decree . . . . They made no attempt to request more specific language; they chose not to exercise their right to the usual remedy for inadequacies of this sort: a motion for clarification or modification of the consent decree."). While this court does not find the absence of seeking clarification on a term of an injunction dispositive on the clear and unambiguous inquiry, it is simply another indication that the defendants understood their obligations under the injunction.

Here, the injunctions provide for ongoing compliance monitoring and the record shows that such monitoring took place. If the Hi-Tech defendants were unsure of what constituted "competent and reliable scientific" evidence while the FTC was monitoring their compliance, they could have easily asked, but they did not. *See Sarcona*, 457 Fed. App'x at 812

(noting that the court was unpersuaded by the contemnor's argument that an injunction violated Rule 65(d) because the contemnor "could have easily asked" about what a term of an injunction meant but did not). The only time Wheat did seek clarity, it was not from the FTC, but from his attorneys. Yet, when Wheat inquired of his attorneys whether several of the exact Fastin claims that are at issue in these proceedings would run afoul of the injunction, his attorneys not only advised Wheat that the claims were not substantiated because they were not backed by any RCTs, but they also specifically cautioned Wheat of the likelihood that he could be found in contempt of the injunction if he went forward with them [Doc. No. 700-105].

Furthermore, the defendants were given an opportunity to object to the scope of the injunctions before they were entered, but they did not object to any of the provisions they ostensibly challenge now. The definition of "competent and reliable scientific evidence" found in the "Definition" section, as well as Sections II, VI, and VII of the FTC's proposed injunctions—the four provisions that are implicated in the instant proceedings—were identical to the final judgments and permanent injunctions that were ultimately entered against the defendants [*Cf.* Doc. Nos. 172-30, 172-31 with 229, 230]. Notably though, the Hi-Tech defendants did not object at all to the definition of "competent and reliable scientific evidence"; they objected only to Section II insofar as it related to Erectile Dysfunction Products, products which are not currently at issue; and they raised no objections of any kind to Sections VI and VII [Doc. No. 220].

Moreover, in the defendants' 2008 appeal, they also did not challenge the injunctions, but rather the court's findings at summary judgment. [See Appeal Brief]. Federal courts have observed, "The time to appeal the scope of an injunction is when it is handed down, not when a party is later found to be in contempt." *TiVo, Inc. v. EchoStar Corp.*, 646 F.3d 869, 880 (Fed. Cir. 2011) (citing *Maggio v. Zeitz*, 333 U.S. 56, 69 (1948) ("It would be a disservice to the law if we were to depart from the long-standing rule that 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.")). While, again, the court does not find the absence of a timely appellate challenge dispositive, it is yet another indication of the Hi-Tech defendants' understanding of the injunction.

iv. Context

The court can also look to the context in which the injunctions were entered when determining if the defendants' obligations thereunder were unambiguous. "Context is often important to meaning, and so it is here." *Riccard v. Prudential Ins. Co.*, 307 F.3d 1277, 1297 (11th Cir. 2002) (finding the context and purpose behind the injunction assisted in interpreting terms contained within the injunction).

When this court granted summary judgment in 2008, it relied on Dr. Aronne's RCT standard as "competent and reliable scientific evidence" for this case because the defendants had failed to challenge that level of substantiation with their own expert evidence. After finding injunctive relief was proper in the same order, the court cautioned the defendants

that, when the court imposed the injunctive relief, it "may be broader than the violations alleged in the complaint." *Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d at 1215. When the injunctions were ultimately entered several weeks later, they contained the very same "competent and reliable scientific evidence" language that was discussed in the summary judgment order. Given the defendants' lack of opposition to the RCT substantiation standard, the court's adoption of that standard, and the court's statement of its intention that injunctive relief might be broader than the precise violations alleged, the court does not find it unreasonable to interpret the injunctions' substantiation requirement precisely the same way the court interpreted it weeks earlier at summary judgment.[15] *Cf. Riccard*, 307 F.3d at 1297 (finding contempt was proper where the district court stated its purpose in imposing injunctive relief and the appellate court found "[t]hat purpose supports interpreting the injunction to cover non-judicial filings," a term that was not specifically included in the injunction itself). Indeed, Hi-Tech's attorneys likewise advised Wheat that it was "reasonable" for the court to find RCTs were necessary to substantiate future claims [Doc. No. 700-105, p. 4].

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[15] *See F.T.C. v. Garden of Life, Inc.*, 516 Fed. App'x 852, 856 (11th Cir. 2013) ("In cases involving the construction of an injunction by the district court that entered it, however, we defer to the district court's interpretation as long as it is reasonable." (citing *Ala. Nursing Home Ass'n v. Harris*, 617 F.2d 385, 388 (5th Cir. 1980) ("Great deference is due the interpretation placed on the terms of an injunctive order by the court who issued and must enforce it.")).

Contrast the foregoing with the context in which the injunction was entered in *United States v. Bayer Corp.*, CV 07-01(JLL), 2015 WL 5822595 (D.N.J. Sept. 24, 2015), a case upon which the defendants extensively and repeatedly rely. While the facts surrounding the litigation in *Bayer* are indeed similar to this case, the procedural posture is noticeably different.

In *Bayer*, the Department of Justice sought to find Bayer, a company that manufactured and distributed dietary supplements, in contempt for violating a consent decree by making claims about its products that the government claimed were unsubstantiated. The district court in Bayer held that the RCT level of substantiation was not found within the four corners of the consent decree, and as such, it was not sufficiently clear and unambiguous for Bayer to be found in contempt. The facts giving rise to that holding are patently different from this case.

First, before the consent decree was entered in *Bayer*, the parties settled the case "without adjudication of the merits of any issue of fact or law." *Id.* at *1. Here, before the injunctions were entered, the court made extensive findings of fact surrounding the defendants' advertising practices, and given the severity of the defendants past and ongoing practices, found injunctive relief was proper.

Second, the court in *Bayer* noted:

> In the seven years after entering the Consent Decree, the Government never told Bayer . . . that drug-level clinical trials or [the government's expert's]—Level RCTs were required. Indeed, counsel for the Government

> conceded in closing argument that "you have to go outside of the four corners of the consent decree" in order to find support for the Government's standard.

Id. at *14. The facts in this case are starkly different. At no point in the nine years after the summary judgment order and injunctions were entered did anyone from the FTC tell the defendants that *anything but* RCTs were required. And, at no point in these proceedings, has the FTC taken the position that one has to go outside the four corners of the injunction to find support for the substantiation standard.

Third, and perhaps most distinguishably, it was not until the commencement of the contempt proceedings in *Bayer*, after the injunction had been entered, that the government for the first time disclosed a substantiation standard similar to what Dr. Aronne provided in this case. *Id.* at *9 (noting that, in moving for contempt, "the Government *for the first time* disclosed the expert opinion of Dr. Loren Laine, who opined that competent and reliable scientific evidence for the . . . claims at issue requires a randomized controlled trial . . . ") (emphasis added). Conversely, the FTC in this case provided Dr. Aronne's RCT standard before the FTC moved for summary judgment in 2008. The defendants then had an opportunity to depose Dr. Aronne over the course of two days in which he was questioned about that standard [Doc. Nos. 186–187]. When the FTC later moved for summary judgment, the defendants failed to counter Dr. Aronne's opinions, so the court relied upon and adopted the RCT standard. Then, after adopting that substantiation standard, the court

entered the injunction that had the same "competent and reliable scientific evidence" language as the summary judgment order, in which the court had already found as a matter of undisputed fact to mean RCTs. The timing in which the FTC's substantiation standard was disclosed, the defendant's opportunity to explore it, their failure to challenge it, and the court's reliance on it, all preceded the date on which the injunctions were entered. These facts are noticeably distinguishable from those in *Bayer*.

The other case the defendants principally rely upon, *Garden of Life, Inc.*, *supra*, is inapposite for the same reasons. Although neither the district court nor the Eleventh Circuit discussed the timing in which the FTC's experts provided the level of evidence necessary substantiate the advertising claims in that case, it is clear from the district court's docket[16] that the FTC's experts were disclosed after it had moved for contempt against the defendant. Thus, similar to *Bayer* and unlike this case, the court in *Garden of Life, Inc.* had not adopted the government's substantiation standard before the contempt proceedings began.

When looking at the totality of the evidence, which the defendants implore this court to do, the court finds that the record clearly and convincingly demonstrates that Wheat understood the injunction required RCTs on the products themselves to substantiate the advertising claims that were made. The evidence also clearly shows that Smith had the same understanding. In fact, in Smith's post-trial

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[16] *See F.T.C. v. Garden of Life, Inc.*, Case No. 9:06-CV-80226, (S.D. Fla. 2012).

briefing he notes while discussing "compliance with the injunction" that "he did not have the power to . . . order double-blind, placebo controlled clinical trials" [Doc. No. 959, pp. 7–8]. This statement is a tacit recognition that RCTs were required in order to comply with the injunction. And, pretermitting whether Smith had enough control to "order" RCTs of the products themselves, the court already found as a matter of fact that Smith had enough independent control of Hi-Tech's product procurement, promotion, and placement, in addition to the running of the day-to-day operations during the time period in question, to effectuate compliance.

Wheat's and Smith's understanding of their obligations under the injunction was also not limited to just the two products that were involved in the 2008 summary judgment proceedings—Thermalean and Lipodrene—because Wheat expressly communicated with Smith and others that RCTs were necessary to substantiate claims for Fastin, a weight-loss product that was not at issue in the 2008 proceedings. In sum, to claim the Hi-Tech defendants believed the term "competent and reliable scientific evidence" as set forth in the Hi-Tech injunction was unclear to them when the advertisements at issue were made is not just unsupported by the record, it is contradicted by it. The FTC has sufficiently carried its burden of proving the Hi-Tech defendants understood their obligations under the injunctions; it is, therefore, clear and unambiguous.

b. Wright's Substantiation

Wright largely incorporates the Hi-Tech defendants' Rule 65(d) arguments to claim Section II

of his injunction was likewise not sufficiently clear and unambiguous. However, the analysis of that inquiry as to Wright is different than that of the other defendants. Section II of the Wright injunction adds a provision that is not included in the Hi-Tech injunction:

> *Provided, however*, that for any representation made as an expert endorser, Defendant must possess and rely upon competent and reliable scientific evidence, and an actual exercise of his represented expertise, **in the form of an examination or testing of the product.**

[Doc. No. 229 (italics in original, bold added)].

The Wright injunction explicitly required him not only to possess competent and reliable scientific evidence when endorsing a product, but also to possess and rely upon "an actual exercise of his represented expertise, in the form of an examination or testing of the product." Wright did not appear or testify in the 2017 bench trial and nowhere in any of his briefs does he contend the express requirement to examine or test the product he endorsed was unclear or ambiguous to him. Simply incorporating and adopting the Hi-Tech defendants' arguments is unavailing because the two provisions are not identically worded. While the court believes there is sufficient evidence that Wright also understood his obligations under his injunction, though differently worded, he has not sufficiently challenged this point.[17] Given the plain meaning of the

[17] Wright also did not object to the substantiation requirement; he did not appeal the scope of it; he did not seek clarity from the

terms contained in Section II of the Wright injunction, his lack of opposition and the evidence in the record, the court finds that the injunction is sufficiently clear and unambiguous.

c. Law of the Case

Putting aside all of the foregoing, the court remains unconvinced that the law of case doctrine is inapplicable and, as such, finds the doctrine provides a separate and distinct basis to conclude that the substantiation standard was clear and unambiguous. *See, e.g., CBS Broad., Inc. v. EchoStar Commc'ns Corp*, 472 F. Supp. 2d 1367, 1371 (S.D. Fla. 2006) (noting that, under the law of the case doctrine, an earlier finding in the litigation was clear and unambiguous, and therefore, the court could not later limit the scope of an injunction because of the earlier ruling).

Although the law of the case rule requires this court to adhere to the Eleventh Circuit's remand order, the appellate court did not find this court erred when it originally relied upon the law of the case doctrine to preclude re-litigation of what constituted competent and reliable scientific evidence in the contempt proceedings. Instead, the Eleventh Circuit held "only that [this court] misapplied collateral estoppel" after "it clarified that it based its ruling that only clinical trials could establish 'competent and reliable scientific evidence' on the doctrine of collateral estoppel, instead of the 'law of the case.'" *Nat'l Urological Grp., Inc.*, 785 F.3d at 481 (emphasis

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FTC; and the context in which his injunction was entered is the same as it was for the Hi-Tech defendants.

added). The Eleventh Circuit has explained the differences between collateral estoppel, or issue preclusion, and the law of the case doctrine. *See In re Justice Oaks II, Ltd.*, 898 F.2d 1544, 1550 n.3 (11th Cir. 1990).

The law of the case "is a rule of practice, based upon sound policy that when an issue is once litigated and decided, that should be the end of the matter." *United States v. U. S. Smelting Ref. & Min. Co.*, 339 U.S. 186, 198 (1950). "Under the law-of-the-case doctrine, [the resolution of] an issue decided at one stage of a case is binding at later stages of the same case." *Toole v. Baxter Healthcare Corp.*, 235 F.3d 1307, 1313 (11th Cir. 2000). "Furthermore, the law-of-the-case doctrine bars relitigation of issues that were decided either explicitly or by necessary implication." *This That And The Other Gift And Tobacco, Inc. v. Cobb Cty., Ga.*, 439 F.3d 1275, 1283 (11th Cir. 2006) (citing *Klay v. All Defendants*, 389 F.3d 1191, 1198 (11th Cir. 2004) ("Realizing that a prior decision is law of the case as to matters decided explicitly and by necessary implication, we find that our prior affirmation of the district court constitutes law of the case here . . . .") (other citations omitted)); *see also Wheeler v. City of Pleasant Grove*, 746 F.2d 1437, 1440 (11th Cir. 1984) (per curiam) (holding that the law of the case doctrine "comprehends things *decided by necessary implication* as well as those decided explicitly") (italics in original).

As noted above, the court found in the 2008 summary judgment proceedings that the defendants had failed to challenge "the testimonies of the FTC's experts regarding what level of substantiation is

required for the claims made in this case." *Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d at 1202 (emphasis added). The phrase "in this case" is important because the instant contempt proceedings are in the same case in which the court already has held "that some form of clinical trial must have been conducted on the product itself or an exact duplicate of the product." *Id.* Thus, while the products and claims at issue in the 2008 proceedings are different from those in the instant contempt proceedings, the court has already resolved the issue of what type of "evidence [is] required to substantiate weight loss claims for *any* product, including a dietary supplement" in this case. *Id.* (emphasis added). That resolution is from an earlier stage of the litigation, making it binding at this later stage of the same litigation. *See Toole, supra; see also Sherley v. Sebelius*, 689 F.3d 776, 782 (D.C. Cir. 2012) (holding law of the case applied to an earlier ruling from a preliminary injunction review to a subsequent motion for summary judgment because the ruling "was established in a definitive, fully considered legal decision based on a fully developed factual record and a decisionmaking process that included full briefing and argument without unusual time constraints"); *Entm't Prods., Inc. v. Shelby Cty., Tenn.*, 721 F.3d 729, 742 (6th Cir. 2013) (rejecting the appellant's challenges to the scope of terms of an ordinance on appeal because the court had previously defined those terms when ruling on a preliminary injunction).

While these contempt proceedings were ongoing in 2013, Hi-Tech filed a declaratory judgment action against the FTC in the United States District Court for the District of Colombia. It sought an order

"declaring that the term 'competent and reliable scientific evidence,' as used in a Final Judgment and Permanent Injunction issued in [this case], 'has no fixed meaning' and 'requires case, product and claim specific adjudication and may result in different meanings even in the same case.'" *Hi Tech Pharm., Inc. v. Fed. Trade Comm'n*, 6 F. Supp. 3d 95, 97 (D.D.C. 2013).[18]

District Judge Emmet Sullivan recounted the procedural posture of the case. Judge Sullivan noted that this court in the 2008 summary judgment order "accepted the FTC expert's conclusions regarding the appropriate level of substantiation," and that, in order to substantiate claims, Hi-Tech was required to conduct RCTs on the product itself or an exact duplicate of the product. *Id.* at 97. According to Judge Sullivan, "[t]hese standards were incorporated in a permanent injunction entered in December 2008." *Id.* Consequently, as it related to the declaratory judgment action, Judge Sullivan held:

> Hi-Tech cannot circumvent Judge Pannell's multiple rulings on the substantiation standard, made after years presiding over the case, by trying to re-litigate an already-decided question in this Court. Contrary to [Hi-Tech's] allegations that the FTC has somehow amended the substantiation standard and now requires 'in all cases, a

[18] The court takes judicial notice of this other case. *United States v. Jones*, 29 F.3d 1549, 1553 (11th Cir. 1994) ("[A] court may take notice of another court's order only for the limited purpose of recognizing the 'judicial act' that the order represents or the subject matter of the litigation.").

> double blind, placebo-controlled, product specific study,' . . . that requirement was imposed by the Court and *is the law of the case in the Enforcement Action.*

Id. at 100 (emphasis added). Thus, Judge Sullivan not only independently concluded that the RCT standard had been incorporated into the injunction and that the law of the case doctrine prevented relitigation of that requirement, but he applied the doctrine to prevent precisely what the Hi-Tech defendants were attempting to do through filing the declaratory judgment action: "panel shopping" the question of what constitutes competent and reliable scientific evidence. *Klay*, 389 F.3d at 1191 (noting one of the purposes of the doctrine is "the discouragement of panel shopping").

Although the defendants claim that it is unjust for the court to impose the substantiation standard relied upon and adopted in the 2008 summary judgment order in these contempt proceedings, the court finds it would be unjust not to. The defendants had a full and complete opportunity to challenge the substantiation standard before the summary judgment stage, but they did not. They instead argue now that their claims are substantiated by ingredient-specific studies which the court previously found to be unavailing. *Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d 1203 n.21. It is both illogical and improper for the court to unwind all of its findings of fact and conclusions of law from an earlier stage of the litigation and the foundation upon which the injunctions now stand only to impose a totally different standard at a later stage of the same proceedings.

The court agrees with the defendants' position that RCTs may not necessarily be required in other FTC enforcement actions, given the FTC's own guidance through its *Dietary Supplements: An Advertising Guide for Industry* ("FTC Advertising Guide") [Doc. No. 701-3]. But, the court has already decided the issue of what evidence is necessary to substantiate claims for any products in *this* case, and that does not mean an RCT standard should be imposed on all products in all cases. *See Fed. Trade Comm'n v. Coorga Nutraceuticals Corp.*, 201 F. Supp. 3d 1300, 1311 (D. Wy. 2016) ("While it is true . . . that the FTC's advertising guide suggests there may be other evidence that could be sufficient and that a double-blind study is not *necessarily* required in all instances, the FTC has established that a human clinical trial is required for the claims made by Defendants.") (emphasis original).

To be clear, the court does not reference the law of the case doctrine so as to preclude the defendants of an opportunity to present evidence regarding whether they met the injunction's substantiation standard when advertising the products at issue. Rather, the court references the doctrine as a means of demonstrating that the scope of the injunctions' substantiation standard has been a decided issue in this litigation for almost a decade, thus further evidencing the defendants' understanding of their obligations under the injunctions. Indeed, given the voluminous evidence showing the Hi-Tech defendants and their attorneys similarly understood the substantiation standard to mean RCTs before the FTC even moved for contempt, confirms their implicit

recognition of the appropriateness of the law of the case doctrine even before the court applied it.

d. Obey The Law Defense

The court has already expressly rejected the defendants' arguments that the injunctions are invalid "obey-the-law" injunctions [*see* Doc. No. 422, pp. 7–9], and the defendants did not raise the argument in their Appeal Brief. Upon reviewing the defendants' new iteration of this same argument, they do not point to any change in authority or circumstances to warrant this court departing from its earlier findings. The defendants previously cited many of the same cases they now rely upon (which this court previously reviewed and distinguished), perhaps explaining why the argument has been relegated to a footnote in their post-trial briefing. In any event, the court will address the argument again.

Challenging an injunction on the grounds that it is an obey the law injunction is simply a Rule 65(d) argument, just stated in different terms. *See Burton v. City of Belle Glade*, 178 F.3d 1175, 1201 (11th Cir. 1999) (stating that injunction which only instructed defendant to "obey the law" would not satisfy the specificity requirements of Rule 65(d)); *see also Smyth*, 420 F.3d at 1233 n.14 (same). "As the name implies, an obey-the-law injunction does little more than order the defendant to obey the law." *Goble*, 682 F.3d at 949. Thus, an injunction that requires someone to simply obey the law fails to meet the specificity requirement of Rule 65(d) because those enjoined must know what conduct the court has prohibited. *Smyth*, 420 F.3d 1225, 1233 n.14.

As the court discussed in detail above, the defendants clearly understood their obligations under the injunctions. For this reason alone, their alternative Rule 65(d) argument fails. Even if, however, the "competent and reliable scientific evidence" terminology used in the injunctions is derived from the FTC Advertising Guide, the guide does not have the force of law and cannot be independently enforced by the FTC. *See Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1204 (2015) (holding that interpretive rules, which are rules "issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers . . . do not have the force and effect of law and are not accorded that weight in the adjudicatory process"); *see also Hi-Tech Pharms., Inc. v. Crawford*, 505 F. Supp. 2d 1341, 1351 (N.D. Ga. 2007) (explaining the difference between substantive and interpretive rules). The cases relied upon by the defendants are inapposite because they involve injunctions that incorporated substantive federal statutes that prohibit certain conduct regardless of whether an injunction is in place. *Cf. Payne v. Travenol Labs., Inc.*, 565 F.2d 895, 898 (5th Cir. 1978) (Title VII); *Burton*, 178 F.3d at 1175 (§ 1983); *Goble*, 682 F.3d 948 (§ 10(b) of 15 U.S.C. § 78j(b)). Requiring the defendants to substantiate advertising claims with RCTs did not obligate them to simply obey the law. The court prohibited certain conduct, and the record is clear that the Hi-Tech defendants were equally aware of that prohibited conduct. *See SEC v. N. Am. Clearing, Inc.*, 656 Fed. App'x 969, 972 (11th Cir. 2016) ("[A] broad, but properly drafted injunction, which largely uses the statutory or regulatory

language may satisfy the specificity requirement of Rule 65(d) so long as it clearly lets the defendant know what he is ordered to do or not do.").

e. Wheat's First Amendment Violation Claim

In a somewhat related argument, Wheat raises a separate claim that imposing product-specific RCTs raises "serious First Amendment concerns." Wheat goes on to state, "[U]nder the government's substantiation standard, scientific certainty would be required before a company like Hi-Tech or an individual like Mr. Wheat could lawfully speak about its products . . . ." [Doc. No. 963, p. 13]. Wheat's argument is specious.

The purported First Amendment violation is simply a repackaged argument the defendants already put forth in the 2008 summary judgment proceedings, which this court found the defendants to have "misapplied." *Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d at 1185 (holding that "the defendants employ circular logic" by contending the court "must use the *Central Hudson* test—which applies only to protected speech—to determine whether speech is protected). Perhaps the court's prior rejection of the defendants' First Amendment violation claim is the reason Wheat concedes shortly after raising the First Amendment concern that the "Court need not wrestle with that [First Amendment] constitutional question" [Doc. No. 963, p. 15]. Wheat raising "serious First Amendment concerns" only to effectively abandon the claim in the same brief is just one example of many illustrating the defendants' attempts to muddy the water with numerous and competing arguments to presumably

divert the court from the primary question before it: whether the defendants are in contempt of a court order.

The First Amendment argument overlooks the fact that the contempt proceedings are exactly that—proceedings to determine whether the defendants violated an order of the court, not whether the government is able to, for example, prospectively restrain certain speech. *Cf. Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) (the only case Wheat substantively relies upon, which notably does not involve contempt proceedings for contumacious conduct). By enforcing the terms of an order that prohibits certain conduct, this court is not attempting to restrain "a company *like* Hi-Tech or an individual *like* Mr. Wheat" from lawfully speaking about its products, as Wheat contends. To the contrary, the court is enforcing a restriction that was placed upon specifically Hi-Tech and specifically Wheat to prevent further deceptive advertising practices. *See Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc*, 425 U.S. 748, 771 (1976) (noting that untruthful commercial speech "has never been protected for its own sake"); *Bristol-Myers Co. v. FTC*, 738 F.2d 554, 562 (2d Cir. 1984) ("[D]eceptive advertising enjoys no constitutional protection.").

Wheat's "one goal" defined on the Hi-Tech website is to "produce the highest-quality, scientifically proven sports nutrition supplements and performance nutraceuticals in the world," and they are "dedicated to setting a higher standard of scientific excellence for

the dietary supplement industry."[19] Requiring Hi-Tech to substantiate its product efficacy claims with a specific level of scientific evidence did not impose any restriction on Hi-Tech that exceeded the high standard of scientific excellence Hi-Tech claims to have already imposed on itself.

3. The Ability to Comply

Having found the injunctions were clear and unambiguous, the court now determines whether the defendants had the ability to comply. Cases that involve a contemnor's inability to comply with an injunction typically involve monetary payments that are required under the injunction. *See, e.g., United States v. Hayes*, 722 F.2d 723, 725 (11th Cir. 1984); *see also Combs*, 785 F.2d at 984. Here, the record clearly establishes that the Hi-Tech defendants had the ability to comply with the injunctions in a number of ways: refraining from selling these products altogether, conducting RCTs on the products to substantiate the existing claims, or advertising by means other than asserting causal efficacy claims. As to Wright, he could have either not endorsed the products or substantiated the endorsement in a manner consistent with the injunction. The evidence clearly and convincingly demonstrates that the defendants had the ability to comply with the injunctions.[20]

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[19] http://hitechpharmaceuticals.com/about_corporate.php (last viewed August 3, 2017).

[20] The court notes that Wheat does posit an inability defense when explaining his noncompliance. At this stage of the contempt framework, however, the court focuses on the FTC's burden and it has convincingly demonstrated that the defendants had the

4. Whether the Defendants Complied

Having found that the FTC has proven by clear and convincing evidence that the injunctions were valid and lawful, they were clear and unambiguous, and the defendants had the ability to comply, the court will determine whether the defendants violated the injunctions.

a. The Hi-Tech Defendants

Section II of the Hi-Tech injunction prohibits the Hi-Tech defendants from claiming their products "cause[] rapid or substantial loss of weight or fat," or "affect[] human metabolism, appetite, or body fat," unless those claims are true and are substantiated by "competent and reliable scientific evidence" at the time the representation was made. Section VII of the Hi-Tech injunction prohibits "any . . . representation . . . about the . . . absolute or comparative benefits of any covered product or service, unless, at the time the representation is made, Defendants possess and rely upon competent and reliable scientific evidence."

Based on its review of the advertisements, the court finds the following: the Hi-Tech defendants made express claims that Fastin, Lipodrene, and Stimerex-ES cause rapid or substantial loss of weight; the Hi-Tech defendants made express claims that Fastin, Lipodrene, Benzedrine, and Stimerex-ES cause rapid or substantial loss of fat and affect body fat; the Hi-Tech defendants made express claims that Fastin and Lipodrene affect human metabolism; the Hi-Tech defendants made express claims that Fastin,

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ability to comply. The court will address Wheat's and the other defendants' explanations of their noncompliance below.

Lipodrene, and Benzedrine affect appetite; and the Hi-Tech defendants made an express claim that Stimerex-ES has comparable efficacy to supplements containing ephedrine alkaloids. Accordingly, these claims trigger the substantiation requirement under Sections II and VII of the Hi-Tech injunction, which means that at the time the representations were made, the Hi-Tech defendants must have possessed competent and reliable scientific evidence in the form of RCTs on the products to substantiate the claims. When the court considers the testimony of all the defendants' experts, it is clear that no one, whether retained by Hi-Tech for this case or not, performed an RCT of any kind on any of the four products. Although some of the Hi-Tech defendants' experts relied on RCTs, those clinical trials were done on other products, not Fastin, Lipodrene, Benzedrine, and Stimerex-ES.

For example, Wheat purportedly relied upon the results from RCTs a competitor did of a product named Meltdown, a dietary supplement that has a different product formulation than each of the four Hi-Tech products at issue. The Meltdown studies fail to satisfy the RCT requirement for this case because it was not done on the products themselves or an exact duplicate. Instead, the studies examined a dietary supplement with significantly different ingredients, potencies, and formulations than the four products in this case. Moreover, none of the Meltdown studies measured end points such as weight loss, fat loss, or appetite suppression and thus cannot be used to substantiate such claims for Hi-Tech's products.

Notably, Wheat did commission three RCTs on behalf of Hi-Tech, and he points to those studies as competent and reliable scientific evidence to substantiate claims for the four products. Those RCTs, however, were done on variants of Fastin: Fastin-XR and Fastin-RR. Consequently, these studies also fail to satisfy the RCT requirement for this case because they were not done on the Fastin product itself or an exact duplicate. Like the Meltdown studies, Fastin-XR and Fastin-RR have ingredients that are not common to Fastin, and of the common ingredients, the ingredients are not present in identical amounts as those in Fastin.

Since the introduction of the Fastin-XR and RR studies, the court has been perplexed by the defendants' apparent reliance on them because they undermine the defendants' position. To begin with, they clearly do not constitute competent and reliable scientific evidence for purposes of this case because they were not done on Fastin or an exact duplicate of it.

Moreover, Hi-Tech commissioning an RCT dismantles their argument that RCTs are fiscally and temporally unviable. Completing RCTs on different products clearly shows the defendants had the means and opportunity to conduct RCTs on the four products at issue, but simply did not. Dr. Jacobs, who performed the tests, was essentially on a retainer during the time period at issue and was qualified, at least from the defendants' perspective, to conduct the clinical trial. Wheat previously testified that he paid Dr. Jacobs "around $42,000" to complete the Fastin-XR metabolism study [Doc. No. 619, 49:12–50:1].

Assuming Wheat had commissioned a similar study of Fastin to substantiate claims for that product, the price for the study would be an infinitesimal portion of the $29,510,292 of billings Hi-Tech made on Fastin during the time period in question [Doc. No. 905]. Hi-Tech was clearly able to afford RCTs on the four products at issue because it did them for other products. Hi-Tech was also able to commission the RCTs for Fastin-XR and RR in time to make claims for those products without them becoming obsolete. Indeed, Wheat admitted in an email to Smith on March 28, 2010, that "[Hi-Tech] could get a [RCT] study done in 3–4 months if we had to . . . ." [Doc. No. 700-90, p. 3].

Furthermore, if the Hi-Tech defendants believed RCTs were not necessary to substantiate efficacy claims, as they claim, the court questions why they were done at all. Wheat testified in the 2014 proceedings that he had asked Dr. Jacobs to conduct the Fastin XR study because he "wanted to be able to make some real claims, some claims as to what the product does rather than generalities. . . . I wanted to make much more certain advertisements." *Id.* at 50:2–8. Yet, when the Hi-Tech defendants attempt to substantiate the claims for Fastin and the other three products, they point to RCTs of different products, containing different product ingredients, having different formulations, during a different time period. The court can only presume the Hi-Tech defendants chose not to commission RCTs of the four products at issue because of the concern that they might not receive the desired outcome necessary to corroborate the claims that they had made. Of course, the court does not know whether any such study would provide

the data to support the causal efficacy claims made for these four products, which is precisely why those claims remain unsubstantiated. The record is devoid of any evidence that the Hi-Tech defendants relied upon RCTs to substantiate the advertising claims for the four products. The claims are unsubstantiated and thus violate the Hi-Tech injunction.

b. Wright

Section II of the Wright injunction requires that, in addition to possessing competent and reliable scientific evidence when endorsing any Hi-Tech product, Wright also rely on "an actual exercise of his represented expertise, in the form of an examination or testing of the product." Wright has not pointed to any evidence showing he tested Fastin before endorsing it. He does claim, however, that he examined the product through an analysis of the particular ingredients [Doc. No. 483, ¶ 22]. In his declaration the court assumes he relies upon to support this statement,[61] Wright does not include any details about actually examining or testing the Fastin product. Rather, he simply refers to ingredient studies that Wheat also purportedly relied upon and then claims, in conclusory fashion, that those studies constitute competent and reliable scientific evidence. Wright's averments do not reference any actual

[61] Wright cited to Doc. No. 372-2, ¶¶ 6–9 to support the statement, but that document is a declaration of Wheat and offers no explanation of Wright's purported examination. The court assumes Wright intended to cite to Doc. No. 372-1, which is Wright's earlier declaration he submitted in opposition to the FTC's motion to show cause why the defendants should not be held in contempt.

testing or examination of the specific ingredients, quantities of ingredients, or formulations in Fastin. Nor does Wright explain how, based on an actual exercise of his represented expertise in bariatrics, the specific ingredients within Fastin substantiate his endorsement that Fastin is, for example, an "extreme fat burner." Surprisingly, Wright even states in another declaration that he "did not believe that the Injunction required testing on the product itself," which is a pronouncement of his candid refusal to comply with that provision [Doc. No. 483, ¶ 25]. The court finds Wright's endorsement of Fastin violated his injunction.

5. Explanation for Noncompliance

Since a prima facie showing of a violation has been made, the burden shifts to the defendants to explain their noncompliance. *Chairs*, 143 F.3d at 1436. The Supreme Court has made clear, however, that "[t]he absence of wilfulness does not relieve from civil contempt." *McComb v. Jacksonville Paper Co.*, 336 U.S. 187, 191 (1949). The Eleventh Circuit has similarly recognized that "substantial, diligent, or good faith efforts are not enough; the only issue is compliance." *Leshin*, 618 F.3d at 1232 (citing *Combs*, 785 F.2d at 984; *Newman v. Alabama*, 683 F.2d 1312, 1318 n.16 (11th Cir. 1982)).

a. Wheat's Noncompliance

Wheat contends in his post-trial briefing that Dr. Aronne has offered conflicting testimony regarding the size and scope of the RCTs necessary to substantiate efficacy claims. The original standard provided by Dr. Aronne in the 2008 proceedings, according to Wheat, required a clinical trial similar to

a Phase III drug trial, which needed up to one thousand test subjects over an eighteen-month period. Wheat estimated that study would cost Hi-Tech $600 million per product to complete. In the 2017 proceedings, however, Wheat claims Dr. Aronne testified that a smaller RCT, having no less than 30 subjects per arm[22] over a six-month period, would constitute competent and reliable scientific evidence. Wheat claims that "had he been aware that he only needed to meet the Aronne Standard version [i.e. the smaller and shorter RCT] . . . he would have acted differently." [Doc. No. 963, p. 11]. Wheat referred to Dr. Aronne's supposed conflicting RCT standard as a "moving goalpost," which was "problematic and inhibited [Wheat's] ability to comply with the Injunction" *Id.* at 10. Thus, Wheat effectively argues that, while he may have had a "general notice of the RCT requirement,"[23] he was unable to comply because the RCT standard itself was unclear.[24]

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[22] An "arm" of a clinical trial is another word for a group of test subjects. For instance, if a clinical trial tests a compound against a placebo, the study would have two arms: a compound group and a placebo group [Doc. No. 945, 55:18–56:2].

[23] Doc. No. 963, p. 10 n.2. The court notes here that Wheat's admission in his post-trial brief of having general notice of the RCT standard is yet another example that Wheat did not have to go outside the four corners of the injunction to understand his obligations.

[24] Wheat appears to have asserted this argument primarily to support his lack of specificity challenge under Rule 65(d). The court rejects that argument for the reasons discussed in Part III(B)(2) *supra*. Since Wheat has also raised the argument to explain his noncompliance, the court will address it in that light herein.

Where, as here, the putative contemnor claims an inability defense, he "must go beyond a mere assertion of inability." *Hayes*, 722 F.2d at 725. "Rather, in this circuit, a party subject to a court's order demonstrates inability to comply only by showing that he has made 'in good faith all reasonable efforts to comply.'" *United States v. Roberts*, 858 F.2d 698, 701 (11th Cir. 1988) (citing *United States v. Rizzo*, 539 F.2d 458, 465 (5th Cir. 1976)). The Eleventh Circuit "construe[s] this requirement strictly," thus making it a "high standard" to overcome. *Combs*, 785 F.2d at 984; *see also Hayes*, 722 F.2d at 725 (finding that not even "some effort" was enough to support an inability to comply defense).

The premise of Wheat's reason for noncompliance—that Dr. Aronne provided conflicting RCT standards—is unsupported by the record. Dr. Aronne testified in the 2017 proceedings that the minimum number of participants one could have in a clinical trial in order to show efficacy is "30 subjects in each arm" [Doc. No. 945, 55:6–17]. Wheat claims that number is inconsistent with Dr. Aronne's opinion from his original expert report, which states "side effects may occur at a rate of 1 in 1000 subjects studied would not necessarily be discoverable in a small study of 20 or 40 subjects. In fact, side effects that may occur at an even higher incidence rate of 1 in 100 subjects studied may still not necessarily be discoverable in such small studies" [Doc. No. 946, 35:14–36:5]. This appears to be Wheat's basis for claiming that Dr. Aronne initially opined that RCTs involving thousands of enrollees were required. Such an argument is unfounded for a number of reasons.

First, the opening sentence to the paragraph of Dr. Aronne's report from which Wheat pulls the moving goalpost theory plainly states, "[T]here is no one magic number of subjects for scientific studies." Hi-Tech's counsel made clear during the 2017 cross examination of Dr. Aronne that the three different versions of his expert reports throughout the years of this litigation have remained unchanged [Doc. No. 946, p. 36]. Therefore, Dr. Aronne has always held the opinion that there is no "magic number" of participants.

Second, Dr. Aronne's opinion regarding larger studies of 1,000 subjects very clearly pertained to trials that measured "side effects" associated with the product. None of the purported violative advertising claims Hi-Tech made were claims about the products having virtually no side effects. Thus, it is neither the FTC's nor Dr. Aronne's position that a study size of 1,000 people is necessary to substantiate the efficacy claims that were made.

Third, when asked what Dr. Aronne would consider the minimum number of subjects necessary to show the effectiveness of a product, Dr. Aronne clearly testified both in his 2016 deposition and in the 2017 bench trial that thirty people per arm would be sufficient. Hi-Tech's counsel attempted to impeach Dr. Aronne during the 2017 bench trial by claiming he previously opined in his deposition that 200 subjects were necessary to establish efficacy claims [Doc. No. 866-4, 199:24–202-18]. But, as Dr. Aronne explained during his deposition and at the bench trial, that figure would be the minimum necessary to determine efficacy, as well as side effects. In fact, during the

same line of questioning that Hi-Tech's counsel omitted from his attempted impeachment during the 2017 proceedings, counsel asked Dr. Aronne if he agreed that a trial could be smaller than 200 if one was only trying to determine efficacy, and Dr. Aronne agreed. Elsewhere in the deposition, Dr. Aronne specifically testified consistent with his in-court testimony that a clinical trial having only thirty subjects per arm would be sufficient [Doc. No. 866-4, 45:20–46:19].

Fourth, Dr. Aronne was first deposed in 2006, and Hi-Tech's counsel questioned him about the RCT standard. Defense counsel has not pointed to any 2006 testimony where Dr. Aronne was asked what he believed the minimum number of subjects would be needed to substantiate causal efficacy claims, and the court, after reviewing the deposition testimony, is also unaware of any such opinion [Doc. No. 186–187]. Therefore, Dr. Aronne did not originally set some unattainable number of study subjects only to reduce that figure in the contempt proceedings as part of some gamesmanship to claim that Hi-Tech could have easily complied but did not. Rather, it was Hi-Tech, who took a snippet from Dr. Aronne's report after the FTC moved for contempt, and claimed Dr. Aronne had advocated an RCT of similar proportion to a pharmaceutical drug trial was the only the type of evidence Hi-Tech could rely upon for efficacy claims. And, because Hi-Tech could not afford such an RCT that Wheat speculated would cost $600 million, its noncompliance should be excused.

However, the record is devoid of any evidence demonstrating Wheat made any effort, much less "all

reasonable efforts," to perform an RCT of any size or duration on the products at issue. Neither he nor any of the Hi-Tech defendants sought clarity from Dr. Aronne or the FTC to clear up any apparent confusion he had about the size of the trial needed. Wheat also did not present any evidence of even an attempt to commission an RCT. He instead chiefly relied upon ingredient specific studies, which Dr. Aronne had rejected, and this court previously found to be unavailing. Hi-Tech then, perplexingly, commissioned RCTs of different products. Since those studies were not done on any of the four products at issue, the only probative value of such evidence is to show Hi-Tech had the wherewithal to complete RCTs but chose not to for these four products. Had Hi-Tech completed RCTs on the four products and the FTC's experts challenged the veracity of those clinical trials, the court would likely agree with the defendants that this case amounted to a battle of the experts. But, those are not the facts before the court. Hi-Tech was not even playing on the same field on which the purported moving goalpost was located.

It bears repeating that Hi-Tech was required to complete RCTs to substantiate the causal efficacy claims that were identified in the injunction. Hi-Tech could have foregone these trials altogether by not making as brazen of claims as it did, like guaranteeing "extreme weight loss," comparing Fastin to a "pharmaceutical-grade dietary supplement indicated for weight loss," or warning consumers not to take the product unless "rapid fat and weight loss" were the desired result.

The record is clear that Wheat knew RCTs were required, and he admits as much in his post-trial brief. Yet, Wheat and Hi-Tech did nothing at all, a far cry from "all reasonable efforts," to effectuate compliance with the RCT requirement. In fact, the evidence in the record demonstrates that Wheat decided to disregard his attorney's advice, which sternly cautioned him against making several of the claims, and the express requirements of the injunction. An email Wheat sent from prison shortly after learning the Eleventh Circuit had denied Hi-Tech's petition for rehearing on the appellate court's opinion affirming the 2008 summary judgment order and injunctions provides a glimpse into his reasoning: "I [Wheat] believe the FTC will probably not start their enforcement until after the Supreme Court rules. In the meantime I am going to go for broke advertising Fastin and HT [Hi-Tech] products." [Doc. No. 700-92, p. 3]. It was time to "swing for the fence" *Id.*

Wheat has failed to support his inability defense with any credible evidence. His explanation does not relieve him from contempt.

b. Smith's Noncompliance

Smith contends he could not effectuate compliance with the injunction because he did not have the requisite control. The court has already rejected the contention that Smith did not have sufficient control in the initial findings of facts. The court similarly rejects that contention here for the reasons enumerated above.

c. Wright's Noncompliance

Wright's attempt at excusing his noncompliance is that his endorsement is adorned with puffery, so

those claims are not actionable. Wright's argument is unsupported. This court has observed that representations generally attributed to puffery include "general opinion . . . such as a representation that [the product] is 'the best' or 'superb,' or other subjective, imprecise representations." *In re Wright Med. Tech. Inc., Conserve Hip Implant Products Liab. Litig.*, 178 F. Supp. 3d 1321, 1359 n.25 (N.D. Ga. 2016), *aff'd in part sub nom. Christiansen v. Wright Med. Tech., Inc.*, 851 F.3d 1203 (11th Cir. 2017). Here, Wright, like the other defendants,[25] made express causal efficacy claims that the product(s) burned fat and caused weight loss, for example. Thus, unlike the claims in *Basic Research, L.L.C. v. Cytodyne Techs., Inc.*, 2:99-CV-343K, 2000 WL 33363261, at *9 (D. Utah Dec. 20, 2000)—an extrajurisdictional case, and the only case, upon which Wright and the Hi-Tech defendants rely—the representations in the Fastin endorsement and the other product advertisements are not "the type of blustering and boasting on which no reasonable person would rely." *Id.* While the court agrees that some of the claims, including the Fastin endorsement, may contain puffery, those claims were "based on the factual predicate" that the products actually caused weight loss, fat loss, etc. *In re Wright*, 178 F. Supp. 3d at 1359 n.25. As the court noted in the 2008 summary judgment order, "[t]he fact that puffery is present cannot serve as a shield for the advertisements' deceptive, factual representations . . . puffery is not a justifiable defense." *Nat'l Urological*

[25] Because the Hi-Tech defendants discuss puffery in their briefing—albeit more indirectly—the court rejects their argument for the same reasons discussed herein.

Grp., Inc., 645 F. Supp. 2d at 1206. The court was not "persuaded by the single paragraph the [defendants] devoted to this argument" in 2012, and the court remains unpersuaded by the single paragraph they devote to the argument now.[26] Wright has failed to explain his noncompliance; he also cannot be relieved from contempt.

6. The Defendants Violated Sections II and VII

After a careful review of the parties' arguments and the record and applying them to this Circuit's civil contempt framework, the court finds the FTC has established by clear and convincing evidence that both the Hi-Tech and Wright injunctions were valid and lawful; Sections II and VII of the Hi-Tech injunction and Section II of the Wright injunction were clear and unambiguous; and the defendants had the ability to comply with those respective provisions but did not. The defendants failing to satisfy the "competent and reliable scientific evidence" standard of the injunctions by not possessing substantiation evidence in the form of RCTs of the four products themselves authorizes a finding of contempt.

C. The Expert Testimony Surrounding the Substantiation Requirement

Rather than relying upon RCTs of the products themselves, the defendants claim to have relied upon numerous other scientific studies that they contend constitute "competent and reliable scientific evidence." This reliance further belies the defendants' assertion that the injunctions were not sufficiently

[26] Doc. No. 390, pp. 6–7.

clear and unambiguous because the defendants evidently recognized the need to possess "competent and reliable scientific evidence," just not the same type of evidence the FTC claims (and the court agrees) was and continues to be required under the injunctions. Yet, even if the court were to credit the defendants' position as to what type of "competent and reliable scientific evidence" was necessary to comply with the injunctions—as advocated by the defendants at the 2017 hearing—the inquiry does not end. In other words, even if the court agreed with the defendants' stated understanding of what type of evidence they must possess to comply with the injunctions, the defendants would still be in contempt if that evidence does not *substantiate* the claims they made.

The phrase "competent and reliable scientific evidence" and the word "substantiates" are contained within the same sentence in both Sections II and VII of the injunctions, thus requiring the defendants to "possess and rely upon competent and reliable scientific evidence that substantiates the representation" [Doc. Nos. 229, 230]. As noted above, "competent and reliable scientific evidence" is defined in the injunction. The term "substantiates" is not explicitly defined, but it is a word of ordinary meaning. To substantiate means "[t]o prove the truth of (a charge, claim, etc.)." *Substantiate*, OXFORD ENGLISH DICTIONARY (June 2017). Tying all of this together, when the defendants made claims that triggered Sections II and VII of their respective injunctions, to avoid violating those sections, they needed to not only possess "competent and reliable scientific evidence" at the time the representations were made, but that

evidence must also prove the truth of the claims asserted.

The defendants devote a majority of their attention to the issue of whether the studies they relied upon constitute "competent and reliable scientific evidence," but when discussing whether that evidence actually "substantiates" the claims, their experts shy away from that word and use others like "aid" and "support." While the difference may be seemingly minor, the court finds that it is not simply a coincidence. Selectively relying upon the word "possess" untethered to the words that follow—"that substantiates the representation"—excludes a central requirement of the injunctions and one of the primary reasons they were issued in the first place. Accordingly, if the court, in "exercis[ing] its discretion to determine the admissibility of any evidence offered by the Commission and by the contempt defendants," finds that the defendants' reliance materials do not actually substantiate the defendants' claims, a finding of contempt is appropriate. *Nat'l Urological Grp., Inc.*, 785 F.3d at 483.

Before discussing the expert testimony in more detail, the court reiterates that both the 2014 and 2017 contempt proceedings were bench trials, which means the court is in the unique position of being both the fact finder and gatekeeper for expert testimony. To that end, the court must not only examine each expert's testimony through the lens of *Daubert* and its progeny, but it must also weigh the testimony of each expert in the court's role as fact finder. The court recognizes that the primary purpose behind *Daubert* of protecting a jury from unreliable expert testimony

is relaxed when the court is making both the reliability and fact finding determinations itself. *See United States v. Brown*, 415 F.3d 1257, 1270 (11th Cir. 2005).

The court will review the testimony of each expert to demonstrate why it believes the defendants' claims have yet to be proven and, thus, why they are unsubstantiated. Before discussing the FTC's expert evidence, the court will address the defendants' pending motions to exclude.

1. Dr. Aronne

The defendants moved to exclude Dr. Aronne's opinions before the 2017 bench trial commenced [Doc. No. 866]. In their motion, the defendants do not challenge Dr. Aronne's qualifications and recognize that he is a "well-respected physician." Given their lack of opposition, the court does not need to discuss Dr. Aronne's qualifications in great detail. Dr. Aronne is qualified as an expert in the fields of weight loss and obesity.

Turning to the defendants' primary argument to exclude Dr. Aronne's testimony, they claim his opinions are not helpful. The court readily finds that argument baseless. In order to analyze whether the defendants complied with the injunctions, the court must determine what constitutes "competent and reliable scientific evidence" sufficient to substantiate the defendants' causal efficacy claims and whether the studies the defendants relied upon meet that standard. Dr. Aronne addresses both of these issues precisely and in great detail. He articulated at the beginning of this case that RCTs are necessary to substantiate causal efficacy claims. The court, as

discussed in extensive detail above, adopted that standard, which the Eleventh Circuit affirmed on appeal. That standard has remained unchanged throughout the course of this litigation, so his opinions in the current proceedings are not a departure from what this court has already found to be helpful and credible. Moreover, Dr. Aronne does not only opine as to the appropriate "competent and reliable scientific evidence" standard, but he also addressed in detail the scientific evidence the defendants relied upon and explained why that evidence does not substantiate the claims. Dr. Aronne plainly addressed the issues before the court.

While the defendants also claim that Dr. Aronne's testimony is unhelpful because it is based on his "personal opinion" from "his own practice and experience," the court finds that this argument similarly lacks merit. Not only does Fed. R. Evid. 702(a) specifically allow for an expert to opine based upon his "knowledge, skill, experience, training, or education," but the competent and reliable scientific evidence standard is explicitly defined in the injunction as "evidence based upon the expertise of professionals in the relevant area." Thus, to answer the question of what level of evidence experts in the field require to substantiate causal efficacy claims, Dr. Aronne drew upon his experience in the field. Contrary to the defendants' contention that Dr. Aronne's "personal" opinion conflicts with the "context-specific" flexible standard of the FTC's Advertising Guide, his opinion is consistent with the Guide [Doc. No. 701-3]. By its very nature, the Advertising Guide does not address a specific type of dietary supplement and specific types of claims for

those products. It is merely a guide. Even so, the Advertising Guide provides that, "[a]s a general rule" RCTs are "the most reliable form of evidence" when substantiating claims, which is entirely consistent with Dr. Aronne's opinions. *Id.* at 10.

The court finds that Dr. Aronne "employ[ed] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire v. Carmichael*, 526 U.S. 137, 152 (1999). The defendants' motion to exclude his testimony [Doc. No. 866] is DENIED.

2. Richard van Breemen, Ph.D.

The defendants moved to exclude the FTC's other substantiation expert, Dr. van Breemen, because they claim his opinions are also not helpful. The court again disagrees. As the FTC pointed out in opposing the motion to exclude, the defendants' expert witnesses criticized Dr. Aronne because the RCT standard he proposed is not, as they claim, the standard that experts in the "dietary supplement field" recognize because Dr. Aronne's expertise is in weight loss and obesity, not dietary supplements. The FTC states that it retained Dr. van Breemen for the purpose of rebutting those contentions. Rebuttal testimony is helpful to the trier of fact, and, sitting as such, the court finds Dr. van Breeman's testimony helpful.

Dr. van Breemen rebuts the notion that experts in the field of dietary supplements do not require product-specific RCTs to prove that a supplement is efficacious. To support that opinion, Dr. van Breemen cited to both his experience and that of other researchers of dietary supplements. Dr. van Breemen also rebuts the defendants' assertion that RCTs are

impracticable because such trials cost hundreds of millions of dollars, as Wheat claims. Dr. van Breemen described numerous examples of experts in his field doing precisely what Wheat and Hi-Tech's experts claimed to be virtually impossible. Dr. van Breemen also offered opinions challenging the defendants' purported substantiation, which the court finds helpful.

The defendants also contend that Dr. van Breemen is not qualified to render opinions as to either the substantiation standard or the feasibility of RCTs for dietary supplements. This court has recognized that "it is not necessary that the witness be recognized as a leading authority in the field in question . . . . Gaps in an expert witness's qualifications or knowledge generally go to the weight of the witness's testimony not its admissibility." *Leathers v. Pfizer, Inc.*, 233 F.R.D. 687, 692 (N.D. Ga. 2006). As noted above, experts can be qualified in "various ways," and "the plain language of Rule 702 makes this clear: expert status may be based on 'knowledge, skill, experience, training, or education.'" *United States v. Frazier*, 387 F.3d 1244, 1260–61 (11th Cir. 2004).

Dr. van Breemen is qualified to offer the opinions he provided in this case. He obtained a Ph.D. in pharmacology from Johns Hopkins University and is currently a Professor of Pharmacy at the University of Illinois at Chicago ("UIC"). He has served as the Director or co-Director of the UIC/NIH Center for Botanical Dietary Supplements Research since the Center was founded. The UIC Center is one of only three botanical centers supported by the National

Institutes of Health's Office of Dietary Supplements. Dr. van Breemen is a member of AOAC International, an organization that develops methods of analysis for botanical dietary supplements. He received the highest honor given by the organization in 2008. He has published over 200 papers on dietary supplements, many of which relate to the research and development of dietary supplements or to methods of developing safe and effective supplements. Dr. van Breemen drew from this training and experience in reaching his opinions in this case.

The court finds that the defendants have raised no valid objections to Dr. van Breemen's qualifications. Having found their arguments to exclude his testimony are groundless, their motion [Doc. No. 865] is DENIED.

3. The RCT Standard

The FTC's substantiation expert from the very beginning of this case has been Dr. Aronne, who explained from the outset that the standard applied by weight-loss experts to evaluate causal efficacy claims is RCTs. Dr. van Breemen corroborated that opinion and opined that it is also the appropriate standard in the dietary supplement field.

The RCT standard is comprised of several components. The court is unable to distill the days of testimony regarding the RCT standard into a few pages, but it will nevertheless attempt to succinctly review each component. More importantly, the court will note various defense experts' concessions regarding why each component is necessary, thus shedding light on why the defendants' own

substantiation evidence that is not comprised of these components is not just inferior but also deficient.

a. Human Clinical Trials

The first aspect of the RCT standard is that a clinical trial of the product needs to be conducted on humans. Dr. Aronne explained in detail why the non-human trials referenced by the defendants and their experts—animal and in vitro studies[27]—are insufficient, either alone or in combination. With respect to in vitro studies, Dr. Aronne testified that understanding certain biochemical reactions outside the body are not indicative of what will occur inside the human body and thus cannot be extrapolated to humans. Regarding animal studies, Dr. Aronne opined that they, too, are insufficient to substantiate efficacy claims because there are many findings that come from animals that are not substantiated in human trials because animals are different from humans. Consequently, animals respond to treatments differently from humans with regard to efficacy. Dr. Aronne provided specific examples of efficacy being shown in animal studies but not human studies.

Several of the defendants' experts agreed that in vitro and animal studies alone are not sufficient. For example, defense expert Dr. Timothy Gaginella, a pharmacologist, agreed that the primary purpose of in vitro studies is to serve as a screening tool and there are situations where a scientist might predict that a substance is going to have certain effect on humans,

[27] Colloquially referred to as "test tube" studies, in vitro studies are done in a controlled environment outside of a living organism.

but it ultimately does not. Indeed, a book co-authored by Dr. Gaginella notes, "Herbal medicines, before appearing in the pharmacy's [sic] as a medicine, should be required to undergo pharmacological and toxicological testing on animals and clinical trials in humans" [Doc. No. 941-10 at 2]. The defendants' other pharmacologist expert, Dr. Matthew Lee, agreed that, even where a substance has a plausible mechanism of action, it may not have efficacy once administered to humans. Dr. Lee admitted that animal studies cannot be used to predict how a human is going to absorb a substance because animal studies bypass certain limitations that might exist in the human body. Another one of the defendants' expert witnesses, Dr. Jay Hoffman, a clinical researcher and professor of medicine, agreed that many dietary supplements have little to no scientific support in human subjects. Dr. John La Puma, another defense expert physician and nutritionist, testified that one can only project what will likely happen physiologically in a person when looking at in vitro studies, and one can only know what happens in a person by studying people.

Accordingly, as recognized by the defendants' experts, only human studies can confirm that a specific substance actually has an effect in humans and extrapolating data obtained from animal studies and in vitro studies to humans has significant limitations.

b. Placebo Controls and Double Blinding

A second component to the RCT standard is that studies must be both placebo-controlled and double-blinded in order to yield accurate and reliable results. A placebo control means a study includes a control

group, or one that does not participate in the intake of the substance that is being examined. Commonly referred to as "the placebo effect," the need for a control group is accepted by experts in the field. When human subjects know that a product is being tested to determine its effect on a condition, that knowledge can influence the results in a way that is unrelated to the content of the product.

Double-blinding is where neither the active treatment group nor the control group knows which treatment it is receiving. The second blinding is that the investigator should also not know what treatment a subject is getting. The purpose of the double blinding is similar to the reasons for the "placebo effect"—to prevent the researchers and subjects from being influenced by a belief that the treatment will or will not be effective.

Like the necessity for human trials, the defendants' experts agreed that placebo controls and double blinding are necessary. For instance, Dr. Hoffman testified that to establish efficacy of a product for weight loss in humans, one needs to have a placebo-controlled study. Dr. Gaginella similarly agreed that it is essential to rule out the placebo effect when evaluating human studies. Dr. Lee also agreed that use of a placebo control and double blinding are procedures generally accepted in the profession to yield accurate and reliable results, as that phrase is used in the definition of "competent and reliable scientific evidence."

c. Randomization

Studies must also be randomized in order to yield accurate and reliable results, according to the FTC's

experts. In other words, subjects should be assigned to either the treatment group or the control group randomly through a process called "randomization." Randomization eliminates selection bias by the researcher and allows the researcher to rely upon the statistical likelihood that the makeup of the treatment and placebo groups will be statistically similar. Defense experts Drs. Lee, Hoffman, and La Puma recognized that randomized studies yield more reliable results.

d. Sufficiently Sized Studies

RCTs should also test enough subjects to permit the conclusion that any measured effect is reliable and generalizable. The defendants' own experts agreed with Dr. Aronne that one can determine the appropriate size of a trial by doing a "power" calculation. Power is affected chiefly by the size of the effect and the size of the sample being used to detect it. Small, or "underpowered," studies could result in findings that occur at random, and Dr. Aronne explained that such studies have a low probability of finding true effects. For example, a ten-person study can be swayed by effects in a single subject, so that if one subject loses weight and nine do not, the data would demonstrate a weight-loss result. Conversely, studies having more participants result in a greater probability of detecting a real treatment effect. While all the experts agree that there is no uniform baseline number of study subjects necessary to substantiate efficacy claims, the defendants' experts recognize that a power calculation is necessary to determine the number of study subjects that were needed. Indeed, this is precisely what Dr. Jacobs did when he

performed the clinical trials on the other Hi-Tech products that are not implicated in these proceedings, Fastin-XR and RR. Thus, the necessity of appropriately sized trials is one that is shared by experts in the field.

e. Appropriate Duration

RCTs must also be of an appropriate duration in order to yield accurate and reliable results. More specifically, Dr. Aronne testified that six months would be the minimum duration for a study to constitute competent and reliable scientific evidence, although most researchers in the field would require a one-year minimum. A shorter duration study, according to Dr. Aronne, may demonstrate results that are transient and may not be sustained beyond a few weeks. Dr. Aronne testified that examples of Prozac and Zoloft illustrate this principle. Both substances were hypothesized to have efficacy for weight loss, and short-term studies supported that hypothesis. Longer duration studies, however, showed that people who initially lost weight on these substances regained it with longer-term use. Both products were rejected as efficacious weight-loss aids. Consequently, "acute metabolic studies"—studies where measurements are made over a few hours—cannot be extrapolated to longer periods of time, and according to Dr. Aronne, a metabolic study lasting three hours cannot substantiate a claim of metabolic effect beyond three hours.

The defendants' experts largely agree with this principle. Dr. Jacobs admitted that taking an acute study by itself does not show what the prolonged effect would be. Dr. Marvin Heuer, a medical doctor with

experience in the supplement industry, agreed that one cannot determine whether actual weight loss occurs based on an acute study. Dr. Gaginella also conceded that one can only hypothesize that an effect seen in an acute test will continue over time. Dr. Hoffman testified that an acute study measuring metabolism over a few hours cannot be extrapolated as to the effect on metabolism beyond a few hours. Dr. Lee similarly opined that a study of longer duration can provide better evidence that the claimed effect will persist.

f. Product and Dosage Specific

Dr. Aronne further opined that product-specific and dosage-specific testing is necessary. He explained that product-specific testing is necessary because, even where an individual ingredient has been shown to be efficacious for the treatment of a particular condition, the ingredient may not have the same properties when combined with other ingredients. Product-specific testing, according to Dr. Aronne, is essential to assess any confounding factors or antagonistic effects. Confounding occurs, for example, when a combination (ingredient A + ingredient B) is reported to promote weight loss in a study, while ingredient C was also part of the combination and contributing to the weight loss observed. Dr. Aronne testified that one cannot extrapolate from the results of a study of one product to a separate product that has different ingredients because the effectiveness is unknown due to the presence of extra components. He pointed to studies in the defendants' own reliance materials that were provided to the FTC, which supported his opinion that one cannot extrapolate

results from a combination of ingredients to a product that did not have the same combination.

Antagonistic effects occur when two or more agents in combination have an overall effect that is less than the sum of their individual effects. For instance, Dr. van Breemen explained that Citrus aurantium, an ingredient contained in the Hi-Tech products, inhibits an enzyme responsible for metabolizing over half of all drugs and natural products. Therefore, Dr. van Breemen opined that mixtures of ingredients have very different effects than those of individual ingredients, and this is especially true of dietary supplements because of the chemical diversity and complexity of botanical dietary supplements. Thus, a product made up of multiple compounds must be studied as a whole, a notion that the defense experts concede.

The defendants' pharmacologist expert, Dr. Gaginella, agreed that ingredients in a product might interfere with each other even though that had not been predicted. Dr. Hoffman has observed that one cannot draw conclusions when examining combination products, like the ones Hi-Tech manufactured, unless one tests the combination product itself. Dr. La Puma conceded at his deposition that it is difficult to identify the single ingredient effect in any dietary supplement that is a combination. He also conceded that he could not rule out the antagonistic effect of a particular study the defendants relied upon because the product being tested was comprised of seven different ingredients.

For many of the same reasons, Dr. Aronne opined that dosage-specific testing is important because

higher or lower dosages of a product will not result in the same efficacy as a particular tested dosage. Dr. Aronne explained by way of example that, if 5 grams of a treatment has been shown to cause a particular effect, scientists cannot assume that 2.5 grams would cause one-half the observed effect. To the contrary, 5 grams might be the threshold amount needed to cause any effect. As a result, studies of larger quantities of a product's ingredients do not constitute reliable evidence that a smaller amount of that ingredient will cause a proportionally reduced effect or any effect at all. One is similarly unable to extrapolate the results of a test of a substance at a low dosage to higher dosages. Dr. Hoffman recognized that it is a problem that many companies rely on research of key ingredient studies, but those studies often involve dosages that are much higher than the dosage of the ingredients used in the product that is actually sold. Dr. Gaginella agreed that, in order to make claims based on scientific testing, the testing should be done on the same dosage.

g. Appropriate Endpoints

RCTs must also examine the appropriate endpoints, or what the study is attempting to quantitatively measure at the end. To determine whether a product is efficacious for causing weight loss, for instance, the study must actually evaluate a change in weight as an endpoint. So, a study that established metabolic endpoints cannot determine whether weight loss will also occur. Therefore, one simply cannot know if a product causes weight loss unless the study itself measures whether the subjects actually lost weight. This notion seems rudimentary

to the court. Dr. Jacobs conceded that metabolic studies do not substantiate fat loss claims, and Drs. Gaginella and Hoffman agreed that studies measuring metabolic or energy expenditure endpoints do not support claims of fat or weight loss.

h. Statistical Significance

Studies also need to have statistically significant result between the treatment and control groups, and according to Dr. Aronne, if there are no differing results between groups, it is difficult to draw any conclusions about a substance's efficacy. Defense experts Drs. Lee, Gaginella, and La Puma agreed that requiring studies to have statistical significance is an accepted scientific technique.

4. Hi-Tech Defendants' Substantiation Evidence

The defendants, on the other hand, pointed not so much to a precise substantiation standard but rather an amalgamation of studies that they contend support their claims for the four products. The studies are summarized in a bibliography Wheat provided to the FTC [Doc. Nos. 944-11, 944-12]. This list of materials was also provided to the defendants' experts, and they relied upon primarily these materials when offering their opinions. The studies fall into two overall categories: ingredient studies and clinical trials of other products.

With respect to the ingredient studies, the defendants maintain that, because Fastin, Lipodrene, Benzedrine, and Stimerex-ES contain many of the ingredients (in varying combinations and amounts) that are examined in the ingredient studies, their product-specific, efficacy claims for the four products

at issue are substantiated. The court finds that the ingredient studies do not substantiate the defendants' claims because of three major flaws articulated by Dr. Aronne.

First, the studies were not specific to Hi-Tech's products, and, as such, it is not possible to predict what will happen when various ingredients are combined, like they are in the four products at issue. This criticism invokes the necessity for product/dosage specific testing, which is a concept that several of the defense experts corroborated.

Second, Dr. Aronne convincingly explained that the results of these ingredient studies, which measure a particular endpoint such as metabolism, cannot be extrapolated to substantiate the claims at issue, which are derived from different endpoints, like weight loss or fat loss. Dr. Aronne discussed how an increase in metabolism can trigger counter-regulatory mechanisms in the body that increases appetite, thus actually making weight or fat loss more difficult. Further, Dr. Aronne opined that the human body can habituate to ingredients like caffeine, which means that even though some of the Hi-Tech products contain caffeine, to achieve the same effects from caffeine over time, one must ingest a correspondingly higher amount. Several of the defendants' experts agreed with these concepts.

Third, Dr. Aronne explained that many of these ingredient studies were of a shorter duration, and therefore, may only demonstrate transient effects. The examples of Prozac and Zoloft Dr. Aronne provided confirm this point. Dr. Aronne also discussed why the studies that occur over only a few hours cannot be

extrapolated to longer periods of time, a concept, again, that several of the defendants' experts recognized.

The defendants and their experts also rely on clinical trials of Meltdown, a competing dietary supplement, and clinical trials of Fastin-XR and Fastin-RR, two Hi-Tech products having different product formulations than the four products at issue, as substantiation evidence. Dr. Aronne explained why all of these trials are inadequate for a number of reasons.

With respect to the Meltdown studies, Dr. Aronne opined that each was acute and not sufficiently sized. Moreover, Meltdown has a different formulation from the Hi-Tech products. There are a number of ingredients in Meltdown that are not present in any of the Hi-Tech products. The inclusion of these ingredients is not trivial for the reasons explained above and recognized by some of the defendants' own experts. Dr. Aronne also explained why the Meltdown studies are insufficient because they do not measure the appropriate endpoints. Finally, Dr. Aronne explained why the Meltdown studies cannot be extrapolated beyond their acute time frames.

For many of the same reasons, Dr. Aronne demonstrated why the Fastin-XR and RR studies do not substantiate the claims at issue. The variants of Fastin have a different formulation than all of the products at issue. Not only do they contain additional ingredients, but the common ingredients are not present in the same amounts as in the four products at issue. Indeed, the reason Hi-Tech saw fit to create an entirely different Fastin product was to market to

its consumers a new and improved product that achieved different results from the original Fastin product.

The FTC also pointed to numerous methodological flaws that discredit the reliability of the Fastin-XR and RR studies. For example, the FTC offered evidence that Dr. Jacobs, who performed the studies, reported results for a smaller amount of participants even though the power calculation called for a great number. Moreover, the FTC presented evidence to suggest Dr. Jacobs concealed that he self-enrolled in the study and that his results were less favorable than the other study participants. Dr. Jacobs also admitted that, during the Fastin-RR metabolism study, he "broke the blind" and re-administered dosages when the results did not meet his expectations. The court also heard evidence that Dr. Jacobs misrepresented the side effects experienced by some of the study participants. Dr. Aronne opined that, due to Dr. Jacobs' breaches of protocol and repeated instances of misreporting the facts of his studies, Dr. Jacobs is not a person in the field qualified to conduct these types of studies.

The court does not stop there, however. In addition to the significant gaps between the science Hi-Tech purportedly relied upon and the claims it made, the court has concerns regarding the credibility of the defendants' experts and their ultimate substantiation opinions.

a. Dr. Gaginella

Hi-Tech's relationship with the first expert who testified on its behalf, Dr. Gaginella, is particularly suspect. Dr. Gaginella's relationship with Wheat and

Hi-Tech began around 1999, when Wheat began running some of his own research through Dr. Gaginella. Relative to the violative advertising claims at issue, however, Hi-Tech had ceased its relationship with Dr. Gaginella when those claims were made. It was not until the contempt litigation arose that Wheat resumed his consulting relationship with Dr. Gaginella. Leading up to the termination of his consulting relationship with Hi-Tech, Dr. Gaginella received $60,000 per year from Wheat or his companies. Thus, not only has Dr. Gaginella been paid for years by Hi-Tech but he resumed his relationship with Hi-Tech after the contempt litigation began. The more prudent approach would have been to simply consult with Dr. Gaginella at the time the claims were actually made—something Hi-Tech apparently had a history of doing before these proceedings began—to determine if the claims were substantiated at that time, before the FTC moved for contempt. Perhaps most concerning though, the FTC presented evidence that, during the time Dr. Gaginella had consulted with Hi-Tech before this case, there were at least two separate occasions where Wheat or his companies forged Dr. Gaginella's signature on letters purporting to show Dr. Gaginella endorsed a particular Hi-Tech product. In each case, Dr. Gaginella's name and fake signatures were placed on letters that he had never seen. Despite the fact that Dr. Gaginella's consulting relationship with Hi-Tech ended in 2006, Hi-Tech continued to hold him out as their "Research & Development Group Chief." While this evidence is more reflective of Wheat's guile, the court mentions it here because the history between Dr. Gaginella and Hi-Tech is dubious.

The court also has concerns with Dr. Gaginella's qualifications. His limited experience in the field of weight loss is derived from his work as a consultant for Hi-Tech. Outside of his work for Hi-Tech, Dr. Gaginella has never done any work in the fields of weight loss or obesity. He retired as a pharmacist in 2010. The last lab research he participated in was in 1994, and, even then, he focused mainly in the field of gastroenterology. Dr. Gaginella's familiarity with dietary supplements comes solely from reading literature. He has never conducted a human clinical trial measuring weight or fat loss. Nor has Dr. Gaginella ever been an investigator on any human clinical trial. Finally, Dr. Gaginella avoided the opinion that the defendants' claims were substantiated and instead opined that there is "competent and reliable scientific evidence" the four products "[a]id in rapid or substantial weight loss, as part of a program of diet and exercise" and "[a]id in substantial fat loss, as part of a program of diet and exercise." When asked specifically about whether the claims for Fastin were substantiated, he said, "[I]t's quite possible, but I—I can't say absolutely yes it would or it wouldn't."

b. Dr. Lee

The court also has concerns regarding Dr. Lee's qualifications, who is a primary care physician having very little experience in the field of weight loss. He has never published any papers or given any presentations in the field of weight loss. He is not a member of any professional societies that focus on weight management. Further, Dr. Lee has never conducted any human clinical trials, animal studies,

or in vitro studies to measure fat loss, appetite suppression, metabolism, thermogenesis, or lipolysis, concepts he discusses in his report. The only peer reviewed article he has done involved the effects THC has on mice.

Even if the court were to assume Dr. Lee is qualified, his substantiation opinions are tenuous at best. Like Dr. Gaginella, Dr. Lee opined that the four products "[a]id in rapid or substantial weight loss, as a part of a program of diet and exercise" and "[a]id in substantial fat loss, as part of program [sic] of diet and exercise." At trial, Dr. Lee testified that the products, based on the mechanism of action, *could* cause weight loss.

c. Dr. La Puma

Although the court does not question whether Dr. La Puma is qualified, he did testify that, in forming his opinions, he relied on the opinions of Drs. Gaginella and Jacobs, which effectively imputes the court's concerns with those experts into its view of Dr. La Puma. Putting that aside, Dr. La Puma's substantiation opinions were equally as feeble as the defendants' other experts. Dr. La Puma testified on direct examination that the products would "aid" or help with weight loss. He similarly opined not that the products would cause fat loss, but rather they would aid in fat loss. La Puma admitted at his deposition that his opinion was that the Hi-Tech products merely aid in the suppression of appetite, but at trial he attempted to change his testimony to claim that the products suppress appetite. At his deposition, Dr. La Puma testified that the products aid in increasing

metabolism, but at trial he changed his testimony to affirmatively claim that they increase metabolism.

d. Dr. Hoffman

Dr. Hoffman admitted that he is not an expert in the field of weight loss, but he does have proven experience as a researcher of dietary supplements, including as a principal investigator in one of the Meltdown studies. Somewhat surprisingly though, Dr. Hoffman conceded at trial that he is not offering any opinions in this case on the products themselves. Rather, Dr. Hoffman's opinions are limited to the ingredients in the four products, but even with respect to those opinions, Dr. Hoffman testified that the ingredients of the products have only "the *potential* to cause weight loss" [Doc. No. 948, 175:18–19 (italics added)]. Dr. Hoffman expressly admitted that he is offering no opinion as to whether the four products cause weight or fat loss, even though those are the type of claims the defendants are required to substantiate.

Dr. Hoffman even admitted that several of Hi-Tech's claims were not substantiated. At his deposition, Dr. Hoffman agreed that the Fastin claim "Increases the release of norepinephrine and dopamine for dramatic weight loss" was not substantiated. He also said he would not feel comfortable offering the opinion that the defendants' possessed substantiation for the Fastin claim, "EXTREMELY POTENT DIET AID! DO NOT CONSUME UNLESS RAPID FAT AND WEIGHT LOSS ARE YOUR DESIRED RESULTS!", or the Benzedrine claim, "simply blows fat away!" In fact, defense counsel objected to Dr. Hoffman being

questioned about several of these specific representations Hi-Tech made on the grounds that he had never reviewed the claims in his expert report.

e. Dr. Jacobs

Dr. Jacobs performed the clinical trials on Fastin-XR and RR. The court has already highlighted some of the evidence discrediting the results of those studies relative to the issues in this case. In addition to Dr. Jacobs' bias towards the results of those studies, the FTC presented evidence showing Dr. Jacobs' bias towards Hi-Tech itself. For example, in 2015, over half of the revenue for Dr. Jacobs' company, Superior Performance Research, came from Hi-Tech. The FTC also elicited evidence that Dr. Jacobs sought money from Wheat to conduct additional studies on Hi-Tech's products, explaining that he was "under a cash flow problem at this time due to other issues."

With respect to his substantiation opinions, Dr. Jacobs, like the other experts, admitted that his opinion regarding weight loss was limited insofar as the products will aid in rapid or substantial weight loss as part of a program of diet and exercise. Paradoxically, Dr. Jacobs even testified that he believes it is inappropriate to use the word "cause" in connection with any of the Hi-Tech products, when the claims Dr. Jacobs was retained to substantiate are causal efficacy claims. The court finds that this is a tacit recognition that the claims either are not, or cannot be, substantiated.

f. Dr. Heuer

Dr. Heuer is perhaps the most qualified of the defendants' substantiation experts. Although he did testify that each of the claims is substantiated, he

testified that one must make two extrapolations and an assumption in arriving at that conclusion. The extrapolations are extending results from acute studies to long term studies and taking the results seen from animal and in vitro studies and applying them to humans. The assumption is that raising heart rate and metabolism causes weight loss and fat reduction [Doc. No. 951, 162:12–164:11]. The FTC also presented evidence that Dr. Heuer is newly employed as CEO of a Canadian dietary supplement company, thus suggestive of a potential bias towards advocating for a more relaxed substantiation standard.

g. Wheat and Wright

The final two substantiation experts are Dr. Wright and Wheat. Although Dr. Wright did not testify in the 2017 bench trial, he has provided declarations in this case claiming to have reviewed the ingredient-specific studies and offered his opinion that the defendants' claims are substantiated. The court finds his reliance on the ingredient specific studies insufficient for the reasons discussed above. In addition, the court has grave concerns with Dr. Wright's credibility.

First, Dr. Wright takes a position that product-specific testing is not required, which is in direct contravention to an explicit requirement of his injunction. Second, the record contains evidence showing Dr. Wright's bias towards Hi-Tech. Between 2009 and 2011, Hi-Tech paid Wright $170,454 for helping Wheat and Hi-Tech with advertising the Hi-Tech products. Third, and perhaps most damaging, Dr. Wright has been reprimanded publically by the Georgia Composite Medical Board. The public consent

order identifies various ways in which Dr. Wright's treatment of two patients fell below the standard of care, including improper use of prescription medication, resulting in Dr. Wright being placed on probation. Several years earlier, Dr. Wright received another public reprimand for treating patients in 1997–1998, and the violations note treatment for obese patients that fell below the standard of care. He was placed on probation for five years following that consent order.

Pleadings in a trademark infringement case Hi-Tech instituted in 2003 in this court compound the court's concerns regarding the relationship between Dr. Wright, Hi-Tech, and Wheat.[28] The defendant in that case sought to take Wheat's deposition, and after he failed to appear, moved to compel his deposition. According to Wheat's attorney, Wheat was ill and under a doctor's order not to participate in a deposition at that time [Doc. No. 97]. On the advice of his treating physician, Wheat had "taken up residence in Belize." *Id.* Because Judge Willis Hunt was unsatisfied with the lack of specificity of Wheat's claimed illness, he ordered Wheat to file a sworn statement from his treating physician. In response, Wheat, through his attorney, filed "an initial report made by *Dr. Mark Wright*, Mr. Wheat's treating *psychiatrist* in June of 2004." [Doc. No. 101 (emphasis added)]. The response stated, "Mr. Wheat and Dr. Wright have had a physician-patient relationship since 1997." [Doc. No. 101]. Subsequent briefing removes any doubt as to whether T. Mark Wright, M.D. is the same

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[28] *See Hi-Tech Pharmaceuticals, Inc. v. Herbal Health Products, Inc.*, 1:03-CV-2486 (N.D. Ga. 2003).

Dr. Wright in this case because he was noted to specialize in "bariatrics" [Doc. No. 115, p. 3 n.2].

Thus, Wright appears to have misrepresented to Judge Hunt that he is a psychiatrist when, in fact, he specializes in bariatrics. Moreover, the court has concerns that Hi-Tech's expert endorser is simply Wheat's treating physician, at least based on what the two represented to Judge Hunt in 2004. Finally, the representation that Wheat moved to Belize for medical reasons is belied by a 2006 indictment, in which the U.S. Attorney for the Northern District of Georgia contended that Wheat had been travelling to Belize around the time the trademark infringement case was pending, not because of an illness, but in furtherance of a conspiracy to manufacture, import, and distribute prescription drugs and controlled substances into the United States, including anabolic steroids, Schedule III narcotic controlled substances, and Schedule IV narcotic controlled substances, to which Wheat ultimately pled guilty. *See United States of America v. Jared Robert Wheat*, 1:06-cr-382 (N.D. Ga. 2009) [Doc. Nos. 1; 740].

With respect to Wheat's opinions, some of the defendants' experts believed that they would consider him a "professional[] in the relevant area" to offer competent and reliable substantiation evidence, while other defense experts believed he is not. The court agrees with the latter. Although Wheat has experience with dietary supplements, he is self educated in the area. He has no formal training or education in the field and no scientific background. He does not participate in any continuing education. He has no

publications of his own or peer-reviewed studies that he has participated in.

Wheat also appears to have implemented no reliable methodology in using the scientific material when crafting the claims for the products at issue. Wheat repeatedly referred to a "war room" that housed numerous research studies from which he created the bibliography that he provided to the FTC, itemizing the substantiation materials he claims Hi-Tech relied upon. Wheat appears to have accumulated this "war room" for situations where he needed to "pacify" retailers before they would put Hi-Tech products on their shelves, so that Wheat could give the retailer "the science that [he] relied upon for whatever claim [he was] making" [Doc. No. 952, 28:9–24].

This process is particularly concerning because one of the requirements under the injunction was that the defendants had to possess competent and reliable substantiation evidence "at the time the representation[s were] made." Since Wheat was not a professional in the relevant area, he did not have the qualifications or expertise to determine which studies in his "war room" actually substantiated the claims at the time they were crafted. It appears that Hi-Tech and Wheat consulted with professionals in the relevant area only *after* the FTC had initiated these contempt proceedings. The process of Hi-Tech using this "war room" to then craft product-specific efficacy claims was completely unscientific.

The email correspondence and telephone call between Wheat and Smith discussing the wording of the Fastin advertisement, for example, confirms the absence of a scientific basis when Hi-Tech crafted

these claims. Wheat and Smith focus on all the claims they could not make because of the limitations of the injunction as opposed to claims they *could* make based on the science that supported it. Indeed, the defendants' own expert, Dr. Hoffman, testified that had Hi-Tech retained him sooner, he would have "advise[d] them differently" on some of the claims, including the Fastin ad, "EXTREME WEIGHT LOSS GUARANTEED!" [Doc. No. 948, 180:12–181:19]. *Cf. Basic Research, LLC*, 2014 WL 12596497 * 2 (noting that the alleged contemptuous defendant had retained a substantiation expert to confirm that the claims were compliant with an injunction before the contempt proceedings were initiated).

Hi-Tech appears to have had no professional in the relevant area advising it when the claims were made. Rather, it was Wheat, someone who is unqualified, making the decision whether the claims were substantiated under the guise of scientific validation, when no scientist ever connected the results of the studies to the claims Hi-Tech was making about its products. As noted by one commentator on the subject, this is not an infrequent occurrence in the dietary supplement industry:

> [L]argely unregulated supplement labels . . . often express unrealistic claims and inaccurate content . . . For example, studies show that consumers tend not only to believe associations that are promoted in the marketing of food supplements . . . but also that the claims have received scientific validation, which is often not the case.

David G. Yosifon, *The Consumer Interest in Corporate Law*, 43 U.C. DAVIS L. REV. 253, 279 (2009).

5. The FTC's Advertising Guide

To further buttress their substantiation argument, the defendants repeatedly cited to the FTC's Advertising Guide for the proposition that the substantiation standard is flexible, and, as such, the FTC wrongly advocates for an overly stringent substantiation standard like RCTs. Contrary to the defendants' argument, the court finds that the Advertising Guide actually supports a finding that the RCT standard is appropriate and further demonstrates why the defendants' substantiation evidence is lacking.

Part 5 of section B, which is entitled "Substantiating Claims," states, "A common problem in substantiation of advertising claims is that an advertiser has valid studies, but the studies do not support the claim made in the ad" [Doc. 701-3, p. 20]. Advertisers are, therefore, instructed to "make sure that the research on which they rely is not just internally valid but also relevant to the specific product being promoted and to the specific benefit being advertised." *Id.* The Advertising Guide also warns, "If there are significant discrepancies between the research conditions and the real life use being promoted, *advertisers need to evaluate whether it is appropriate to extrapolate from the research to the claimed effect. . . .*" *Id.* (emphasis added). If the defendants had relied upon the Advertising Guide when making the representations, as they claim, they should have asked themselves the questions the FTC provides in the Advertising Guide:

> How does the dosage and formulation of the advertised product compare to what was used in the study?
>
> Does the advertised product contain additional ingredients that might alter the effect of the ingredient in the study?
>
> Is the advertised product administered in the same manner as the ingredient used in the study?
>
> Does the study population reflect the characteristics and lifestyle of the population targeted by the ad?

Id. Based on the record before the court, it is clear that the defendants did not ask themselves any of these questions, but rather, made "[c]laims that do not match the science," and as the Advertising Guide states, "[N]o matter how sound that science is, [the claims] are likely to be unsubstantiated." *Id.*

6. The Defendants' Claims Are Unsubstantiated

In sum, the defendants argue that, when looking at their scientific evidence in its totality, the claims are substantiated. In order to reach that conclusion, the court would have to pile speculation on top of speculation, making an analytical leap between the science and the claims made. "[A] district judge asked to admit scientific evidence must determine whether the evidence is genuinely scientific, as distinct from being unscientific speculation offered by a genuine scientist." *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1316 (11th Cir. 1999). Claiming these ingredient studies and clinical trials of other products

substantiate the defendants' product specific representations is simply "unscientific speculation offered by . . . genuine scientist[s]." *Id.*

At the risk of belaboring the point, the court reiterates that it must look to the claims Hi-Tech actually made and whether those representations are substantiated. The defendants very clearly made claims that these four products caused a specific result—whether it be weight loss, fat loss, effects on body fat, effects on appetite, or effects on metabolism. They did not represent that the products contained an ingredient that has been shown to increase metabolism, for example. As the Supreme Court observed, "Trained experts commonly extrapolate from existing data . . . [but a] court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). The court is simply unable to bridge the analytical gap between the studies the defendants relied upon and the product-specific, causal efficacy claims Hi-Tech made. *See, e.g., Jack v. Glaxo Wellcome, Inc.*, 239 F. Supp. 2d 1308, 1319 (N.D. Ga. 2002) (finding expert testimony unreliable where it was "extrapolated from incomplete data"); *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194 (11th Cir. 2002) (finding the district court did not abuse its discretion by not extrapolating the results of animal studies to humans).

Notwithstanding the court's concerns with several of the defendants' substantiation experts' qualifications, the court has considered all of their testimony and finds it unconvincing. "In other words, the court-as-gatekeeper [will] let the court-as-

factfinder consider [the defendants' experts'] testimony, but the court-as-factfinder decide[s] not to give it much weight." *Brown*, 415 F.3d at 1270. Simply because the parties offered differing expert testimony and the defendants had more experts than the FTC, does not preclude the court from finding contempt is appropriate. *See St. Martin v. Mobil Exploration & Producing U.S., Inc.*, 224 F.3d 402, 408 (5th Cir. 2000) ("The district court admitted testimony from experts on both sides, and was entitled to weigh the evidence presented by each . . . . It did not commit clear error in choosing one explanation over another where both were properly admitted.").

Had the studies the defendants relied upon contained the various components of the RCT standard which Dr. Aronne discussed (e.g., product/ dosage specific, double-blinding, randomization, etc.), such evidence would lessen the analytical gap that exists. In the absence of those components, however, when confronted with the question of whether the defendants' evidence substantiates the claims made, the court, like the defendants and their experts, is left with only assumptions, which is the antithesis of substantiation.[29]

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[29] The court notes that it has already provided an exhaustive discussion regarding the defendants' and their experts' failure to rely upon the specific type of "competent and reliable scientific evidence" that the court previously adopted (i.e., RCTs) for this case. And, since the defendants had notice of that requirement when making the representations for these four products, a finding of contempt is proper. Thus, the court makes its finding of a lack of substantiation in the alternative to its earlier findings regarding the defendants' failure to satisfy the RCT standard of the injunctions.

Accordingly, even if the court were to assume that the Hi-Tech defendants did not know RCTs of the products were required under the injunction (an assumption that is unequivocally belied by the record), and assuming further that the evidence the defendants claim to have relied upon constituted "competent and reliable scientific evidence" as defined in the injunction, the defendants' claims are not substantiated. It is not the function of this court to determine what the substantiation standard should be for all cases, but it is the function of the court, serving as the fact finder, to determine whether the evidence presented before it demonstrates that Hi-Tech's products do what the defendants represented them to do; the court finds the defendants have fallen short. The FTC has clearly and convincingly established that the defendants did not possess "competent and reliable scientific evidence that substantiates the representation[s]" when they were made.

E. Section VI Violation

Compounding the violations of Sections II and VII, the record is unequivocal that the Hi-Tech defendants also violated Section VI of the Hi-Tech injunction by not placing the required yohimbine warning on the four products. It is undisputed that the advertising and/or promotional material for Fastin, Lipodrene, Benzedrine, and Stimerex-ES all make efficacy claims and each of the products contains yohimbine, thus triggering the warning requirement of Section VI. It is also undisputed that the product packaging and labels for the four products from January 1, 2009 through late 2012 did not contain the required warning. Wheat admitted at his deposition

that the warning was not incorporated. Despite this admission, however, Wheat believed the product labels "encompassed these warnings" [Dep. Wheat 125:13–25]. Due to an apparent "misunderstanding" that the warning "had to be word-for-word"—notwithstanding the explicit language of the injunction that plainly required it—he claimed that it was not until the FTC moved for contempt that he decided to "purge" himself by "redoing those labels to contain this verbiage." *Id.* The FTC presented evidence, however, that more than a year after Wheat claims to have placed the warning on the products, it was still absent from some of the products.

Despite all of these undisputed facts, the Hi-Tech defendants nevertheless contend that the court should overlook the violation and not sanction them because they claim the FTC failed to show consumers acted in reliance on the warning label or its omission. They argue, "In order to obtain sanctions, the FTC must establish consumers acted in reliance on the statement or omission at issue" [Doc. No. 961 (citing *McGregor v. Chierico*, 206 F.3d 1378, 1388 (11th Cir. 2000)]. The Hi-Tech defendants continue, citing again to *Chierico*, stating that a "presumption of actual reliance arises once the [FTC] has proved that the defendant made material misrepresentations, that they were widely disseminated, and that consumers purchased the defendant's product." *Id.*[30]

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[30] Like many of their other legal arguments, the defendants cherry-pick the legal standard the Eleventh Circuit espoused in *Chierico* and omit the sentence that is between the two sentences referenced above: "Proof of individual reliance by each purchasing customer is not a prerequisite to the provision of

Thus, according to the Hi-Tech defendants, by eliciting testimony that the yohimbine warning was not material, they have rebutted the presumption of consumer reliance, and, therefore, sanctions are not warranted. They posit two grounds for their immateriality argument: (1) the on-product warning labels are ineffective at communicating with consumers and (2) consumers would have understood the main messages of the yohimbine warning from the Hi-Tech's labels that had similar warning language and/or from other sources. The two experts the Hi-Tech defendants relied upon to support these arguments are Dr. Gerald Goldhaber and Linda Gilbert, respectively.

1. Dr. Goldhaber

Dr. Goldhaber opined that the products' warning labels—even though they did not comply with injunction—would have communicated to all consumers who read them the content of the warning contained in Section VI of the injunction. The court heard evidence, unchallenged by the FTC, that Dr. Goldhaber is qualified in the area of product warnings. Despite his undisputed expertise, the FTC moved to exclude Dr. Goldhaber's opinions because it contends he failed to apply any reliable methodology in forming his opinions, instead relying on his own *ipse dixit*. The court agrees.

The gatekeeping function of the court "requires more than simply 'taking the expert's word for it.'" *Frazier*, 387 F.3d at 1261 (quoting Fed. R. Evid. 702

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equitable relief needed to redress fraud." *Chierico*, 206 F.3d at 1388.

advisory committee note). "If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." *Id.*

The FTC argues that, in his expert report, Dr. Goldhaber disclosed no methodology at all in forming his opinion. The Hi-Tech defendants' response to this point simply references Dr. Goldhaber's credentials and they argue that the court is permitted to find the testimony reliable "based on his significant experience alone" [Doc. No. 857 (citing *Long v. Amada*, 2004 WL 5492705 (N.D. Ga. Mar. 31, 2004)]. By repeatedly pointing to Dr. Goldhaber's qualifications, without identifying any methodology he used to connect those qualifications to his opinions, the Hi-Tech defendants simply evade the FTC's reliability challenge.

The notion that an expert may generally rely on his experience alone to support his opinions is contrary to Eleventh Circuit jurisprudence. The Eleventh Circuit has recognized that the "reliability criterion remains a discrete, independent, and important requirement for admissibility." *Frazier*, 387 F.3d at 1261. "Our caselaw plainly establishes that one may be considered an expert but still offer unreliable testimony." *Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1342 (11th Cir. 2003); *see also Rider*, 295 F.3d at 1197 ("[T]estimony based solely on the experience of an expert [is] not . . . admissible."); *Dukes v. Georgia*, 428 F. Supp. 2d 1298, 1315 (N.D. Ga. 2006) ("Accepting [the expert's] experience alone as evidence of the reliability of his

statements is tantamount to disregarding entirely the reliability prong of the *Daubert* analysis.").

In *Kumho Tire*, a case on which the defendants also rely, "the Supreme Court made it clear that testimony based solely on the experience of an expert would not be admissible." *Rider*, 295 F.3d at 1197. Indeed, the only case the Hi-Tech defendants substantively rely upon, *Long, supra*, similarly held that, in order for an expert opinion to be considered reliable, the expert must "explain how [his] experience leads to the conclusion reached" and "how that experience is reliably applied to the facts." *Id.* at *12.

If the court were to remove from Dr. Goldhaber's expert report and testimony his background information, his recitation of the Hi-Tech product warning language, and warning language of competitors' products, what remains are conclusory opinions that the noncompliant warnings on the Hi-Tech products "would, in all probability, have communicated to the average consumer" the net effect of the injunction's yohimbine warning. The general principles he outlines that form the basis of his opinions reference a single academic reference, but Dr. Goldhaber fails to explain how that excerpt relates to his opinions in this case.

The only possible explanation Dr. Goldhaber provides connecting his experience to the labels and opinions in this case is his review of third party materials. However, his reliance on these materials and any opinions derived therefrom are irrelevant. Dr. Goldhaber testified that the three most important things he considers are hazards known to exist with the product, labels of competitors' products, and the

regulatory environment [Doc. No. 949, 32:21–33:11]. These issues would be relevant for developing a warning and deciding whether one needs to be added to a product, something Dr. Goldhaber undoubtedly has experience with, but they are of no importance to a situation where, as here, a specific manufacturer is explicitly ordered by a court to place a specific warning on specific products.

The Hi-Tech defendants effectively ask the court to simply take Dr. Goldhaber's word for it that the noncompliant warning would have communicated to consumers the content of the warning contained in Section VI of the injunction, which does not satisfy the rigors of *Daubert*. *See Frazier*, 387 F.3d at 1261; Fed. R. Evid. 702. Accordingly, the court GRANTS the FTC's motion to exclude Dr. Goldhaber's opinions regarding the Hi-Tech warnings [Doc. No. 855] as unreliable.

Since the gatekeeping function of the court is relaxed because the court is also the fact finder, the court notes that, even if Dr. Goldhaber's opinions were not excluded, the court would give his testimony little weight. Hi-Tech's noncompliant warning language was buried in a larger warning in small font in a large block of capital letters. Some of the products also required the label to be peeled back in order to expose the warning. Moreover, Dr. Goldhaber opined that the product warnings at issue would have communicated "to the average consumer who has high blood pressure" the intended warning, but the warning in Section VI of the injunction is targeted to all potential consumers, not just those with a pre-existing condition like high blood pressure. Given the differing context of

the warning labels Dr. Goldhaber reviewed and the one provided in the injunction, his opinions do nothing to rebut the presumption of materiality.[31]

2. Linda Gilbert

The FTC moved to exclude the defendants' other warnings expert, Linda Gilbert, a purported consumer research survey expert, who designed and executed a survey that she claimed was intended to determine whether language on the warning labels "successfully communicate[s] that this supplement can increase one's blood pressure" and "that consumers should consult with their doctor before using this supplement." The court has to look no further than Ms. Gilbert's own testimony to determine whether she is an expert in this field. On March 29, 2013, Ms. Gilbert provided deposition testimony in an unrelated case, where she admitted, under oath, that she did not consider herself to be "an expert in survey design or analytics," the expertise that underpins the survey she created for this case [Doc. No. 949, 88:9–89:6]. Given Ms. Gilbert's recent admission that she is not an expert in the areas in which she is being offered, the court GRANTS the FTC's motion [Doc. No. 875], thus excluding her testimony. *See Bowers v. Norfolk S. Corp.*, 300 Fed. App'x 700, 703 (11th Cir. 2008) (finding the district court did not abuse its discretion excluding an expert witness "because he admitted he

[31] Because the court has excluded Dr. Goldhaber's opinions, and, alternatively gives them little weight, it is unnecessary for the court to rule on the defendants' motion to exclude Susan Blalock, Ph.D., who was retained for the purpose of rebutting Dr. Goldhaber's opinions. Accordingly, that motion [Doc. No. 858] is DENIED as MOOT.

was not qualified" to offer the opinions he was retained to provide in the case).

Even if the court were to not exclude Ms. Gilbert, the court would give the opinions she derived from her survey little weight for the reasons offered by the FTC's rebuttal expert, Dr. Kenneth L. Bernhardt. Dr. Bernhardt provided numerous reasons why Ms. Gilbert's survey results are unreliable and cannot be used to provide credible evidence of what consumers would have gathered from the Hi-Tech product packaging and labels because of methodological and design flaws.

First, Ms. Gilbert's survey did not replicate marketplace conditions. Rather than show survey respondents the actual, noncompliant product labels, Ms. Gilbert showed them excerpted language from the labels in isolation from the rest of the labels' statements and in an easier-to-read format. Ms. Gilbert even testified that she designed the survey "to focus consumers' attention on those things that we felt were most important."

The survey also contained true/false questions. As explained by Dr. Bernhardt, focusing respondents' attention on certain statements and then asking true/false questions, effectively turned the survey into an "open-book reading comprehension test" rather than an appropriate test of how the consumers would understand warnings from having actually experienced them. Dr. Bernhardt also explained how inherent within Ms. Gilbert's survey were biases that primed and telegraphed to consumers the researchers' interests, thus skewing the results in the defendants' favor. Dr. Bernhardt also discussed how the survey

encouraged guessing, which results in a tendency to endorse any assertion made in a question, regardless of its content. Accordingly, even assuming that Ms. Gilbert has the requisite survey design expertise, which she admitted she does not, the FTC sufficiently discredited her opinions that the noncompliant warnings successfully communicated the spirit of the warning found in the injunction.

The court finds that the Hi-Tech defendants have failed to rebut the presumption of materiality. *Accord Nat'l Urological Grp.*, 645 F. Supp. 2d at 1191 ("[W]hen a customer makes a decision to purchase a health product that he or she will ingest for purported health benefits, any claim on the label regarding the health benefits (i.e., any product efficacy claims) or any claims regarding the safety of the product can be presumed material").

F. Sanctions

The FTC has established that the defendants violated the injunctions. The record is clear that the misrepresentations were material, were widely disseminated, and that consumers purchased these four products. Thus, the presumption of consumer reliance applies. *See Chierico*, 206 F.3d at 1387; *see also Fed. Trade Comm'n v. BlueHippo Funding, LLC*, 762 F.3d 238, 244 (2d Cir. 2014) (holding that in a contempt case "the FTC is entitled to a presumption of consumer reliance upon showing," among other things, that "the defendant made material misrepresentations or omissions").

"Given this presumption, the FTC need not prove subjective reliance by each customer, as it would be virtually impossible for the FTC to offer such proof,

and to require it would thwart and frustrate the public purposes of FTC action." *Chierico*, 206 F.3d at 1388 (11th Cir. 2000) (quotation and citation omitted). Because it is clear from the record that the defendants failed to successfully rebut the presumption of consumer reliance raised by the FTC's evidence, "all that is left for [the court] to review is the . . . valuation of the losses sustained by [Hi-Tech's] customers." *Id.*

The FTC seeks compensatory sanctions to redress the defendants' numerous violations. The Eleventh Circuit has held that disgorgement of gross receipts is an appropriate compensatory remedy. *Leshin*, 618 F.3d at 1237. The court, using its discretion,[32] finds that valuing losses in terms of profits is not the proper form of relief because, as the court previously noted, "[r]equiring the defendants to return the profits that they received rather than the costs incurred by the injured consumer would be the equivalent of making the consumer bear the defendants' expenses." *National Urological Group, Inc.*, 645 F. Supp. 2d at 1213.

Due to the conduct of Hi-Tech, Wheat, and Smith in violating Sections II and VII of the Hi-Tech injunction from January 1, 2009, through at least August 31, 2013, the court concludes that consumer redress in the amount of the gross receipts for the four products is appropriate. The court finds by a

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[32] *See FTC v. Leshin*, 719 F.3d 1227, 1235 (11th Cir. 2013) (holding that district court's have "wide discretion in fashioning an equitable remedy for civil contempt") (quotation and citation omitted).

preponderance of the evidence[33] (and by stipulation of the parties), that the gross receipts for the sale of the violative products—Fastin, Lipodrene, Benzedrine, and Stimerex-ES—during this period of time total $40,120,950.

The FTC also requests that the court impose a separate sanction of $34,441,227[34] to compensate consumers for the Hi-Tech defendants' violation of Section VI. The court declines the FTC's request. Although the violations of Sections II and VII are separate from the Section VI violation, since there is an overlap of time in which both violations occurred, the court finds imposing separate compensatory sanctions results in duplicity. The court notes, however, that the Hi-Tech defendants' violation of Section VI during the same time period they violated Sections II and VII demonstrates the pervasiveness of their contumacious conduct, thus further demonstrating why $40,120,950 in compensatory sanctions is appropriate.

The court has also found that Wright engaged in conduct violating the Wright injunction from at least September 1, 2010, through at least August 26, 2013. A preponderance of the evidence and stipulation of the parties shows that the gross receipts for the sale of Fastin during this period of time totals

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[33] *Chierico*, 206 F.3d at 1387 (finding that, "in a civil contempt action, we hold that damages must be proven by a preponderance of the evidence").

[34] This figure is the amount of revenues Hi-Tech received for the four products between January 1, 2009 and December 21, 2012, which is the time period in which the products did not have the required yohimbine warning.

$21,493,557.64. The court elects not to exercise its authority to impose a sanction of this magnitude in light of Wright's earlier agreement to be banned from the industry and his voluntary disassociation with Hi-Tech, Wheat, and the entire supplement industry [Doc. No. 964, pp. 5–6]. Instead, the court finds that Wright must pay compensatory sanctions of $120,000, the amount he was paid by Hi- Tech in 2010, 2011, and 2012, combined.

The court concludes that Hi-Tech, Wheat, and Smith must pay compensatory sanctions, jointly and severally,[35] in the amount of $40,000,950; and that Wright must pay compensatory sanctions in the amount of $120,000. The court orders that the FTC must use these funds to reimburse consumers who purchased these products during the relevant time period. The court further orders that all funds, either voluntarily paid by the defendants or otherwise collected by the FTC, must be paid into the Registry of the Court. The FTC may access the funds only with an order by the court granting permission to access and distribute the funds to the affected consumers. The FTC may use a reasonable portion of the compensatory sanction award to cover the costs of reimbursement, including locating the affected consumers and other expenses. Finally, if any funds remain after proper distribution to the affected consumers, the court will then make a determination of the appropriate distribution of those funds.

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[35] *See Leshin*, 618 F.3d at 1236–37 ("Where . . . parties join together to evade a judgment, they become jointly and severally liable for the amount of damages resulting from the contumacious conduct.").

The court recognizes that the compensatory sanctions are significant, but so, too, was the defendants' contumacious conduct. While the defendants essentially claim that several of the violations were honest mistakes, the record is replete with evidence—both direct and circumstantial—showing an intentional defiance of the court's injunctions. Moreover, the court has not gone into great detail regarding the other evidence that was elicited during the 2014 bench trial, but the record contains additional evidence that the Hi-Tech defendants repeatedly provided inaccurate and incomplete information in compliance reports submitted to the FTC, and they did not attempt in good faith to pay the underlying 2008 judgment. The defendants very clearly exhibited a pattern of contemptuous conduct since these proceedings began. Additionally, the amount of compensatory sanctions awarded accounts for only a percentage of Hi-Tech's overall sales.[36] As the court observed once before, "the defendants dispensed deception to those with the greatest need to believe it, and—not surprisingly—generated a handsome profit for their efforts." *Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d at 1209.

IV. Summary

For the reasons discussed above, the court rules on the parties' pending motions as follows: the motion to exclude Dr. Goldhaber [Doc. No. 855] is GRANTED; the motion to exclude Linda Gilbert [Doc. No. 875] is GRANTED; the motion to exclude Susan Blalock [Doc.

[36] Hi-Tech's 2012 U.S. Income Tax Return shows that the total billings for these four products was only 20 percent of Hi-Tech's gross receipts or sales less returns and allowances for that year.

No. 858] is DENIED as MOOT; the motion to exclude Dr. van Breemen [Doc. No. 865] is DENIED; the motion to exclude Dr. Aronne [Doc. No. 866] is DENIED; and the defendants' motion for summary judgment [Doc. No. 876] is DENIED.

The court ORDERS disgorgement of $40,120,950 in compensatory sanctions. Hi-Tech, Wheat, and Smith are jointly and severally liable for $40,000,950. Wright is liable for $120,000. The parties are ORDERED to administer the compensatory sanctions as directed above. In addition, the court ORDERS Hi-Tech, Wheat, and Smith, to the extent it has not been done already, to recall from retail outlets all Fastin, Lipodrene, Benzedrine, and Stimerex-ES with violative product packaging and labels. The FTC is DIRECTED to submit a proposed judgment **within twenty (20) days** of this order, after giving the defendants the opportunity to review same as to form.

SO ORDERED this 10th day of October, 2017.

/s/ Charles A. Pannell, Jr.
CHARLES A. PANNELL, JR.
United States District Judge

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

Civil Action No. 1:04-CV-3294-CAP

FEDERAL TRADE COMMISSION,
Plaintiff,

v.

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

Filed May 14, 2014
ECF Document 650

ORDER

This matter is before the court to determine the nature and amount of sanctions to impose against Hi-Tech Pharmaceuticals, Inc. ("Hi-Tech"), Jared Wheat, Sean Smith, and Dr. Terrell Mark Wright. The court also addresses the Federal Trade Commission's ("FTC") renewed motions seeking to modify two final judgment and permanent injunctions [Doc. Nos. 561 and 562], the FTC's motions for an order of final disposition in garnishment as to SunTrust Bank and Quantum National Bank [Doc. Nos. 577 and 583], Hi-Tech and Wheat's motion for an order to show cause [Doc. No. 615], and the FTC's motion for leave to file a surreply in opposition to the motion for an order to show cause [Doc. No. 631].

I. Introduction

On November 11, 2004, the FTC filed a complaint alleging that several defendants had violated Sections 5 and 12 of the Federal Trade Commission Act (hereinafter "the FTC Act"), 15 U.S.C. §§ 45(a) and 52, by making false and unsubstantiated claims in connection with their advertising and sale of various dietary supplements [Doc. No. 1]. The court granted summary judgment in favor of the FTC on June 4, 2008. *See FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d 1167 (N.D. Ga. 2008), *aff'd*, 365 F. App'x 358 (11th Cir. 2009), *cert. denied*, 131 S. Ct. 505 (2010). The court entered two separate final judgment and permanent injunctions against the defendants on December 16, 2008, enjoining them from several activities related to their previous violations of the FTC Act. The first final judgment and permanent injunction is against National Urological Group, Inc., Hi-Tech, Wheat, Thomasz Holda, and Smith [Doc. No. 230] (hereinafter "the Hi-Tech Order"). The second final judgment and permanent injunction is against Wright [Doc. No. 229] (hereinafter "the Wright Order.")

Section II of each of the injunction orders prohibits the defendants from advertising weight-loss products using claims that the products cause rapid or substantial weight loss and fat loss or claims that the products affect metabolism, appetite, or fat unless those claims are substantiated with "competent and reliable scientific evidence." Section VII of the Hi-Tech Order also prohibits defendants Hi-Tech, Wheat, and Smith from making claims concerning the comparative efficacy or benefits of weight-loss

supplements that are not substantiated with "competent and reliable scientific evidence." Finally, Section VI of the Hi-Tech Order requires Hi-Tech, Wheat, and Smith to include a specific health-risk warning on any advertisement, product package, and product label that makes efficacy claims relating to yohimbine-containing products.

On November 1, 2011, the FTC filed a motion seeking an order from the court directing Hi-Tech, Wheat, and Smith to show cause why they should not be held in contempt of the permanent injunction [Doc. No. 332]. The FTC contended that the defendants had made revised statements about four Hi-Tech products that are not substantiated by competent or reliable scientific evidence despite such evidence being required by the permanent injunction. On March 21, 2012, the FTC filed a similar motion for an order against Wright based on his endorsements of one product, Fastin [Doc. No. 377]. On May 11, 2012, the court granted both motions and scheduled a status conference to address scheduling and discovery [Doc. No. 390] (hereinafter "the May 11 Order"). The court held a status conference with the parties on May 31, 2012. Following the status conference, the court ordered Hi-Tech, Wheat, Smith, and Wright to show cause why they should not be held in contempt for failing to comply with the requirements of the final judgment and permanent injunctions against them [Doc. No. 399] (hereinafter "the May 31 Show Cause Order").

The May 11 Order and the May 31 Show Cause Order collectively set out the procedure the court would follow to resolve the questions of the

defendants' alleged contempt. The court (1) required the FTC to file a specific list of factual allegations and the defendants to admit or deny those allegations (akin to a complaint and answer), (2) permitted limited discovery on relevant issues, and (3) contemplated a "pre-hearing motion" to determine whether there were disputed questions of material fact regarding the defendants' alleged contempt. *See* May 11 Order at 13–14 [Doc. No. 390]; May 31 Show Cause Order [Doc. No. 399]. The procedure set forth by the court is supported by Eleventh Circuit case law. *See Mercer v. Mitchell*, 908 F.2d 763 (11th Cir. 1990); *Nat'l Union Fire Ins. Co. of Pittsburgh, Pa. v. Olympia Holding Corp.*, 140 F. App'x 860, 864–65 (11th Cir. 2005) (discussing the "flexible" due process requirements for civil contempt proceedings). The court prescribed this procedure because it anticipated there would be a limited number of facts in dispute and the scope of any eventual contempt hearing could be significantly narrowed by addressing legal questions based on written briefs. Thus, the defendants have had notice and a full opportunity to be heard on the question of their contempt. *See FTC v. Leshin*, 719 F.3d 1227, 1235 (11th Cir. 2013) (hereinafter "*Leshin* II") ("It is by now well-settled law that due process is satisfied when a civil contempt defendant receives notice and an opportunity to be heard . . . .").

The contempt proceedings progressed essentially as prescribed. First, the FTC filed its complaint-like allegations [Doc. No. 394, at 2–17]. Then, the defendants answered. *See* [Doc. No. 405] (Hi-Tech and Wheat's response); [Doc. No. 406] (Wright's response); [Doc. No. 467] (Smith's adoption of Hi-Tech and

Wheat's response as his own).[1] On October 22, 2012, the FTC filed a motion for (summary) contempt judgment [Doc. No. 446]. The defendants responded: admitting or denying (though mostly admitting) the FTC's alleged undisputed material facts, adding their own additional material facts, and arguing why summary contempt judgment should not be granted. *See* [Doc. Nos. 475, 479, 480, 482]. The FTC replied [Doc. Nos. 485 and 486], and the court allowed Wheat and Hi-Tech to file a surreply [Doc. No. 487-2]. On August 8, 2013, the court entered an order wherein it concluded that Hi-Tech, Wheat, Smith, and Wright had made certain representations without substantiation by competent and reliable scientific evidence, as prohibited by the permanent injunctions in this case [Doc. No. 524] (hereinafter "the August 8 Contempt Order"). The court found Hi-Tech, Wheat, Smith, and Wright to be in contempt of the permanent injunctions.[2] But the court reserved judgment on the nature and amount of sanction for the defendants' contempt of the court's orders. Beginning on January 21, 2014, and ending on January 24, 2014, the court held an evidentiary hearing to determine the

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[1] The court allowed Smith's "adoption" of his co-defendants' response "as if timely made" in its December 11, 2012 order [Doc. No. 470 at 3].

[2] The court made its findings of civil contempt based on clear and convincing evidence. Clear and convincing evidence established that the court's orders were valid and lawful, that the orders were clear and unambiguous, that the defendants had the ability to comply with the orders, and that the defendants violated the court's orders. There was no evidence presented at the sanctions hearing that would cause the court to revisit these findings.

appropriate nature and amount of sanctions. Following the evidentiary hearing, the parties submitted proposed findings of fact and conclusions of law and post-trial briefing [Doc. Nos. 600, 623, 624, 629, 630, 632, 633, 634]. The following order sets forth the court's findings of fact and conclusions of law regarding the nature and amount of sanctions as required by Federal Rule of Civil Procedure 52 and addresses related pending motions.

II. Sanctions

On August 8, 2013, the court concluded that Hi-Tech, Wheat, and Smith had violated the Hi-Tech Order by making unsubstantiated advertising claims for Fastin, Lipodrene, Benzedrine, and Stimerex-ES and by failing to include a required health-risk warning for those products. In addition, the court concluded that Wright had violated the Wright Order by providing an unsubstantiated endorsement for Fastin that Hi-Tech, Wheat, and Smith used in Fastin print advertisements. Accordingly, the court held the defendants in contempt of the Hi-Tech Order and the Wright Order. The court reserved judgment on the nature and amount of sanctions and scheduled a sanctions hearing to resolve this issue. This order resolves the issue of the nature and amount of sanctions imposed against the defendants following the sanctions hearing.

A. Findings of Fact

The court makes the following findings of fact based on the clear and convincing evidence presented by the parties or otherwise stipulated.

1. Control Over Hi-Tech's Marketing Practices

Wheat is the sole owner, president, chief executive officer, secretary, and treasurer of Hi-Tech. Wheat is responsible for the labeling, promotion, and advertising of Fastin, Lipodrene, Benzedrine, and Stimerex-ES. Smith is the senior vice-president in charge of sales of Hi-Tech products, including Fastin, Lipodrene, Benzedrine, and Stimerex-ES. He oversees the sales force and has the authority to decide which retailers sell Hi-Tech products. Smith is also the head of the Food, Drug, and Mass division of Hi-Tech. He is responsible for acquiring retail accounts with food stores, drug chains, and mass merchandisers. Smith has helped to place violative advertising for Fastin, Lipodrene, Benzedrine, and Stimerex-ES with various publications and agencies. In addition to his current job responsibilities, Smith was responsible for the day-to-day operations of Hi-Tech while Wheat was incarcerated from March 16, 2009, through September 15, 2010.[3]

2. Violative Advertising

From September 2010 through at least December 14, 2012, Hi-Tech, Wheat, and Smith (hereinafter "the Hi-Tech defendants") disseminated print advertisements for Fastin containing claims that violate the Hi-Tech Order through national magazines such as *Allure*, *Cosmopolitan*, *First*, *Fitness*, *Flex*, *Globe*, *In Touch*, *Life & Style*, *Martha Stewart*

[3] Smith testified that it was his job to "hold down the fort" while Wheat was incarcerated. Tr. of Sanctions Hr'g, Jan. 21, 2014 at 68:1–69:1 [Doc. No. 618].

Weddings, *Muscle & Fitness*, *MuscleMag International*, *Muscular Development*, *National Enquirer*, *OK*, *Redbook*, *Self*, *Star*, *US Weekly*, *USA Today Women's Health Guide*, *Whole Living*, *Women's Day*, and *Women's World*.[4] In addition to the national magazines, the Hi-Tech defendants disseminated the violative Fastin print advertisements through the company website[5] through early January 2014. Since September 17, 2010, the Hi-Tech defendants have advertised and offered Fastin for sale on the company website using violative advertising claims; these violative actions continued through January 21, 2014.[6] Since January 1, 2009, the Hi-Tech defendants have advertised Fastin through product packaging and labels that contain violative claims. Even after the sanctions hearing, the Hi-Tech defendants continue to advertise Fastin through violative product packaging and labels that remain in the marketplace.

From October 2010 through at least December 14, 2012, the Hi-Tech defendants disseminated print advertisements for Lipodrene that contain claims that violate the Hi-Tech Order through national magazines such as *Flex*, *Muscle & Fitness*, and *MuscleMag International*. In addition, they disseminated the violative Lipodrene print advertisements through the company website through early January 2014. Since

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[4] The FTC has notified the court in response to a post-trial motion by Hi-Tech and Wheat that violative print advertisements have been disseminated as recently as November 2013 in *Flex* magazine [Doc. No. 637]. The court cannot make a finding as to the validity of this allegation at this time.

[5] The company website is www.hitechpharma.com.

[6] The first day of the sanctions hearing was January 21, 2014.

September 17, 2010, the Hi-Tech defendants advertised and offered Lipodrene for sale on the company website using violative advertising claims; these violative actions continued through January 21, 2014. Since January 1, 2009, the Hi-Tech defendants have advertised Lipodrene through product packaging and labels that contain violative claims. The Hi-Tech defendants have continued to advertise Lipodrene through violative product packaging and labels even after the sanctions hearing.

From September 2010 through at least November 2011, the Hi-Tech defendants disseminated print advertisements for Benzedrine that contain claims that violate the Hi-Tech Order through national magazines such as *Flex*, *Muscle & Fitness*, *MuscleMag International*, and *Muscular Development*. In addition, they disseminated the violative Benzedrine print advertisements through the company website through early January 2014. From September 17, 2010, the Hi-Tech defendants advertised and offered Benzedrine for sale on the company website using violative claims; these violative acts continued through January 21, 2014. Since January 1, 2009, the Hi-Tech defendants have advertised Benzedrine through product packaging and labels that contain violative claims.

From October 2010 through at least December 14, 2012, the Hi-Tech defendants disseminated print advertisements for Stimerex-ES that contain claims that violate the Hi-Tech Order through national magazines such as *Flex*, *Muscle & Fitness*, *MuscleMag International*, and *Muscular Development*. They also disseminated the violative print advertisements

through the company website through January 21, 2014. Since September 17, 2010, the Hi-Tech defendants advertised and offered Stimerex-ES for sale on the company website using violative claims; they continued these violative acts through January 21, 2014. From January 1, 2009, the Hi-Tech defendants have advertised Stimerex-ES through product packaging and labels that contain violative claims. They continue to advertise Stimerex-ES through violative product packaging and labels.

3. Review of Advertising by Legal Counsel

On June 1, 2010, Wheat asked Joseph Schilleci[7]—counsel for Hi-Tech and Wheat—to review a proposed Fastin advertisement.[8] A few days after this request, Schilleci, Arthur Leach, Victor Kelley, and Tim Fulmer—counsel for Hi-Tech and Wheat—drafted a memorandum, dated June 4, 2010, to Wheat relating to the proposed Fastin advertisement (hereinafter "the June 4 Memo").[9] In the memorandum, counsel stated, "[B]ased upon our review, we have grave concerns that the publication of the proposed Fastin® advertisement would not be in compliance with the broad scope of the FTC injunction."[10] Plt.'s Ex. 117 at 2

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[7] Joseph Schilleci also goes by the name Jody.

[8] The subject line for Wheat's email to Schilleci states, "One last set of eyes." In addition, Wheat stated in his email to Schilleci that all of the claims in the Fastin advertisement were included on the Fastin packaging and labels. Defs.' Ex. 8 at 1 [Doc. No. 487-5 at 6].

[9] Wheat received a copy of the June 4 Memo.

[10] While the June 4 Memo did not specifically address proposed web pages to be used by Hi-Tech, counsel indicated that they

[Doc. No. 485-2 at 2]. Counsel also identified specific statements that they believed were prohibited. These statements were believed to refer to the product Fastin rather than the ingredients, thus requiring proper substantiation. Counsel offered their opinion in the June 4 Memo that certain forms of advertising would be in compliance with the Hi-Tech Order. The Hi-Tech defendants did not adopt counsel's suggested approach for advertising Fastin. Despite receiving the June 4 Memo, they continued to make the claims that counsel believed were prohibited.

Between July 2010 and September 2010, Edmund Novotny reviewed print advertisements and web pages for Fastin, Lipodrene, Benzedrine, and Stimerex-ES; he did not review product packaging and labels, and he did not provide an opinion on Wright's endorsement of Fastin.[11] On July 20, 2010, Novotny recommended that the following claim be removed from the Fastin advertisement: "Warning: Extremely Potent Diet Aid! Do Not Consume Unless Rapid Fat And Weight Loss Are Your Desired Result." Defs.' Ex. 13 at 1, 4 [Doc. No. 487-5 at 12, 15]. Despite the recommendation, this language continued to appear on Fastin packaging through at least December 31, 2011. Following his review, Novotny approved certain claims, including, "Rapid Fat Loss Catalyst," "Rapid Fat Loss," "Increases the Metabolic Rate, Promoting Thermogenesis (The Burning of Stored Body Fat),"

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contained similar types of representations that would likely be considered non-compliant.

[11] Novotny did not review claims that appeared on images of product packaging and labels included in the print advertising or web pages.

and "Rapid Fat Burner." Regarding Novotny's approval of the claim "fat loss," Wheat stated in a phone conversation with Smith, "I don't know if Ed [Novotny] just was pulling that out of his rear or what." Plt.'s Ex. 106 at 7:14–16 [Doc. No. 446-13 at 235].

With regards to the advice he received from counsel on the advertising claims, Wheat stated, "I just wanted something in writing from these cats." Plt.'s Ex. 106 at 7:17–18 [Doc. No. 446-13 at 235]. He also stated, "I'm going to have to put these cats up on my stand if, you know—if we ever have to get drug back before Panelle [sic], I'm going to put Jody [Schilleci] and Ed [Novotny] up—you know, they're the scapegoats, in essence. Hey, you gave me this advice." Plt.'s Ex. 106 at 14:2–6 [Doc. No. 446-13 at 242].

4. Yohimbine Warning

The court issued the Hi-Tech Order on December 16, 2008, which set forth a specific yohimbine warning required to be included on all packaging and labels. Proofs provided by the printer indicate that the required warning was incorporated into product packaging and labels in 2012. Despite this evidence, an investigator with the FTC purchased a bottle of Fastin from a CVS Pharmacy store in Washington, DC, on August 2, 2013, that did not contain the required yohimbine warning on the product packaging.

5. Substantiation Requirement

During the period of time that the Hi-Tech defendants disseminated violative advertising, they were aware that double-blind, placebo-based, clinical

studies were required to substantiate weight-loss claims for the dietary supplements. On March 28, 2010, in an email from Wheat to Smith, Wheat stated, "Ullman and Shapiro are not aware of the recent ruling in the 11th circuit against us because if the verdict stands it will allow FTC to win any advertisement case that a company has not done a double-blind placebo study on the product itself." Plt.'s Ex. 96 at 3 [Doc. No. 446-13 at 172]. In the June 4 Memo, counsel for Hi-Tech and Wheat stated, "[B]ased upon Judge Pannell's previous findings, it is reasonable to assume that he would take a position consistent with the FTC that double-blind, clinical trials of the product were necessary . . . ." Plt.'s Ex. 117 at 4 [Doc. No. 485-2 at 4]. On July 7, 2010, in an email from Wheat to Leach and Schilleci—counsel for Hi-Tech and Wheat—Wheat stated, "[I]f our set of facts is not good enough then a double-blind placebo study would be required." Plt.'s Ex. 100 at 3 [Doc. No. 446-13 at 189]. The Hi-Tech defendants have not performed double-blind, placebo-based, clinical studies to substantiate the weight-loss claims as required by the Hi-Tech Order.

6. Violative Advertising After August 8 Contempt Order

On August 30, 2013, an investigator with the FTC purchased Lipodrene from the company website. The bottle that he received in the mail contained violative claims on the product label. On August 30, 2013, the investigator purchased Benzedrine from the website Amazon.com. The bottle that he received in the mail contained violative claims on the product packaging and did not include the required yohimbine warning.

On December 14, 2013, the investigator once again purchased Lipodrene from the company website. The bottle that he received in the mail contained violative claims on the product label. On December 20, 2013, the investigator purchased Fastin from a General Nutrition Centers, Inc. ("GNC") store in Washington, DC, that contained violative advertising claims on the product packaging and label. On January 20, 2014, the investigator obtained Fastin from an Atlanta-area GNC store that contained violative advertising on the product packaging and label.

The Hi-Tech defendants did not remove violative advertising from the company website until January 2014, approximately 5 months after the court had found the defendants in contempt. The violative advertising on the company website included copies of the violative print advertisements. On the first day of the sanctions hearing, January 21, 2014, the public was still able to access the violative advertising hosted on the company website through internet search engines such as Google and Bing.[12]

7. Inaccurate and Incomplete Responses

The Hi-Tech defendants repeatedly provided inaccurate and incomplete information in compliance reports submitted to the FTC, and in response to requests for information by the FTC. For example, on August 19, 2013, the FTC made a compliance demand on the Hi-Tech defendants that requested them to identify and describe any entity for which Hi-Tech or

[12] The Hi-Tech defendants merely disabled links to the violative advertising on the company's website prior to January 21, 2014.

Wheat is an officer, director, principal, owner or shareholder. In response to a demand letter, dated September 11, 2013, the Hi-Tech defendants stated that Hi-Tech Publishing, Inc. ("Hi-Tech Publishing") does not sell or advertise weight-loss products. Contrary to this assertion, Hi-Tech Publishing is wholly owned by Wheat and has published a catalog titled "Hi-Tech Health & Fitness," which was sent to retailers to be offered to customers. The "Hi-Tech Health & Fitness" magazine contains print advertisements for Hi-Tech products and articles intended as a form of advertising. The Hi-Tech defendants also failed to provide the FTC with complete and accurate information regarding advertisements and the product packaging and labels for Hi-Tech products on repeated occasions.

8. Other Dietary Supplement Businesses

Wheat acquired Hi-Tech Nutraceuticals, LLC ("Nutraceuticals") in 2012; he is the sole owner of the company. Nutraceuticals is a nutritional and dietary supplement manufacturer. Wheat owns a consulting company called PharmaTech Consulting, Inc. ("PharmaTech"), which claims to specialize in Food and Drug Administration ("FDA") and FTC regulatory matters. This company offers consulting, submission, and auditing services, including the review of dietary supplement labels and advertising for compliance with FDA and FTC regulations.[13]

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[13] Patrick Jacobs, who was called as a witness by the defendants during the sanctions hearing, is identified on the company website for Nutraceuticals as affiliated with the company, and Wheat testified during the sanctions hearing that he is affiliated with PharmaTech. Jacobs testified during the

The Hi-Tech defendants acquired APS Nutrition ("APS") on November 3, 2011, and they acquired ALR Industries ("ALRI") on December 28, 2012. Both companies engage in activities covered by the Hi-Tech Order. The Hi-Tech defendants did not inform the FTC of these acquisitions. In addition, Wheat acquired Nutraceuticals in September 2012, which engages in activities covered by the Hi-Tech Order, and did not inform the FTC of this acquisition.

9. Dr. Mark Wright

Wright violated the Wright Order by providing an unsubstantiated endorsement for Fastin. Beginning in October 2010, print advertisements were disseminated that featured an unsubstantiated endorsement by Wright. These violative print advertisements were also featured on the company website through at least December 30, 2013. In addition to providing an endorsement of Fastin that was used in the advertising of the product, Wright authored articles printed in the "Hi-Tech Health & Fitness" magazine promoting Hi-Tech weight loss products.[14] These articles were disseminated in violation of the Wright Order.

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sanctions hearing that he was unaware prior to preparing for the sanctions hearing that he was identified as affiliated with these companies. Wheat also testified during the sanctions hearing that PharmaTech offers the services of Novotny to potential clients. Novotny testified during the sanctions hearing that he was unaware prior to the sanctions hearing that he was being held out as associated with PharmaTech.

[14] The articles were published in issues of the "Hi-Tech Health & Fitness" magazine dated April 2009 and January 2011.

10. Gross Receipts

The Hi-Tech defendants have sold Fastin, Lipodrene, Benzedrine, and Stimerex-ES without interruption since January 1, 2009. For the time period of January 1, 2009, through August 31, 2013, the gross sales less refunds and returns from the sale of Fastin, Lipodrene, Benzedrine, and Stimerex-ES totaled $40,120,950. For the time period of January 1, 2009, through August 26, 2013, during which Hi-Tech used Wright's endorsement to advertise Fastin, the gross sales less refunds from the sale of Fastin totaled $21,493,557.64.

11. Unpaid Judgment

On September 15, 2012, Wheat wrote a check to the FTC in the amount of $150,000; this is the only voluntary payment made by Wheat. The parties stipulate that as of January 22, 2014, approximately $3,799,303.05 of the $15,900,000 judgment entered by the court against Hi-Tech, Wheat, Holda, and Smith, jointly and severally, remains unpaid.

During the sanctions hearing, Wheat testified that he attempted in good faith to pay the underlying judgment. The evidence does not support his testimony.[15] On April 19, 2010, while incarcerated, Wheat sent an email to Kelley, which stated, "I spoke with Art [Leach] on Friday and we discussed it may be wise to set up another bank account for Hi-Tech in case the FTC tries to execute against our current bank after they recieve [sic] the banking information

[15] Wheat asserted his Fifth Amendment right against self-incrimination with respect to many questions concerning finances.

revealed in the subpoena." Plt.'s Ex. 97 at 3 [Doc. No. 446-13 at 175]. After this email conversation, Kelley set up a bank account in the name of Affiliated Distribution, Inc. ("Affiliated")[16] to be used by Hi-Tech as its operating account. On November 3, 2011, after the FTC initiated this contempt action, Hi-Tech purchased APS Nutrition ("APS") for $1,200,000. In 2012, Wheat paid $2,000,000 from his personal bank account towards the purchase of Neutraceuticals. On December 28, 2012, Hi-Tech paid $600,000 as a down payment towards the $3,000,000 purchase price of ALRI.

On April 25, 2013, Wheat withdrew $1,000,000 from a bank account with East-West Bank. On January 18, 2012, an official check was purchased in the amount of $425,000 using funds from the Affiliated bank account with Fifth Third Bank. On January 26, 2012, an official check was purchased in the amount of $439,166.68 using funds from the Affiliated bank account with Fifth Third Bank. Between 2012 and 2013, Wheat received millions of dollars in dividends from Hi-Tech. On January 8, 2013, Wheat entered into a contract to purchase a Lamborghini Gallardo for $135,087. He paid a $2,000 deposit on January 10, 2013, and paid the balance of the purchase price on January 11, 2013.

12. Recall

The Hi-Tech defendants have not recalled all Fastin, Lipodrene, Benzedrine, and Stimerex-ES with product packaging and labels containing violative claims. Fastin, Lipodrene, Benzedrine, and Stimerex-

[16] A wholly owned subsidiary of Hi-Tech.

ES with product packaging and labels containing violative claims remain in the marketplace at retail stores.

B. Conclusions of Law

This matter concerns civil contempt by the defendants. District courts have wide discretion in fashioning an equitable remedy for civil contempt. *Leshin* II, 719 F.3d at 1231. The Eleventh Circuit Court of Appeals has held, "'[S]anctions in civil contempt proceedings may be employed for either of two purposes: to coerce the defendant into compliance with the court's order, and to compensate the complainant for losses sustained.'" *Id.* (quoting *Local 28 of Sheet Metal Workers' Int'l Ass'n v. EEOC*, 478 U.S. 421, 443 (1986)). Coercive sanctions are limited by the principle that "once a contemnor's contumacious conduct has ceased or the contempt has been purged, no further sanctions are permissible." *Id.* However, "'the district court's discretion in imposing noncoercive sanctions is particularly broad and only limited by the requirement that they be compensatory.'" *Id.* (quoting *Howard Johnson Co. v. Khimani*, 892 F.2d 1512, 1521 (11th Cir. 1990)). Confirming this broad discretion, the United States Supreme Court has held, "The measure of the court's power in civil contempt proceedings is determined by the requirements of full remedial relief." *McComb v. Jacksonville Paper Co.*, 336 U.S. 187, 193 (1949). With respect to the form of compensatory sanctions, the court of appeals has held that disgorgement of gross receipts is an appropriate compensatory remedy. *FTC v. Leshin*, 618 F.3d 1221, 1237 (11th Cir. 2010) (hereinafter "*Leshin* I"). The court does not believe

profits is the proper form of relief because "[r]equiring the defendants to return the profits that they received rather than the costs incurred by the injured consumer would be the equivalent of making the consumer bear the defendants' expenses." *F.T.C. v. National Urological Group, Inc.*, 645 F. Supp. 2d 1167, 1213 (N.D. Ga. 2008). Finally, the amount of compensatory damages must be proven by a preponderance of the evidence. *McGregor v. Chierico*, 206 F.3d 1378, 1387 (11th Cir. 2000).

As set forth in the preceding section of this order, the court has found that the Hi-Tech, Wheat, and Smith engaged in conduct violating the Hi-Tech Order from January 1, 2009, through at least August 31, 2013. The court concludes, by a preponderance of the evidence, that the gross receipts for the sale of the violative products—Fastin, Lipodrene, Benzedrine, and Stimerex-ES—during this period of time total $40,120,950.[17] The court has also found that Wright engaged in conduct violating the Wright Order from at least September 1, 2010, through at least August 26, 2013. The court concludes, by a preponderance of the evidence, that the gross receipts for the sale of Fastin during this period of time totals $21,493,557.64.[18] These calculations are based on the total billings for the products during the relevant time periods minus

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[17] The court bases this conclusion on a table used by the defendants at the sanctions hearing, Defs.' Ex. 65 at 19 [Doc. No. 565 at 19], and other evidence before the court.

[18] The court bases this conclusion on a stipulation by the defendants as to the gross revenues of Fastin for this time period and a letter from counsel for the defendants to counsel for the FTC. Stipulations of Fact ¶ 5 [Doc. No. 534-1 at 3]; Plt.'s Ex. 167.

refunds and returns. "'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* I, 618 F.3d at 1236–37. Accordingly, the court finds that $40,120,950 in compensatory sanctions is owed to consumers. The court finds that Hi-Tech, Wheat, and Smith must pay compensatory sanctions, jointly and severally, in the amount of $40,000,950. The court also finds that Wright must pay compensatory sanctions in the amount of $120,000.[19] The court has the authority to impose a greater amount of compensatory sanctions against Wright, but the court elects not to exercise this authority in light of his consent to a permanent injunction as discussed more fully in Section III.C of this order.

In *F.T.C. v. Trudeau*, 579 F.3d 754 (7th Cir. 2009), the Seventh Circuit Court of Appeals held, "Beyond explaining its calculations, the court must also outline how the sanction should be administered." *Id.* at 774. In this matter, the court orders that the FTC must use these funds to reimburse consumers who purchased these products during the relevant time period. The court orders that all funds, either voluntarily paid by the defendants or otherwise collected by the FTC, must be paid into the Registry of the Court. The FTC may access the funds only with an order by the court granting permission to access and distribute the funds

[19] The court arrives at this amount based on Wright's counsel's statements during the sanctions hearing that Wright was paid a total of $120,000 by Hi-Tech for his services in 2010, 2011, and 2012, combined. Tr. of Sanctions Hearing, 1/24/2014 at 69:14–21 [Doc. No. 621].

to the affected consumers. The FTC may use a reasonable portion of the compensatory sanction award to cover the costs of reimbursement, including locating the affected consumers and other expenses. Finally, if any funds remain after proper distribution to the affected consumers, the court will then make a determination of the appropriate distribution of those funds.

District courts may impose incarceration as a coercive sanction in civil contempt proceedings. *Combs v. Ryan's Coal Co., Inc.*, 785 F.2d 970 (11th Cir. 1986). The Supreme Court of the United States has held, "The paradigmatic coercive, civil contempt sanction . . . involves confining a contemnor indefinitely until he complies with an affirmative command such as an order 'to pay alimony, or to surrender property ordered to be turned over to a receiver, or to make a conveyance.'" *Int'l Union, United Mine Workers of America v. Bagwell*, 512 U.S. 821 (1994). "Imprisonment for a fixed term similarly is coercive when the contemnor is given the option of earlier release if he complies." *Id.* According to the Eleventh Circuit Court of Appeals, "Our sole inquiry into the legitimacy of incarceration for contempt, *per se*, is into the purpose of imprisonment. If the court's goal is to coerce, rather than to punish, then incarceration is viewed as civil even though imprisonment has concomitant punitive effects." *Combs*, 785 F.2d at 981.

As the court held in its August 8 Contempt Order, the absence of willfulness is not a defense in a civil contempt proceeding. *Leshin* I, 618 F.3d at 1232. "[S]ubstantial, diligent, or good faith efforts are not enough; the only issue is compliance." *Id.* The

defendants' diligence and good faith are, at best, relevant to coercive contempt sanctions, but not compensatory sanctions. *See TiVo Inc. v. EchoStar Corp.*, 646 F.3d 869, 880 (Fed. Cir. 2011). The court is not swayed by the defendants' attempt to offer a good faith, diligence defense to their contumacious conduct. The evidence does not support such an argument. The defendants received advice from counsel that specific claims would violate the court's orders. Rather than heed the advice they received from counsel, the defendants sought advice from additional counsel not in good faith. The FTC presented evidence of conversations between the defendants that shows the real motive of the defendants was to obtain advice from counsel to use as a shield to any contempt proceedings, even if they knew the advice was incorrect.

In this case, the Hi-Tech defendants' contumacious conduct continued after the court's August 8 Contempt Order. With respect to the violative advertising claims disseminated through the company website, the Hi-Tech defendants did not correct their contumacious conduct until after the first day of the sanctions hearing. Wheat has testified that he was unable to make the necessary changes to the company website because of illnesses in his immediate family. The court is sympathetic to his situation, but any difficulties he faced did not excuse him of his duty to comply with the court's orders, particularly after the court had entered its August 8 Contempt Order.[20]

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[20] Wheat's purported justification for the delay in complying with the court's order is suspect. Wheat testified during the sanctions hearing that he is essential to the operations of Hi-

More troubling is the fact that the contumacious conduct is ongoing. The defendants have not conducted a recall of the product from retail stores. Following the sanctions hearing, the parties submitted letters to the court to update the court on the presence of violative product packaging and labels in the retail market. Hi-Tech and Wheat indicated that representatives of the company had spoken to approximately 65% of its customers.[21] Hi-Tech and Wheat also state that they have produced new product packaging and labels for the products at issue. These efforts are insufficient. First, the court is skeptical that retail outlets will use the new product packaging and labels. In fact, an investigator with the FTC has submitted a declaration to the court stating that, as of February 6, 2014, the product was available for purchase at two retail outlets in Washington, DC, with violative product packaging and labels. Second, the court does not approve the new product packaging and labels. The new labels submitted to the court contain violative claims. The Fastin and Lipodrene labels include the word "thermogenic," while the Benzedrine label includes the word "anorectic." The court's August 8 Contempt Order identified these words as representations that the products affect human metabolism, appetite, or body fat. While the

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Tech. Despite his importance to the operations of the company, it continued to operate during the period of time of his family issues. Either Wheat continued to perform his responsibilities and chose to not make the necessary changes to the company website, or the company was able to operate without his involvement.

[21] The defendants have not informed the court regarding the substance of what the representatives said to customers.

defendants attempt to define "thermogenic" as signifying the production of heat, the defendants previously defined the term as meaning the burning of stored body fat. The latter definition was included on advertisements found to be violative by the court. With respect to the word "anorectic," the court included a footnote in the August 8 Contempt Order noting that "anorectic" is defined as lacking appetite. Use of "thermogenic" and "anorectic" on product packaging and labels violates the Hi-Tech Order.

Hi-Tech, Wheat, and Smith remain in contempt of the court's order as long as product packaging and labels remain in the retail market with violative claims. Therefore, the court orders a recall of Fastin, Lipodrene, Benzedrine, and Stimerex-ES with violative product packaging and labels from all retail outlets. The parties are required to submit written reports to the court within 60 days of this order on the status of the product recall.[22] Any of the parties may include a request for a hearing regarding the status of the recall. The court will order coercive incarceration if the defendants have not taken sufficient action to effect a complete recall.

C. Conclusion

The court ORDERS disgorgement of $40,120,950 in compensatory sanctions. Hi-Tech, Wheat, and Smith are jointly and severally liable for $40,000,950. Wright is liable for $120,000. The parties are ORDERED to administer the compensatory sanctions as directed above. In addition, the court ORDERS Hi-

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[22] Any written reports submitted to the court must be under oath.

Tech, Wheat, and Smith to recall from retail outlets all Fastin, Lipodrene, Benzedrine, and Stimerex-ES with violative product packaging and labels. The parties are ORDERED to notify the court of the status of the recall as directed above.

III. Motions to Alter Final Judgment and Permanent Injunction

The FTC has filed two motions seeking to modify two separate final judgment and permanent injunctions [Doc. Nos. 561 and 562]. Through its first motion [Doc. No. 561], the FTC seeks to modify the Hi-Tech Order. The FTC seeks to modify the Hi-Tech Order with respect to only Hi-Tech, Wheat, and Smith.[23] The FTC proposes the following modifications:

> (1) [B]an [Hi-Tech, Wheat, and Smith] from participating in the advertising, marketing, promoting, offering for sale, sale, or distribution of any dietary supplement and/or weight-loss product, program, and service; (2) broaden coverage of order provisions to cover any product or service; and (3) enhance monitoring and reporting provisions designed to give the Commission enhanced oversight of [Hi-Tech, Wheat, and Smith's] future compliance with the Hi-Tech Order.

Mem. in Supp. of Plt.'s Renewed Mot. to Modify at 8 [Doc. No. 561-1]. And through its second motion [Doc. No. 562], the FTC seeks to modify the Wright Order. The FTC proposes the following modifications:

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[23] The Hi-Tech order is against National Urological Group, Inc., Hi-Tech, Wheat, Thomasz Holda, and Smith.

> (1) [B]an Wright from participating in marketing any dietary supplement and/or weight loss product, including through endorsements; (2) broaden the order to cover false and unsubstantiated claims in the marketing of any product or service; and (3) enhance monitoring and reporting provisions designed to give the Commission oversight of Wright's future compliance with the [Wright] Order.

Mem. in Supp. of Plt.'s Renewed Mot. at 6 [Doc. No. 562-1]. Collectively, the motions seek to impose greater restrictions on the defendants.

A. Legal Standard

The FTC seeks to modify the final judgment and permanent injunctions pursuant to Rule 60(b). Pursuant to Rule 60(b), the court may modify an injunction when "applying it prospectively is no longer equitable." The Eleventh Circuit Court of Appeals has held that a district court has the power to modify a judgment or order if the moving party has shown that the judgment or order has failed to accomplish the results it was designed to achieve. *Epic Metals Corp. v. Souliere*, 181 F.3d 1280, 1283 (11th Cir. 1999) (citing *United States v. United Shoe Mach. Corp.*, 391 U.S. 244, 247 (1968)). In subsequent cases, the court of appeals has refined the standard further by holding that the district court's authority to modify a judgment or order is subject to the constraints set forth in *Rufo v. Inmates of Suffolk County Jail*, 502 U.S. 367 (1992). *Sierra Club v. Meiburg*, 296 F.3d 1021, 1033 (11th Cir. 2002). According to the court of appeals, in *Rufo*, "the Supreme [Court] said that the

party seeking modification of a consent decree must show, first, 'a significant change either in factual conditions or in law,' and, second, that 'the proposed modification is suitably tailored to the changed circumstance.'" *Id.* (quoting *Rufo*, 502 U.S. at 384, 391). A party seeking modification of a consent decree may satisfy the first prong of the test by demonstrating that the consent decree has failed to achieve its purpose. *FTC v. Garden of Life, Inc.*, No. 06-80226-CIV, 2012 WL 1898607 at *3 (11th Cir. May 25, 2012). While *Sierra Club* and *Garden of Life* concerned the modification of consent decrees, the court applies the standard set forth in these cases to the modification of the non-consent injunctions at issue in this case.

B. The Hi-Tech Order

The FTC states that the Hi-Tech Order's purpose is to protect the public from deceptive claims and from the health risk posed by yohimbine-containing supplements. The FTC argues that the order should be modified because it has failed to achieve this objective. The basis for the FTC's motion to modify the order is the Hi-Tech defendants' "pervasive and flagrant" order violations and the expansion of their violative conduct. While it is true that the Hi-Tech defendants have violated the Hi-Tech Order, this is not sufficient evidence to warrant modification. The FTC has not demonstrated that the Hi-Tech Order has failed to achieve its purpose. Pursuant to this order, the court has ordered compensatory sanctions to make affected consumers whole and will order coercive incarceration if a complete recall is not completed. The Hi-Tech defendants have not been able to skirt the Hi-

Tech Order with impunity. The Hi-Tech Order, as currently drafted, remains capable of achieving its objective provided those who are bound by the order comply. If the court were to grant the FTC's requested relief, then any violation of an injunction would require modification of the injunction. Furthermore, the FTC has not presented other evidence that shows a significant change either in the factual conditions or the law.[24] The court does not address the second prong of the analysis, whether the proposed modification is suitably tailored to the changed circumstances.

C. The Wright Order

The FTC states that the Wright Order's purpose is to protect the public from Wright's deceptive claims, including his deceptive expert endorsements, by prohibiting him from making unsubstantiated representations about weight-loss products. The FTC argues that the Wright Order has failed to achieve its purpose. The court's analysis is different with respect to the Wright Order because Wright has consented to part of the FTC's request to modify the order. Wright consents to a permanent injunction barring him from being an endorser or consultant in the dietary supplement business. The court believes this modification encompasses the first proposed

[24] The court believes evidence that the Hi-Tech defendants are making claims that violate the Hi-Tech Order through other dietary supplement companies would qualify as a significant change to the factual conditions. In this case, the FTC has established only that Hi-Tech and Wheat have acquired other dietary supplement companies. The FTC has not established that these companies make advertising claims that violate the Hi-Tech Order.

modification by the FTC. With respect to the remaining modifications sought by the FTC, the court concludes that the FTC has not demonstrated that the Wright Order has failed to achieve its purpose. Nor has the FTC established a significant change either in the factual conditions or law. Once again, the court does not address whether the proposed modification is suitably tailored to the changed circumstances.

D. Conclusion

The court DENIES the FTC's motion to modify the Hi-Tech Order [Doc. No. 561]. The Hi-Tech Order remains in effect. The court GRANTS IN PART and DENIES IN PART the FTC's motion to modify the Wright Order [Doc. No. 562]. The court ORDERS that Wright be barred permanently from being an endorser or consultant in the dietary supplement business. The court AMENDS the Wright Order to include the additional limitation that Wright is barred from being an endorser or consultant in the dietary supplement business. The Wright Order remains in effect with the modification noted above.

IV. Motion to Show Cause[25]

The final issue for the court to address is the alleged unprofessional conduct of Stephen Dowdell, an attorney for the FTC. Hi-Tech and Wheat have filed a motion requesting that the court issue an order directing Dowdell to show cause why he should not be disciplined for unprofessional conduct [Doc. No. 615]. On May 9, 2012, Dowdell filed a notice of appearance

[25] The court GRANTS the FTC's motion for leave to file a surreply in opposition to Hi-Tech and Wheat's motion to show cause [Doc. No. 631].

on behalf of the FTC. He subsequently signed filings related to the ongoing garnishment efforts by the FTC against Hi-Tech and Wheat. Hi-Tech and Wheat argue that Dowdell engaged in the unauthorized practice of law and the unethical practice of law. The court analyzes the motion for an order to show cause similar to a Rule 12(b)(6) motion: The court assumes the facts as alleged (in the motion for show cause) are true and asks whether those facts state a violation of Dowdell's professional obligations.

A. Unauthorized and Unethical Practice

Hi-Tech and Wheat allege that Dowdell engaged in the unauthorized practice of law by entering a notice of appearance and signing pleadings without being a member of the Georgia Bar or being admitted *pro hac vice*. The FTC admits that Dowdell engaged in the unauthorized practice of law but argues that the mistake was made in good faith because of his mistaken belief that he was eligible to practice in this district based on his previous position as an attorney with the United States Department of Justice. Based on the court's review of this matter, the court finds that sanctions are not warranted against Dowdell for his unauthorized practice of law.[26] Dowdell may not

[26] While counsel for Hi-Tech and Wheat argue that Dowdell should not be afforded leniency, they have committed a similar error in a related matter. *See Hi-Tech Pharmaceuticals, Inc. v. Federal Trade Commission*, 1:13-CV-4306-CAP (counsel for Hi-Tech made filings in this court prior to entry of appearance and without having applied to appear *pro hac vice*). The court believes it is just and prudent to forego sanctions against Dowdell. If the court were to impose sanctions against Dowdell for his unauthorized practice of law, the court would consider sanctions against counsel for Hi-Tech and Wheat in the related matter.

appear before this court in this or any other matter until he has become a member of the Georgia Bar or is admitted *pro hac vice*.

In addition to allegations of unauthorized practice of law, Hi-Tech and Wheat allege that Dowdell engaged in the unethical practice of law by not including his bar number on the pleadings he signed and submitted to this court and by making repeated and deliberate misstatements of the truth. The specific allegations of Dowdell's misstatements of truth include the following: (1) the date on which demand of payment was made, (2) the certificate of service, and (3) the date he sent the writs of garnishment to the banking institutions. Hi-Tech and Wheat withdrew the first allegation based on its misreading of the relevant statutory provision. However, they continue to assert the remaining allegations. The FTC denies both of the remaining allegations of misconduct by Dowdell. After careful review of the motion and accompanying briefs, the court finds that Hi-Tech and Wheat have not set forth sufficient factual allegations to support its claims of unethical conduct by Dowdell.

B. Pending Motions for Entry of Final Disposition Order

The parties brought the issue of Dowdell's unauthorized practice to the court's attention after the court had already entered previous final disposition orders improperly filed by Dowdell. The court does not invalidate these orders. However, there are two motions pending for entry of final disposition orders in garnishment against SunTrust Bank [Doc. No. 577] and Quantum National Bank [Doc. No. 583]. Both

motions were filed prior to Hi-Tech and Wheat's motion to show cause, and the motions are signed by Dowdell. The court denies the motions as improperly filed. The court grants the FTC leave to file renewed motions signed by an attorney with the requisite authority to sign the motions.

C. Conclusion

The court DENIES Hi-Tech and Wheat's motion for an order to show cause [Doc. No. 615]. The court DENIES the FTC's motions for entry of final disposition order as improperly filed [Doc. No. 577 and 583]. However, the court GRANTS the FTC leave to file renewed motions signed by an attorney with the requisite authority to sign the motions.

V. Conclusion

The court ORDERS disgorgement of $40,120,950 in compensatory sanctions to redress consumers. The court DIRECTS the clerk of the court to enter a judgment against Hi-Tech, Wheat, and Smith, jointly and severally, in the amount of $40,000,950. The court DIRECTS the clerk of the court to enter a judgment against Wright in the amount of $120,000. The parties are ORDERED to administer the compensatory sanctions as directed in Section II.B., page 24, of this order. The court ORDERS Hi-Tech, Wheat, and Smith to recall all Fastin, Lipodrene, Benzedrine, and Stimerex-ES with violative product packaging and labels from retail stores. The parties are ORDERED to notify the court of the status of the recall as directed in this order. The court DENIES the FTC's motion to modify the Hi-Tech Order [Doc. No. 561], and GRANTS IN PART and DENIES IN PART the FTC's motion to modify the Wright Order [Doc. No. 562]. The

court DENIES Hi-Tech and Wheat's motion for an order to show cause [Doc. No. 615]. The court DENIES the FTC's motions for entry of final disposition order as improperly filed [Doc. No. 577 and 583]. However, the court GRANTS the FTC leave to file renewed motions signed by an attorney with the requisite authority to sign the motions. The court GRANTS the FTC's motion for leave to file a surreply in opposition to Hi-Tech and Wheat's motion to show cause [Doc. No. 631].

SO ORDERED this 14th day of May, 2014.

/s/ Charles A. Pannell, Jr.
CHARLES A. PANNELL, JR.
United States District Judge

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

Civil Action No. 1:04-CV-3294-CAP

FEDERAL TRADE COMMISSION,
Plaintiff,

v.

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

Filed August 7, 2012
ECF Document 422

ORDER

This matter is before the court on the motion for reconsideration by contempt defendants Hi-Tech Pharmaceuticals, Inc. (Hi-Tech), Jared Wheat, and Stephen Smith [Doc. No. 396][1] of the court's May 11, 2012 order [Doc. No. 390] (the May 11 Order). The motion is DENIED because the *Pom Wonderful* decision the defendants cite is, as they concede, not an intervening change in controlling law and because there was no clear error of law. Rather, the defendants' arguments as to the supposed clear errors

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[1] Contempt defendant Dr. Mark Wright joins in support of the motion [Doc. No. 397].

are generally repetitive of arguments they already raised and the court already rejected.

The court also briefly addresses Arthur W. Leach's motion to strike [Doc. No. 411] and the FTC's motions to alter or amend the judgment [Doc. Nos. 333, 378]. Those motions are also DENIED.

I. Standard of Review

Reconsideration of a court's order is an "extraordinary remedy" to be "employed sparingly." *McCorvey v. Smith*, No. 1:08-0151-WS-C, 2009 WL 2176344, at *2 (S.D. Ala. July 15, 2009) (quoting *Gougler v. Sirius Prods., Inc.*, 370 F. Supp. 2d 1185, 1189 (S.D. Ala. 2005)). As the defendants set out in their own motion, reconsideration is justified when there is (1) newly discovered evidence, (2) an intervening development or change in controlling law, or (3) a need to correct a clear error of law or fact. Mot. to Reconsider 3 [Doc. No. 396] (citing *Bryan v. Murphy*, 246 F. Supp. 2d 1256, 1258-59 (N.D. Ga. 2003); *Instituto de Prevision Militar v. Lehman Bros.*, 485 F. Supp. 2d 1340, 1343 (S.D. Fla. 2007)). Further, a motion for reconsideration is an inappropriate vehicle to present arguments already made and rejected by the district court, "repackage familiar arguments to test whether the court will change its mind," or try to "show the court how it could have done better." *See Romala Stone, Inc. v. Home Depot USA, Inc.*, No. 1:04-CV-2307-RWS, 2009 WL 1405058, at *2 (N.D. Ga. May 18, 2009) (quoting *Bryan*, 246 F. Supp. 2d at 1259).

II. Analysis

The defendants' motion asks the court to reconsider the portion of the May 11 Order that

addressed what evidence will be relevant to show whether the defendants possessed and relied upon "competent and reliable scientific evidence" to substantiate the claims at issue in the present contempt proceedings. The defendants do not suggest "newly discovered evidence" justifies reconsideration. Rather, they move for reconsideration because (1) the administrative decision in *POM Wonderful LLC*,[2] "provides strong persuasive authority for the [c]ourt to reconsider its decision," and (2) the court clearly erred by concluding the fact question of what constitutes "competent and reliable scientific evidence" had been conclusively determined and, therefore, the defendants would not be able to re-litigate this issue during the contempt proceedings. The defendants suggest the court made three clear errors of law in its order: (1) Dr. Arrone's definition of competent and reliable scientific evidence was not incorporated into the final judgment and injunction, (2) the standard as applied to the permanent injunction is beyond the power of the FTC and fundamentally unfair to the defendants, and (3) the May 11 Order unduly restricts contempt defendants' evidence of good faith.

The court finds no basis to reconsider the May 11 Order or the conclusions therein. Aside from the discussion of the noncontrolling administrative decision *Pom Wonderful*, the defendants have repackaged their previous arguments in new form. The motion can therefore be denied for this reason alone. But the court also concludes the defendants

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[2] No. 9344, 2012 WL 2340406, 2012 FTC LEXIS 106 (F.T.C. May 17, 2012), available at http://www.ftc.gov/os/adjpro/d9344/120521pomdecision.pdf

have largely misunderstood the rationale of the May 11 Order, so this order will expand on the court's reasoning to show why it was not clear error to preclude relitigation of the "competent and reliable scientific evidence" issue.

A. There is No Intervening Change in Controlling Law

As an initial matter, even the legal standard the defendants cite requires an intervening change in *controlling* law in order to make a motion for reconsideration absolutely necessary. *See* Mot. to Reconsider 3 [Doc. No. 396] (citing *Bryan*, 246 F. Supp. 2d at 1258–59). The intervening authority the defendants introduce is an initial decision by an administrative law judge (ALJ) in an administrative proceeding brought by the FTC against *Pom Wonderful*. In the motion for reconsideration, the defendants, rightly, never suggest the *Pom Wonderful* decision is controlling. Instead they repeatedly hold up *Pom Wonderful* as "strong persuasive authority" for this court to consider. *E.g.* Mot. to Reconsider 2, 4, 8 [Doc. No. 396]. The defendants point to no intervening change in controlling law, so reconsideration is not warranted on the basis of the *Pom Wonderful* decision.

Even if the court were to consider the ALJ decision, it does not dictate any change to the court's holdings. As the defendants described the decision:

> According to the ALJ, neither the FTC Act nor applicable case law imposes a requirement of randomized, double-blind, placebo-controlled clinical trials to substantiate all health-related efficacy claims made in the advertising of dietary

> supplements. Rather, the ALJ found that, consistent with this Court's prior holdings, the appropriate level of substantiation was a "question of fact to be determined based upon the expert testimony adduced at trial."

Mot. to Reconsider 2, 4, 8 [Doc. No. 396] (citations omitted). As noted by the defendants, this court has not said the law imposes a *general* requirement to substantiate claims in this matter. Rather, as described more fully in Part II.C below, this court held (on summary judgment) there was no question of fact as to what constitutes competent and reliable scientific evidence, so the defendants are precluded from re-litigating that fact question in these contempt proceedings. *Pom Wonderful* does not provide a basis to reconsider the May 11 Order.

B. Clear Error of Law

Each of the three purported errors the defendants argue the court made are merely repackaged versions of arguments previously raised by them and rejected by the court.

1. Dr. Arrone's Interpretation

First, the defendants complain that Dr. Arrone's testimony regarding what constitutes "competent and reliable scientific evidence" cannot be applied to that term in the injunction. They argue that because an injunction must give notice of what it forbids, no ordinary person would read the ambiguous definition of competent and reliable scientific evidence[3] in the

[3] The permanent injunction defines this term as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that ha[ve] been

way Dr. Arrone has.[4] "[T]he question of what constitutes 'competent and reliable scientific evidence' under the definition found in the Injunction is where the debate lies. . . . [And t]he Contempt Defendants are entitled to the benefit of any ambiguities in the Injunction." Mot. to Reconsider 12–13 [Doc. No. 396]; *see also id.* at 13 ("The Court's summary judgment decision does not cure the ambiguity contained in the injunction."). Further, because the claims at issue now are supposedly different than the claims at issue then, Dr. Arrone's interpretation should not apply. *Id.* at 13–14. The defendants state in their reply brief, attempting to counter the claim that this was a repeated argument, "Even a *cursory review* of the motion [to reconsider] reveals that the Contempt Defendants' arguments center upon the ambiguous nature of the Court's injunction. Here, *for the first time*, the Contempt Defendants assert that the Court's May 11, 2012 order relies upon matters outside the four corners of the injunction . . . ." Reply Br. 8 [Doc. No. 408] (emphasis added).

The words "cursory" and "first" do not mean what the defendants appear to think they mean, because this is almost exactly the same argument they made before the May 11 Order. For example, in the

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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. No. 230, at 5].

[4] As described in the May 11 Order, Dr. Arrone's interpretation of this definition requires a double-blind, clinical trial on the product itself to substantiate weight loss claims. *See* May 11 Order 7–8 [Doc. No. 390].

opposition to the motion for show cause, the defendants argued that the injunction contains a different, less-restrictive definition than the one adopted from Dr. Arrone's testimony in the summary judgment order, and "any ambiguities in the order to be enforced are to be resolved in favor of the Contempt Defendants." Defs.' Br. in Opp'n 15–16 [Doc. No. 356, at 21–22]. Further, they have already argued that "expert opinion on what is the appropriate level of substantiation for these new claims may differ, as the Court noted, it is context and claim specific." *Id.* at 17–18*; see also* [Doc. No. 368, at 12–13].

The only new-ish portion of this argument is that the injunction must inform the defendants "precisely what the court intends to forbid," so that they should not be "required to look to another order . . . to divine the meaning of the terms" of the injunction. They point to *Hughey v. JMS Development Corp.*, in which the Eleventh Circuit stated, "A person enjoined by court order should only be required to look within the four corners of the injunction to determine what he must do or refrain from doing." 78 F.3d 1523, 1532 n.12 (11th Cir. 1996) (vacating injunction from discharging storm water "in violation of the Clean Water Act" because it was an impermissible "obey the law" injunction that was not "an operative command capable of enforcement"). More recently, in a securities enforcement action, the Eleventh Circuit recognized, "[G]iven Congress's authorization to enjoin violations of the Exchange Act and the fact that this is a civil enforcement action brought by the SEC, less particularity [in the terms of an injunction] is required in this context." *SEC v. Goble*, 682 F.3d 934, 952 (11th Cir. 2012) ("[W]here the public interest is

involved, the court's equitable power has a 'broader and more flexible character.'" (quoting *Commodity Futures Trading Comm'n v. Levy*, 541 F.3d 1102, 1114 (11th Cir. 2008))). Ultimately, the *Goble* court invalidated restraints against violating two sections of the Exchange Act and their accompanying regulations because they did not "specifically describe the acts addressed by the injunction. And, without a compendious knowledge of the codes, [the defendant] ha[d] no way of understanding his obligations under the injunction." *Id.*

Here, the language is not nearly so broad as the kind of "obey the law" injunctions of *Hughey* and *Goble*. Instead, we have a specific term of the injunction with a specific definition that was specifically interpreted in an earlier stage of the litigation between these parties. The defendants did not need to search and interpret vast swaths of the law to understand the obligations under the injunction; they only needed to look to the final judgment and the conclusively determined issues in this case. The law requires "fair notice" of what conduct risks contempt. *Goble*, 682 F.3d at 951. The evidence shows Mr. Wheat had such notice that the advertisements at issue now might risk contempt, some (though not all) of the legal advice he received confirmed this risk, and he made a business decision to accept that risk. *See* [Doc. Nos. 408-1; 366-1, at 17]].[5] Accordingly, although the answer to what type of evidence constitutes competent and reliable scientific evidence technically lies

[5] Of course, the court does not conclude at this time the defendants actually *did* violate the injunction.

"outside the four corners" of the injunction, it was not a clear error of law to preclude re-litigation of it.

2. Beyond Power of FTC and "Fundamentally Unfair"

Next, the defendants argue the May 11 Order precluding relitigation of what constitutes competent and reliable scientific evidence is "fundamentally unfair" to the defendants because it exceeds the scope of the injunction, exceeds the scope of the FTC's authority, and places the defendants at a competitive disadvantage relative to other dietary supplement producers. The first argument is essentially a repeat of already-rejected bases for reconsideration. Mot. to Reconsider 16 [Doc. No. 396] ("[A]s argued above, this interpretation of the Injunction stretches it beyond its language to the detriment of the Contempt Defendants."). The second argument, that the FTC cannot impose a requirement as interpreted by the court, is an exact duplicate of arguments already raised in opposition to the motion for show cause, including citation of the same statutes and cases for the same propositions. *Compare id.* at 16–18, *with* Defs.' Br. in Opp'n 18-21 [Doc. No. 346, at 24–27]. Finally, the defendants fail to argue how the competitive disadvantage they might bear creates "a clear error of law or fact" that necessitates reconsideration. Instead, the defendants simply make clear they think the court "could have done it better." *Bryan*, 246 F. Supp. 2d at 1259. Accordingly, this trio of arguments mostly repackages old wine in new bottles and fails to show a clear error of law to warrant reconsideration.

3. The May 11 Order Does Not Unduly Restrict Evidence of Good Faith

The final grounds the defendants raise for reconsideration is that the court has unduly restricted their evidence of good faith. They state, "The Court's May 11, 2012 Order correctly holds that evidence of the Contempt Defendants' good faith or substantial compliance *is* relevant as to what sanction, if any, should ultimately be imposed in these proceedings." Mot. to Reconsider 19 [Doc. No. 396] (emphasis added). They argue this holding conflicts with the portion of the order limiting expert evidence regarding the defendants' compliance. *Id.* at 20–21. However, the defendants misread the court's holding. They have quoted the court's order almost word-for-word, but they replaced the phrase "may be" with "is." *Compare id.* at 19, *with* May 11 Order 11 [Doc. No. 390] ("[T]he court also agrees with the Contempt Defendants' argument that evidence of good faith or substantial compliance *may be* relevant to what sanction, if any, should ultimately be imposed." (emphasis added)).

The court purposefully chose this open-ended language in the May 11 Order. *See* Bryan A. Garner, *A Dictionary of Modern Legal Usage* 552 (2d ed. 2001) (defining "may" as "has discretion to; is permitted to," or "possibly will," and referring to a third definition, "shall," as "a lexical perversion"). Given the contentious nature of this litigation, the goal of that portion of the order was "to direct the parties' arguments and evidence in response to the show cause order" in light of the wildly divergent legal positions taken by both sides. May 11 Order 6 [Doc. No. 390]. Thus, the court explicitly excluded good faith from the

issue of compliance with the injunction, while leaving open the relevance of good faith to the sanction imposed. *Id.* at 10–11.[6]

In any case, even if good faith is relevant to the sanction imposed, limiting the expert evidence as to what constitutes competent and reliable scientific evidence does not unduly restrict the defendants' evidence of good faith. They could still present other evidence of their attempts to comply with the injunction, some of which is identified in the motion for reconsideration. The court does not see how it has created a clear error of law by excluding expert testimony as it has, while not foreclosing other avenues of evidence.

C. Clarification of the May 11 Order

Finally, the court observes that the defendants' motion for reconsideration often misses the mark as to the reason for the court's holding barring relitigation of the competent and reliable scientific evidence issue. For example, they argue the court "conflates" its summary judgment decision with the injunction, Mot. to Reconsider 10 [Doc. No. 396], and that the May 11

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[6] At the status conference on May 31, 2012, counsel for the FTC, argued that at most, good faith is only relevant to the coercive sanction of incarceration, not to the compensatory sanctions the FTC also seeks. Status Conference Tr. 13 [Doc. No. 400]; *see also id.* at 27-28 (presumably citing *McComb v. Jacksonville Paper Co.*, 336 U.S. 187 (1949)). The court would not be surprised to see further discussion of the relevance of the defendants' good faith as these contempt proceedings progress. Of course, if the FTC's position is correct, and good faith is only relevant to whether the defendants should be incarcerated to coerce their compliance, then the FTC could take that issue completely off the table by seeking *only* compensatory sanctions.

Order and the summary judgment order sets the substantiation standard too high compared to the *Pom Wonderful* ALJ decision, *id.* at 6–10. But the defendants never directly challenge the basis for the court's conclusion that they were barred from "re-litigat[ing] an already decided question." *See* May 11 Order 7–9 [Doc. No. 390]. Therefore, the court takes this opportunity to clarify the rationale of that order.

In its initial motion for a show cause order, the FTC argued the same substantiation standard applied on summary judgment should apply in the contempt proceedings. *See* Mot. for Show Cause 22 [Doc. No. 332-1, at 27]. Then, in reply to the defendants' argument that it should be able to present expert opinions on the level of substantiation required, the FTC argued, "[R]elitigation of these settled issues would be improper under res judicata principles," and "[U]nder res judicata principles, it is not proper to relitigate what constitutes competent and reliable scientific evidence for weight-loss products." FTC Reply Br. 5–6 [Doc. No. 366, at 8–9].

While the FTC invoked "res judicata principles" several times, it actually cited to the doctrine of collateral estoppel—also known as issue preclusion—which bars relitigation of an *issue* that has already been litigated and resolved in a prior proceeding. *Id.* at 6 (citing *In re Justice Oaks II, Ltd.*, 898 F.2d 1544, 1550 n.3 (11th Cir. 1990).

> To claim the benefit of collateral estoppel the party relying on the doctrine must show that: (1) the issue at stake is identical to the one involved in the prior proceeding; (2) the issue was actually litigated in the prior proceeding;

> (3) the determination of the issue in the prior litigation must have been "a critical and necessary part" of the judgment in the first action; and (4) the party against whom collateral estoppel is asserted must have had a full and fair opportunity to litigate the issue in the prior proceeding.

Pleming v. Universal-Rundle Corp., 142 F.3d 1354, 1359 (11th Cir. 1998) (citation omitted). Application of collateral estoppel is within the court's discretion. *Balbirer v. Austin*, 790 F.2d 1524, 1526 (11th Cir. 1986). And it is this doctrine that the court (somewhat vaguely) relied on to hold the only evidence relevant to whether the contempt defendants possessed competent and reliable scientific evidence was the kind previously described by Dr. Aronne and adopted by the court. *See* May 11 Order 7–10 [Doc. No. 390].[7]

The prior proceeding here was the parties' cross-motions for summary judgment. As discussed in the May 11 Order, the FTC had alleged the defendants' lack of reasonable basis claims were unsubstantiated, and it was a question of fact for expert interpretation what type of tests would properly substantiate the claims. *FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d 1167, 1202, 1190 (N.D. Ga. 2008). In support

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[7] The court inartfully stated the resolved fact question was "part of the law of the case," which calls to mind a related, but different legal doctrine. *Cf.* 18B Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 4478 (2d ed. 2002) ("There are, to be sure, occasions on which courts absent-mindedly . . . rely on law-of-the-case expressions to support conclusions that might better rest on some other preclusion theory.").

of its motion for summary judgment, the FTC presented expert evidence by Dr. Aronne regarding the level of substantiation required for the lack of reasonable basis claims. Rather than attempt to counter this evidence, the defendants "simply argued that the claims were not made and . . . maintained that the numerous studies regarding the products' ingredients that they relied upon support their ingredient-specific claims." *Id.* at 1202 n.21. "Accordingly, the court conclude[d] that there [was] no issue of fact regarding the requisite levels of substantiation." *Id.* at 1202. The defendants had admitted their products had not been tested in the manner required, so the court found the claims were unsubstantiated and granted summary judgment. *Id.* at 1203.

There is no legitimate dispute that at least three elements of the issue preclusion doctrine are satisfied in the present contempt proceeding.[8] It is clear the issue of what constitutes competent and reliable scientific evidence was actually litigated, and that the

[8] Additionally, issue preclusion can apply in a civil contempt to enforce a judgment, even though they are not entirely separate proceedings. *See* 18 Wright & Miller, *supra*, § 4422 ("A judgment that resolves issues by a preponderance of the evidence, for example, precludes relitigation of those issues in proceedings that seek to prove civil contempt of the judgment by clear and convincing evidence."); *see also United States v. Rylander*, 460 U.S. 752, 756 (1983); *Monarch Life Ins. Co. v. Ropes & Gray*, 65 F.3d 973 (1st Cir. 1995) (affirming bankruptcy court's application of issue preclusion in contempt proceedings to enforce the bankruptcy court's injunction). *But see In re Justice Oaks*, 898 F.2d at 1550 n.3 ("Law of the case differs from issue preclusion in that the former applies only to proceedings within the same case, while the latter applies to proceedings in different cases.").

determination of the issue in favor of the FTC played a critical, necessary part in the grant of summary judgment. The defendants had a full and fair opportunity to present their own expert evidence to challenge Dr. Arrone, perhaps creating a question of material fact sufficient to withstand summary judgment. They chose not to.

The only element the defendants essentially dispute—though never by name or citation to any law of issue preclusion—is whether the issues on summary judgment and now are "identical." Throughout these proceedings, from the initial response to FTC's motion to show cause to the present motion for reconsideration, the defendants have argued the challenged advertising claims are different from those at issue on summary judgment. *E.g.* [Doc. No. 346, at 23]; [Doc. No. 396, at 8–9]. The defendants correctly pointed out that the court had previously stated the substantiation needed is context specific and varies with advertising claims. Defs.' Reply Br. 10 [Doc. No. 368, at 13] (quoting *Nat'l Urological Group*, 645 F. Supp. 2d at 1186); Mot. to Reconsider 13 [Doc. No. 396]. But the court concluded in the May 11 Order that Dr. Arrone's report was broad enough to encompass the claims at issue now, so the same standard should be applied to these claims. Thus, the identical issue is what substantiation is needed, not what claims were made. That issue is precluded from relitigation by the defendants during the contempt proceedings after they passed on the previous opportunity to do so. *See Comm'r v. Sunnen*, 333 U.S. 591, 598 (1948) ("Once a party has fought out a matter in litigation with the other party, he cannot later renew that duel.").

The defendants arguments in its motion for reconsideration do not alter this conclusion. They point out no clear error of law or fact made by the court. They generally repeat the arguments previously raised. Like the other bases for the motion to reconsider, the court will not "change its mind" absent a showing of a clear error of law or fact. *See Romala Stone*, No. 1:04-CV-2307-RWS, 2009 WL 1405058, at *2. Accordingly, the motion for reconsideration is DENIED.

III. Other Motions

The court will also address the FTC's long-ago filed motions to alter or amend the judgment and Arthur Leach's motion to strike. First, the FTC's motions rest on the premise that the court has found the defendants in contempt. The court has not done so, and, at the rate we're going, could not for some time. Accordingly, the FTC's motions are DENIED with leave to refile only if the court ultimately finds any of the defendants in contempt.

Second, Mr. Leach moves to strike two footnotes from two documents the FTC filed during these contempt proceedings. "The court may strike from a *pleading* . . . any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f) (emphasis added). Mr. Leach refers to the documents at issue as "pleadings," but they are not pleadings under the federal rules. *Compare* Fed. R. Civ. P. 7(a) (listing seven pleadings that are "allowed"), with *id.* 7(b) (distinguishing "motions and other papers" from pleadings). The motion may be denied on this basis alone.

Mr. Leach claims, "[T]he FTC has made allegations in two footnotes contained in separate documents that Mr. Leach and Mr. Vic Kelley, another attorney, conspired with Contempt Defendant, Jared Wheat ("Wheat") to perform some illegal act," and these allegations should be stricken because they are "reprehensible, utterly false and irrelevant to the issues." [Doc. No. 411, at 1–2]. The court has reviewed both the footnotes in question and the exhibits to which they refer. While the definition of "conspire" does implicate an illegal act, *see Black's Law Dictionary* 329 (8th ed. 2004), its use here has not confused the court or prejudiced any party in the contempt proceedings before the court. *See Smith v. Mercer*, No. 1:09-CV-3008-RWS, 2012 WL 1314127, at *3, (N.D. Ga. Apr. 16, 2012), *quoted in* [Doc. No. 411]. Nor, on the basis of the FTC's source documents, does the court have any reason to believe Mr. Leach has violated any law while aggressively protecting his clients' interests. However, his and his clients' arguments that Hi-Tech "recognizes the debt that it owes and is willing to pay the debt as quickly as possible" rings hollow in light of the outstanding unpaid judgment, the length of time since the judgment was affirmed (and certiorari denied), and Hi-Tech's apparent revenue stream. If Hi-Tech is willing to pay as quickly as possible, it could start writing checks whenever it likes. In any case, the FTC is entitled to draw inferences and make arguments from the emails in its possession.

So, the court sees no reason to strike these statements from the footnotes in the FTC's response or its status report—inflammatory and unnecessary though they may be. If the court were to strike every

exaggerated statement made by any of these parties "in an effort to gain a litigation advantage," [Doc. No. 413, at 7], the docket would be pared down indeed. The court cautions the parties against attempting disparaging remarks against the other. Stick to the facts and the law; the court can separate the wheat from the chaff on its own. Mr. Leach's motion is DENIED.

IV. Conclusion

The motion for leave to file excess pages [Doc. No. 407] is GRANTED. The defendants' motion for reconsideration [Doc. No. 396, 397] is DENIED. Arthur W. Leach's motion to strike [Doc. No. 411] is DENIED. Finally, the FTC's motions to alter or amend the judgment [Doc. Nos. 333, 378] are DENIED WITHOUT PREJUDICE.

SO ORDERED, this 7th day of August, 2012.

/s/ Charles A. Pannell, Jr.
CHARLES A. PANNELL, JR.
United States District Judge

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

Civil Action No. 1:04-CV-3294-CAP

FEDERAL TRADE COMMISSION,
Plaintiff,

v.

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

Filed May 11, 2012
ECF Document 390

ORDER

This matter is before the court on the following motions:

1. The Federal Trade Commission's (FTC) Motion for an order to show cause why Hi-Tech Pharmaceuticals, Jared Wheat, and Stephen Smith (the Contempt Defendants) should not be held in contempt [Doc. No. 332];
2. The Contempt Defendants' motion for a status conference and entry of scheduling order [Doc. No. 351];
3. The FTC's motion for a protective order quashing the contempt defendants' discovery requests [Doc. No. 367];

4. The FTC's motion for leave to file a supplemental reply in support of its motion for a show cause order [Doc. No. 374]; and

5. The FTC's motion for an order to show cause why Dr. Terrill Mark Wright should not be held in contempt [Doc. No. 377].

As an initial matter, the FTC's motion for leave to file a supplemental reply [Doc. No. 374] is unopposed; thus, that motion is GRANTED. *See* LR 7.1(B), NDGa.

I. Introduction

In 2004, the FTC filed this action against the defendants alleging they violated Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, by making false and unsubstantiated claims in connection with their advertising and sale of various dietary supplements. On June 4, 2008, the court granted the FTC's motion for summary judgment. *See FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d 1167 (N.D. Ga. 2008), *aff'd*, 356 F. App'x 368 (11th Cir. 2009), *cert. denied*, 131 S. Ct. 505 (2010). On December 16, 2008, the court entered final judgment against the defendants, including permanently enjoining them from several activities related to their previous violations of the FTC Act [Doc. Nos. 229, 230].

At issue now are several of those prohibited activities. The FTC's motion for a show cause order alleges the Contempt Defendants' conduct violates the following provisions of the final judgment order: (1) Section II, prohibiting the Contempt Defendants from claiming their products "cause[] rapid or substantial loss of weight or fat," or "affect[] human metabolism, appetite, or body fat," unless those claims are substantiated by "competent and reliable scientific

evidence"; (2) Section VII, prohibiting the Contempt Defendants from making representations regarding "comparative benefits, performance, safety, or efficacy" for covered products unless such representations are substantiated by "competent and reliable scientific evidence"; and (3) Section VI, requiring the Contempt Defendants to "make clearly and prominently" a specified warning when they make efficacy claims about any covered product containing yohimbine. *See* [Doc. No. 230, at 12–13, 15–17]; [Doc. No. 332-1, at 20–25]. The FTC also claims Dr. Wright violated Section II of the judgment order against him, prohibiting him from making any representations regarding "any weight loss product" that claim such product "causes rapid or substantial loss of weight or fat" or "affects human metabolism, appetite, or body fat" unless such representation is substantiated by "competent and reliable scientific evidence." *See* [Doc. No. 229, at 7–8]; [Doc. No. 377-1, at 12–14]. The FTC filed voluminous exhibits in support of its motions.

After the FTC moved for the show cause order in November 2011, the Contempt Defendants filed their response [Doc. No. 346]. In its reply (and other briefs on other motions), the FTC argues the Contempt Defendants failed to create a genuine question of material fact, and therefore the court should hold the defendants in contempt on the papers without a hearing. All the defendants object to this request and demand a hearing. *See, e.g.*, [Doc. Nos. 350, 380].

II. FTC's Motions for Show Cause Orders

A. Legal Standard

In *Mercer v. Mitchell*, the court outlined the "typical (although by no means exclusive) contempt proceeding." 908 F.2d 763, 767 (11th Cir. 1990). To initiate a contempt proceeding, the plaintiff:

> requests the court to order the defendant to show cause why he should not be held in contempt and sanctioned until he complies. If the court finds that the conduct as alleged would violate the prior order, it enters an order requiring the defendant to show cause why he should not be held in contempt and conducts a hearing on the matter.

Id. at 768 (citation omitted). But the due process requirements for civil contempt proceedings are "flexible, varying with the circumstances of each case," and the process described is not *necessary* if there are no disputed questions of fact. *Id.* at 769 n.11 ("[W]hen there are no disputed factual matters that require an evidentiary hearing, the court might properly dispense with the hearing prior to finding the defendant in contempt and sanctioning him."); *see also Nat'l Union Fire Ins. Co. v. Olympia Holding Corp.*, 140 F. App'x 860, 864–65 (11th Cir. 2005) (holding district court did not abuse its discretion by holding party in contempt without evidentiary hearing because there were "no material issues of fact" where the contempt defendants had "challenge[d] the interpretation of the facts but not the existence of the facts").

So, the initial analysis of a motion to show cause why a defendant should not be held in contempt is

somewhat like that of a Rule 12(b)(6) motion: The court assumes the facts as alleged (in the motion for show cause) are true and asks whether those facts state a violation of the permanent injunction in the final judgment.

B. Analysis

The facts in the FTC's motions for show cause orders state violations of the permanent injunctions against the defendants. According to the FTC, the Contempt Defendants' advertising and product packaging make unsubstantiated claims that their products cause rapid or substantial fat or weight loss, affect metabolism and decrease consumers' appetites, and the yohimbine warning does not appear as directed by the judgment order. Further, the FTC alleges Dr. Wright's endorsement of the weight-loss dietary supplement Fastin contains unsubstantiated claims that the product will cause rapid or substantial weight or fat loss. The exhibits and attachments included with the FTC's motions support these allegations. Assuming the facts stated are true, this conduct would violate the permanent injunctions against these defendants. Thus, under the "typical" civil contempt process, the court should grant the FTC's motion for a show cause order.

1. Issues Relevant to Scope of Show Cause Response

In their response to the motion for a show cause order, the Contempt Defendants make various arguments as to why the show cause order should not

issue and why their conduct did not violate the order.[1] Most of these arguments are either unpersuasive or inapplicable at this point in the process. A discussion of a few of these issues is required now because they are relevant to direct the parties' arguments and evidence in response to the show cause order.

First, the Contempt Defendants argue all the claims made—and they dispute that they made all the claims the FTC alleges—were non-actionable "puffery", which cannot form the basis of a violation of the final judgment. *See* [Doc. No. 346, at 13–14]. However, in the order on summary judgment, the court previously "caution[ed] the defendants" that injunctive relief may be broader than the precise violations alleged. *Nat'l Urological Group, Inc.*, 645 F. Supp. 2d at 1215. The court is not persuaded by the single paragraph the Contempt Defendants devoted to this argument that the court cannot not hold them in contempt where an advertisement as a whole makes a claim that would violate the broad terms of the judgment order, even if the advertisements are "riddled with puffery." *Id.* at 1206.

Second, the Contempt Defendants argue any claims they made are substantiated by "competent and reliable scientific evidence" as required by the judgment order. It is clear from the substance of the

[1] Dr. Wright filed a "Statement in Response" to the FTC's motion for a show cause order [Doc. No. 380]. In his statement, he chose to "withhold offering a substantive response" to the motion until the court actually issues such an order. *Id.* at 4. Thus, the court considers the FTC's motion for an order to show cause with regard to Dr. Wright unopposed. *See* LR 7.1(B), NDGa.

parties' various briefs that the defendants (possibly including Dr. Wright) intend to re-litigate an already decided question. The final judgment orders provide that the claims at issue must be substantiated by "competent and reliable scientific evidence." That term is defined in the judgment orders, [Doc. Nos. 230, at 5; 229, at 4], and the same term and definition were at issue in the motions for summary judgment: the court "adopt[ed] [the FTC's] definition" and concluded "what constitutes competent and reliable scientific evidence in this case is a question of fact for expert interpretation." *Nat'l Urological Group, Inc.*, 645 F. Supp. 2d at 1190.

In its summary judgment motion, the FTC had "presented expert testimony to establish what constitutes 'competent and reliable scientific evidence'" for claims regarding safety and efficacy of dietary supplements:

> The FTC's expert, Dr. Aronne, stated that the type of evidence required to substantiate *weight loss claims for any product, including a dietary supplement*, is appropriately analyzed results of 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. Dr. Aronne also stated that to scientifically establish the truth of a claim that a product such as Thermalean or Lipodrene has been clinically proven to be

> efficacious or safe, a reliable clinical study showing that outcome must have been conducted on the product itself. Dr. Aronne further clarified that anecdotal evidence (i.e. reports from patients) are insufficient to prove the efficacy of a product.

Id. at 1202 (emphasis added). The defendants did not counter Dr. Aronne's expert testimony. "Accordingly, the court conclude[d] that there [was] no issue of fact regarding the requisite levels of substantiation, and [relied] upon the standards set forth by Dr. Aronne," which "establish that some form of clinical trial must have been conducted *on the product* itself or an exact duplicate of the product to substantiate the defendants' claims regarding the overall product." *Id.* at 1202–03 (emphasis added). Thus, because the defendants had admitted their products (instead of the ingredients) had not been tested, the court found the claims were unsubstantiated. *Id.*

The fact question of what constitutes "competent and reliable scientific evidence" to substantiate a weight loss claim for any product is part of the law of the case for this matter; it is not subject to re-litigation. *See United States v. Rylander*, 460 U.S. 752, 756 (1983) (stating the "long-standing rule that 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 Contempt Defendants try to argue this determination does not apply now because the court previously stated the standard was "context specific"—varying by advertising claim—and we are now dealing with new claims and products.

Defs.' Reply Br. 10 [Doc. No. 386]. However, Dr. Aronne's report was broad enough to establish what constituted substantiation of weight loss claims "for any product, including dietary supplements." Further, the "lack of reasonable basis claims" at issue then included claims related to fat loss, affecting metabolism and appetite. *See, e.g., Nat'l Urological Group, Inc.*, 645 F. Supp. 2d at 1192 ("LORB Claim 4: Thermalean inhibits the absorption of fat, suppresses appetite, and safely increases metabolism without dangerous side effects[.]"). This is the same "context" from which the FTC's present allegations arise. Thus, the court's conclusion that there was "no issue of fact regarding the requisite levels of substantiation," and the court's application of that fact to establish "that some form of clinical trial must have been conducted on the product itself or an exact duplicate of the product" encompass all the lack of substantiation claims at issue in the FTC's motions for a show cause order. The only evidence that will be relevant to show whether the defendants "possess[ed] and rel[ied] upon competent and reliable scientific evidence" to substantiate any representation is the kind of evidence previously described by Dr. Aronne and previously adopted by the court.

Third, the Contempt Defendants argue they made a good faith attempt to comply with the permanent injunction. The court is inclined to agree with the FTC that good faith is irrelevant to the question of whether the defendants should be held in contempt. The defendants in *FTC v. Leshin* similarly argued "they made a 'good faith effort' to comply with [an] injunction, . . . and that their substantial compliance made the contempt order unwarranted." 618 F.3d

1221, 1232 (11th Cir. 2010). The Eleventh Circuit reasoned:

> The Supreme Court has made clear that the absence of willfulness is not a defense to a charge of civil contempt. The decisions of our Court and our predecessor court have held that substantial, diligent, or good faith efforts are not enough; the only issue is compliance. We do not focus "on the subjective beliefs or intent of the alleged contemners in complying with the order, but whether in fact their conduct complied with the order at issue."

Id. at 1232–33 (citations omitted); *see also id.* ("We are not concerned with excusable neglect but with whether the contempt defendants complied with the injunction."). *But see Howard Johnson Co. v. Khimani*, 892 F.2d 1512, 1516 (11th Cir. 1990) ("Conduct that evinces substantial, but not complete, compliance with the court order *may* be excused if it was made as part of a good faith effort at compliance." (emphasis added)). Thus, on the question of whether the defendants can show cause why they should not be held in contempt, "the only issue is compliance." *Leshin*, 618 F.3d at 1232. However, the court also agrees with the Contempt Defendants' argument that evidence of good faith or substantial compliance may be relevant to what sanction, if any, should ultimately be imposed.

Finally, the Contempt Defendants' reply brief in support of their motion for a status conference and scheduling order erroneously implies the FTC must introduce "consumer survey evidence" to support an interpretation of the advertisements to make the

claims alleged. [Doc. No. 368, at 9]. The court discussed this situation in the order on summary judgment: "In this case, the FTC has not presented any evidence of what claims consumers perceived the advertisements to make; accordingly, any claims that the FTC contends that the advertisements make must be clear and conspicuous from the face of the advertisements." *Nat'l Urological Group, Inc.*, 645 F. Supp. 2d at 1189; *see also id.* at 1189 n.12 (stating consumer survey evidence is "only necessary when the asserted claims fall on the 'barely discernable' side of the continuum"). The court is again well-equipped to discern express claims or clear and conspicuous implied claims from the face of the advertisements.[2]

III. Contempt Defendants' Motion for Status Conference and Scheduling Order and FTC's Motion for Protective Order

The FTC also argues in briefs on the various motions that the Contempt Defendants have created no material question of fact as to the alleged violations, so no evidentiary hearing is necessary; the

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[2] For example, the FTC contends the Contempt Defendants claim their products cause rapid or substantial weight or fat loss. The Contempt Defendants statement that "[t]he actual claims do not say this" and "[n]one of [their] claims promise consumers that the products cause rapid and substantial weight loss," [Doc. No. 368, at 9]. However, this statement is blatantly false, based on the FTC's exhibits, because at least *some* of the products make express claims to cause rapid fat loss. *See, e.g.*, FTC Exhibit 3, Attachment 18 (prominently displaying text "RAPID FAT LOSS" and "RAPID FAT LOSS CATALYST" on the front and side of Fastin packaging and warning consumers, "DO NOT CONSUME UNLESS RAPID FAT AND WEIGHT LOSS ARE YOUR DESIRED RESULT").

court should simply hold the defendants in contempt based on the motions. The Contempt Defendants assert they have raised (at least) five questions of fact relevant to whether they should be held in contempt: (1) whether the challenged advertisements were puffery, (2) whether the Contempt Defendants actually made the claims alleged by the FTC, (3) whether any claims made are substantiated by competent and reliable scientific evidence, (4) whether the yohimbine warnings they provided were adequate, and (5) whether good faith precludes a finding of contempt or mitigates a possible sanction.[3] Thus, the Contempt Defendants have moved for a status conference and scheduling order for the contempt proceedings. The Contempt Defendants also ask for limited discovery of several items. *See* [Doc. No. 368, at 6–8].

Regardless of whether the Contempt Defendants have "created" a question of material fact in their response to the motion for show cause order, the court will not hold the defendants in contempt merely on the papers presented so far. The better procedure, as suggested by *Mercer*, is to issue an order requiring the defendants to show cause why they should not be held in contempt for the alleged violations of the judgment order. To facilitate the defendants' response, the court will require the FTC to file a specific, numbered list of factual allegations the FTC contends the defendants committed in contempt of the court's order (not unlike a complaint). After consideration by the court at a

[3] As discussed above, the court has answered the third and fifth questions; they are no longer in dispute.

status conference, the court will set a date for the defendants to respond.

Given this initial outline of contempt proceedings, the court will consider permitting the parties to conduct limited discovery. Accordingly, the court GRANTS the Contempt Defendants' motion for a status conference and provisionally DENIES the FTC's motion for a protective order. The court will conduct a status conference on May 31, 2012, at 10:00 AM. The parties shall prepare and file the following items on or before May 24, 2012, for review at the status conference:

1. The FTC's specific, numbered list of factual allegations the FTC contends the defendants committed in contempt of the court's order—each allegation referencing a specific section or subsection of the judgment order;
2. A list of specific matters that either party believes discovery should be conducted by (a) deposition, (b) interrogatory, or (c) requests for admission;
3. An estimated length of a hearing on the show cause order, should such hearing be necessary;
4. The terms of proposed sanctions the FTC is seeking specific to each defendant.[4]

The scope of the limited discovery will be settled at the status conference.

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[4] The FTC's motion for show cause order asked for both "coercive incarceration" and "the full amount consumers paid for Contempt Defendants' products" as sanction. The court seeks more information on how these sanctions would coerce any contemnors in this case into compliance and how they might purge themselves of such contempt.

IV. Conclusion

The FTC's motions for an order directing defendants Hi-Tech Pharmaceuticals, Jared Wheat, Stephen Smith to show cause why they should not be held in contempt, for leave to file a supplemental reply, and for an order directing defendant Dr. Terrill Mark Wright to show cause why he should not be held in contempt [Doc. Nos. 332, 374, 377] are GRANTED.

The Contempt Defendants' motion for a status conference and entry of a scheduling order is GRANTED [Doc. No. 351]. The court will conduct a status conference on May 31, 2012, at 10:00 AM in courtroom 2307. The parties are ORDERED to file the specified documents on or before May 24, 2012. The court will issue the show cause order after the status conference.

The FTC's motion for a protective order is provisionally DENIED [Doc. No. 367], pending settling the scope of limited discovery at the status conference.

SO ORDERED, this 11th day of May, 2012.

/s/Charles A. Pannell, JR.
CHARLES A. PANNELL, JR.
United States District Judge

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

Civil Action No. 1:04-CV-3294-CAP

FEDERAL TRADE COMMISSION,
Plaintiff,

v.

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

Filed December 16, 2008
ECF Document 230

FINAL JUDGMENT AND PERMANENT INJUNCTION AGAINST NATIONAL UROLOGICAL GROUP, INC., HI-TECH PHARMACEUTICALS, INC., JARED WHEAT, THOMASZ HOLDA, AND STEPHEN SMITH

This matter comes before the Court on complaint of Plaintiff, Federal Trade Commission ("FTC" or "Commission"), against Defendants National Urological Group, Inc. d/b/a Warner Laboratories, Inc. ("NUG"), National Institute for Clinical Weight Loss, Inc. ("NICWL"), Hi-Tech Pharmaceuticals, Inc. ("Hi-Tech"), Jared Wheat ("Wheat"), Thomasz Holda ("Holda"), Michael Howell ("Howell"), Stephen Smith ("Smith"), and Terrill Mark Wright, M.D ("Wright"). On November 10, 2004, the Commission filed a

Complaint for a permanent injunction and other equitable relief in this matter pursuant to Sections 5(a) and 12 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. §§ 45(a) and 52. The FTC charged Defendants NUG, NICWL, Hi-Tech, Wheat, Holda, Howell, Smith, and Wright with engaging in deceptive acts or practices in connection with the marketing and sale of dietary supplement products, in violation of Section 5 of the FTC Act, 15 U.S.C. § 45. On June 1, 2005, this Court entered a Stipulated Final Order For Permanent Injunction and Settlement of Claims For Monetary Relief against Defendant Howell.

The Commission filed a motion for summary judgment along with the entry of a separate set of Findings of Fact and Conclusions of Law. On June 4, 2008, the court granted the FTC's motion for summary judgment against NUG, NICWL, Hi-Tech, Wheat, Holda, Smith, and Wright as to monetary relief, and against the same defendants, with the exception of dissolved corporation NICWL, as to injunctive relief. Accordingly, it is hereby ORDERED, ADJUDGED, AND DECREED:

FINDINGS

1. This Court has jurisdiction of the subject matter of this case and the parties hereto pursuant to 28 U.S.C. § § 1331, 1337(a) and 1345 and 1355, and 15 U.S.C. §§ 45(a), 53(b), and 57b.
2. Venue in the Northern District of Georgia is proper as to all parties under 15 U.S.C. § 53(b) and 28 U.S.C. § 1391(b) and (c).
3. On June 4, 2008, the court granted the FTC's motion for summary judgment against NUG,

NICWL, Hi-Tech, Wheat, Holda, Smith, and Wright as to monetary relief, and against the same defendants, with the exception of dissolved corporation NICWL, as to injunctive relief.

4. The activities of Defendants NUG, NICWL, Hi-Tech, Wheat, Holda, Howell, Smith, and Wright are in or affecting commerce, as defined in the FTC Act, 15 U.S.C. § 44.

5. The Complaint states a claim upon which relief may be granted against Defendants NUG, NICWL, Hi-Tech, Wheat, Holda, Howell, Smith, and Wright under Sections 5(a) and 12 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. §§ 45(a) and 52.

6. This is a final order with respect to Corporate Defendants NUG, NICWL, and Hi-Tech, and Individual Defendants Wheat, Holda, and Smith.

7. This Final Order is in addition to, and not in lieu of, any other civil or criminal remedies that may be provided by law.

8. Entry of this Final Order is in the public interest.

DEFINITIONS

For purposes of this order, the following definitions shall apply:

1. Unless otherwise specified, "Defendants" shall mean National Urological Group, Inc. d/b/a Warner Laboratories, Inc., Hi-Tech Pharmaceuticals, Inc., Jared Wheat, Thomasz Holda, and Stephen Smith; "Corporate Defendants" shall mean National Urological Group, Inc. d/b/a Warner Laboratories, Inc. and Hi-Tech Pharmaceuticals, Inc.; "Individual

Defendants" shall mean Jared Wheat, Thomasz Holda, and Stephen Smith.

2. "Advertising" or "Advertisement" means any written or verbal statement, illustration, or depiction that is designed to effect a sale or create interest in the purchasing of goods or services, whether it appears in a brochure, newspaper, magazine, pamphlet, leaflet, circular, mailer, book insert, free standing insert, letter, catalogue, poster, chart, billboard, public transit card, point of purchase display, packaging, package insert, label, film, slide, radio, television or cable television, audio program transmitted over a telephone system, program-length commercial ("infomercial"), Internet website (including metatags), or in any other medium.

3. "Competent and reliable scientific evidence" shall 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 manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

4. "Clear(ly) and Prominent(ly)" shall mean as follows:

   A. In an advertisement communicated through an electronic medium (such as television, video, radio, and interactive media such as the Internet, online services and software), the disclosure shall be presented simultaneously in both the audio and visual portions of the advertisement. *Provided*,

however, that in any advertisement presented solely through visual or audio means, the disclosure may be made through the same means in which the ad is presented. *Provided*, *further*, that in any advertisement communicated through interactive media which is presented predominantly through visual or audio means, the disclosure may be made through the same means in which the ad is predominantly presented. The audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. The visual disclosure shall be of a size and shade, with a degree of contrast to the background against which it appears, and shall appear on the screen for a duration and in a location, sufficiently noticeable for an ordinary consumer to read and comprehend it.

B. In a print advertisement, promotional material, or instructional manual, the disclosure shall be in a type size and location sufficiently noticeable for an ordinary consumer to read and comprehend it, in print that contrasts with the background against which it appears.

C. On a product label, the disclosure shall be in a type size and location sufficiently noticeable for an ordinary consumer to read and comprehend it and in print that contrasts with the background against which it appears. *Provided, however,* if a disclosure on a bottle label or package label is made in a

location other than the principal display panel, the bottle label or package label shall (i) include the statement, "**See important safety warning(s) on [insert disclosure location]**," in a type size and location on the principal display panel sufficiently noticeable for an ordinary consumer to read and comprehend it and in print that contrasts with the background against which it appears; *and* (ii) place the disclosure on the bottle label and, if applicable, the package label, within a border that is a color or shade that contrasts with the background against which it appears. *Provided further*, that in a multi-page insert, the disclosure shall appear on the cover page or first page.

D. In the case of advertisements disseminated by means of an interactive electronic medium, such as software, the Internet, or online services, "in close proximity" means on the same Web page, online service page, or other electronic page, and proximate to the triggering representation, and does not include disclosures accessed or displayed through hyperlinks, pop-ups, interstitials, or other means.

E. The disclosure shall be in understandable language and syntax. Nothing contrary to, inconsistent with, or in mitigation of the disclosure shall be used in any advertisement or on any label.

5. "Product label" shall mean any label or other written, printed or graphic matter upon any

product or accompanying any product, including package labels, bottle labels, and package inserts.

6. "Weight Loss Product" shall mean any product, program, or service designed, used, or marketed to prevent weight gain or produce weight loss, reduce or eliminate fat, slim, or increase caloric deficit in a user of the product, program, or service.
7. "Erectile Dysfunction Product" shall mean any product, program, or service designed, used, or marketed to affect erectile function or impotence in users of the product, program, or service.
8. "Thermalean" shall mean any product containing sida cordifolia, kola nut, citrus aurantium, cassia nomame, green tea extract, and 5-HTP that is manufactured, supplied, distributed, offered for sale, sold, marketed, advertised, or promoted by Defendants under the name Thermalean.
9. "Lipodrene" shall mean any product containing sida cordifolia, citrus aurantium, caffeine, coleus forskohlii, naringen, green tea, ginseng, and lcaritine that is manufactured, supplied, distributed, offered for sale, sold, marketed, advertised, or promoted by Defendants under the name Lipodrene.
10. "Spontane-ES" shall mean any product containing xanthoparmelia scabrosa extract, cnidium monnier extract, yohimbine extract, epimedium extract, gingko biloba extract, mucuna pruriens extract, and l-arginine that is manufactured, supplied, distributed, offered for sale, sold, marketed, advertised, or promoted by Defendants under the name Spontane or Spontane-ES.

11. "Covered product or service" shall mean any health-related service or program, weight loss product, erectile dysfunction product, dietary supplement, food, drug, or device.
12. "Yohimbine" shall mean a source of yohimbine, including, but not limited to, quebracho bark extract, quebrachacine HCL, yohimbine HCL, either derived from natural sources or synthetically produced.
13. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
14. "Affiliate" shall mean any person, other than Defendants, who promotes or sells Thermalean, Lipodrene, and Spontane-ES, or any other products sold by Defendants through a website on the Internet or through any other medium.
15. "Endorsement" shall mean as defined in 16 C.F.R. § 255.0(b).
16. The term "including" in this Order means "without limitation."
17. The terms "and" and "or" in this Order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.
18. "Food" and "drug" shall mean as defined in Section 15 of the FTC Act, 15 U.S.C. § 55.

ORDER

I.

PROHIBITED FALSE CLAIMS FOR WEIGHT LOSS PRODUCTS

IT IS HEREBY ORDERED that Defendants, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and their officers, agents, servants, representatives, employees, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Thermalean, Lipodrene, or any other weight loss product, is permanently restrained and enjoined from misrepresenting, in any manner, expressly or by implication, including through the use of endorsements, that:

a. Such product is clinically proven to be or is an effective treatment for obesity;

b. Such product is clinically proven to cause or causes rapid and substantial weight loss;

c. Such product causes substantial weight loss, including as much as 125 pounds;

d. Such product is clinically proven to enable or enables users to lose 19% of their total body weight, lose 20–35% of abdominal fat, reduce their overall fat by 40–70%, decrease their stored fat by 300%, or increase their metabolic rate by 50% or more;

e. Such product is clinically proven to inhibit the absorption of fat, suppress appetite, or

increase metabolism without dangerous side effects;

f. Such product inhibits the absorption of fat, suppresses appetite, or increases metabolism without dangerous side effects;

g. Such product is clinically proven to be or is safe;

h. Such product is clinically proven to have or has virtually no side effects.

II.

PROHIBITED UNSUBSTANTIATED CLAIMS FOR WEIGHT LOSS PRODUCTS

IT IS FURTHER ORDERED that Defendants, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and their officers, agents, servants, representatives, employees, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any weight loss product, are hereby permanently restrained and enjoined from making any representation, in any manner, expressly or by implication, including through the use of endorsements, that:

a. Such product is an effective treatment for obesity;

b. Such product causes rapid or substantial loss of weight or fat;

c. Such product causes a specified loss of weight or fat;

d. Such product affects human metabolism, appetite, or body fat;

e. Such product is safe;

f. Such product has virtually no side effects; or

g. Such product is equivalent or superior to any drug that the Food and

Drug Administration has approved for sale in the United States for the purpose of treating obesity or causing weight loss; unless the representation, including any such representation made through the use of endorsements, is true and non-misleading, and, at the time the representation is made, Defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

PROHIBITED FALSE CLAIMS FOR ERECTILE DYSFUNCTION PRODUCTS

IT IS FURTHER ORDERED that Defendants, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and their officers, agents, servants, representatives, employees, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Spontane-ES or any other substantially similar product containing one or more of the active ingredients in Spontane-ES, in or affecting commerce,

is permanently restrained and enjoined from misrepresenting, in any manner, expressly or by implication, including through the use of endorsements, that:

a. Such product is clinically proven to be effective in treating erectile dysfunction in any specified percentage or proportion of users;

b. Such product is clinically proven to be effective in treating men with erectile dysfunction; or

c. Such product is clinically proven to cause no harmful side effects.

IV.

PROHIBITED UNSUBSTANTIATED CLAIMS FOR ERECTILE DYSFUNCTION PRODUCTS

IT IS FURTHER ORDERED that Defendants, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and their officers, agents, servants, representatives, employees, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any erectile dysfunction product, are hereby permanently restrained and enjoined from making any representation, in any manner, expressly or by implication, including through the use of endorsements, that:

a. Such product is effective in treating erectile dysfunction in any specified percentage or proportion of users; or

b. Such product is safe;

unless, the representation, including any such representation made through the use of endorsements, is true and non-misleading, and, at the time the representation is made, Defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation.

V.

MISREPRESENTATION OF TESTS OR STUDIES

IT IS FURTHER ORDERED that Defendants, directly or through any partnership, corporation, subsidiary, division, trade name, or other device, and their officers, agents, servants, representatives, employees, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service, in or affecting commerce, shall not misrepresent, in any manner, directly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test or study.

VI.

WARNING OF HEALTH RISKS OF YOHIMBINE

IT IS FURTHER ORDERED that, in any advertisement, promotional material, or product label for any covered product or program containing yohimbine that contains any representation about the

efficacy, benefits, performance, safety, or side effects of such product, and during any discussion relating to the use of such product communicated via electronic mail or any telephone line, Defendants, their officers, agents, servants, representatives, and employees shall make clearly and prominently, the following disclosure:

> WARNING: This product can raise blood pressure and interfere with other drugs you may be taking. Talk to your doctor about this product.

VII.

OTHER PROHIBITED CLAIMS

IT IS FURTHER ORDERED that Defendants, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and their officers, agents, servants, representatives, employees, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of endorsements, about the health benefits, absolute or comparative benefits, performance, safety, or efficacy of such product or service unless, at the time the representation is made, Defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation.

VIII.

NONDISCLOSURE OF MAILING LISTS

IT IS FURTHER ORDERED that Defendants and their officers, agents, servants, employees, and attorneys, and all other persons or entities in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, are permanently restrained and enjoined from selling, renting, leasing, transferring, or otherwise disclosing the name, address, telephone number, credit card number, bank account number, e-mail address, or other identifying information of any person who paid any money to any Defendant named in this Action for Thermalean, Lipodrene, or Spontane-ES or shipping and handling therefor, at any time prior to entry of this order. *Provided, however*, that Defendants may disclose such identifying information to a law enforcement agency or as required by any law, regulation, or court order.

IX.

CONSUMER REDRESS AND
OTHER EQUITABLE RELIEF

IT IS FURTHER ORDERED that:

A. Judgment in the amount of $15,882,436.00 is hereby entered in favor of the Commission and against Defendants and NICWL, jointly and severally, for consumer redress, with post-judgment interest, at the legal rate.

B. All payments shall be made by certified check or other guaranteed funds payable to and delivered to the Commission, or by wire

transfer in accord with instructions provided by the Commission.

C. All funds paid pursuant to this Order shall be deposited into a fund administered by the Commission or its agent to be used for equitable relief, including but not limited to consumer redress, and any attendant expenses for the administration of such equitable relief.

D. In the event that the Commission in its sole discretion determines that direct redress to consumers is wholly or partially impracticable or funds remain after redress is completed, the Commission may apply any remaining funds for such other equitable relief (including consumer information remedies) as it determines to be reasonably related to the practices of the Defendants and NICWL, as alleged in the Complaint. Any funds not used for such equitable relief shall be deposited to the United States Treasury as disgorgement. Defendants and NICWL shall have no right to challenge the Commission's choice of remedies under this Paragraph or the manner of distribution chosen by the Commission. No portion of any payments under the judgment herein shall be deemed a payment of any fine, penalty, or punitive assessment.

E. In accordance with 31 U.S.C. § 7701, Defendants and NICWL are hereby required, unless they have done so already, to furnish to the Commission their respective taxpayer

identifying numbers (social security numbers or employer identification numbers), which shall be used for the purposes of collecting and reporting on any delinquent amount arising out of the relationship of the Defendants and NICWL with the government.

X.

COMPLIANCE MONITORING

IT IS FURTHER ORDERED that, for the purpose of monitoring and investigating compliance with any provision of this Order,

A. Within ten (10) days of receipt of written notice from a representative of the Commission, NUG, Hi-Tech, Wheat, Holda, and Smith each shall submit additional written reports, sworn to under penalty of perjury; produce documents for inspection and copying; appear for deposition; and/or provide entry during normal business hours to any business location in such Defendant's possession or direct or indirect control to inspect the business operation;

B. In addition, the Commission is authorized to monitor compliance with this Order by all other lawful means, including but not limited to the following:

1. obtaining discovery from any person, without further leave of court, using the procedures prescribed by Fed. R. Civ. P. 30, 31, 33, 34, 36, and 45; and

2. posing as consumers and suppliers to: NUG, Hi-Tech, Wheat, Holda, or Smith, employees of NUG, Hi-Tech, Wheat, Holda, or Smith, or any other entity managed or controlled in whole or in part by NUG, Hi-Tech, Wheat, Holda, or Smith, without the necessity of identification or prior notice; and

C. NUG, Hi-Tech, Wheat, Holda, and Smith shall permit representatives of the Commission to interview any employer, consultant, independent contractor, representative, agent, or employee who has agreed to such an interview, relating in any way to any conduct subject to this Order. The person interviewed may have counsel present.

Provided, however, that nothing in this Order shall limit the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1, to obtain any documentary material, tangible things, testimony, or information relevant to unfair or deceptive acts or practices in or affecting commerce (within the meaning of 15 U.S.C. § 45(a)(1)).

XI.

COMPLIANCE REPORTING BY DEFENDANTS

IT IS FURTHER ORDERED that, in order that compliance with the provisions of this Order may be monitored:

A. For a period of five (5) years from the date of entry of this Order,

1. Each Individual Defendant shall notify the Commission of the following:
   a. Any changes in residence, mailing addresses, and telephone numbers of Individual Defendant, within ten (10) days of the date of such change;
   b. Any changes in employment status (including self-employment) of Individual Defendant, and any change in the ownership of the Individual Defendant in any business entity, within ten (10) days of the date of such change. Such notice shall include the name and address of each business that the Individual Defendant is affiliated with, employed by, creates or forms, or performs services for; a statement of the nature of the business; and a statement of the Individual Defendant's duties and responsibilities in connection with the business or employment; and
   c. Any changes in the Individual Defendant's name or use of any aliases or fictitious names; and
2. The Individual Defendants and Corporate Defendants shall notify the Commission of any changes in corporate structure that Corporate Defendant(s) or any business entity that an Individual Defendant(s) directly or indirectly control(s), or has an ownership interest

in, that may affect compliance obligations arising under this Order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order; the filing of a bankruptcy petition; or a change in the corporate name or address, at least thirty (30) days prior to such change, *provided* that, with respect to any proposed change in the corporation about which Defendant(s) learn less than thirty (30) days prior to the date such action is to take place, Defendant(s) notify the Commission as soon as is practicable after obtaining such knowledge.

B. Sixty (60) days after the date of entry of this Order, NUG, Hi-Tech, Wheat, Holda, and Smith each shall provide a written report to the FTC, sworn to under penalty of perjury, setting forth in detail the manner and form in which he has complied and is complying with this Order. This report shall include, but not be limited to:

1. For each Individual Defendant:

   a. The then-current residence address, mailing addresses, and telephone numbers of the Individual Defendant;

   b. The then-current employment and business addresses and telephone

numbers of the Individual Defendant, a description of the business activities of each such employer or business, and the title and responsibilities of the Individual Defendant, for each such employer or business;

2. For all Defendants:

   a. A copy of each acknowledgment of receipt of this Order, obtained pursuant to Paragraph XIII; and

   b. Any other changes required to be reported under Paragraph A of this Section.

C. For the purposes of this Order, Defendants, unless otherwise directed by the Commission's authorized representatives, mail all written notifications to the Commission to:

Associate Director for Enforcement
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580
Attn: FTC v. National Urological Group, Inc., et. al. (N.D. Ga.)
Civil Action No. 1:04-CV-3294

D. For purposes of the compliance reporting and monitoring required by this Order, the Commission is authorized to communicate directly with Defendants.

XII.

RECORD KEEPING PROVISIONS

IT IS FURTHER ORDERED that, for a period of eight (8) years from the date of entry of this Order, Corporate Defendants and Individual Defendants and any business where (1) an Individual Defendant is the majority owner or an officer or director of the business, or directly or indirectly manages or controls the business, or where (2) the business engages, or assists others engaged in, the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any weight loss product, erectile dysfunction product, or covered product, program, or service, and an Individual Defendant's agents, employees, officers, corporations, successors, and assigns, and those persons in active concert or participation with the Individual Defendant who receive actual notice of this Order by personal service or otherwise, are hereby restrained and enjoined from failing to create and retain the following records:

A. Accounting records that reflect the cost of goods or services sold, revenues generated, and the disbursement of such revenues;

B. Personnel records accurately reflecting: the name, address, and telephone number of each person employed in any capacity by such business, including as an independent contractor; that person's job title or position; the date upon which the person commenced work; and the date and reason for the person's termination, if applicable;

C. Customer files containing the names, addresses, phone numbers, dollar amounts

paid, quantity of items or services purchased, and description of items or services purchased, to the extent such information is obtained in the ordinary course of business;

D. Complaints and refund requests (whether received directly, indirectly or through any third party) and any responses to those complaints or requests;

E. Copies of all sales scripts, training materials, advertisements, Web sites, or other marketing materials for any weight loss product, erectile dysfunction product, or any covered product, program, or service;

F. All records and documents necessary to demonstrate full compliance with each provision of this Order, including but not limited to, copies of acknowledgments of receipt of this Order and all reports submitted to the FTC pursuant to this Order.

G. All materials that were relied upon in making any representations contained in the materials identified in Paragraph E of this Section, including all documents evidencing or referring to the accuracy of any claim therein or to the efficacy of any weight loss product, erectile dysfunction product, or any covered product, program, or service, including, but not limited to, all tests, reports, studies, demonstrations, or other evidence that confirm, contradict, qualify, or call into question the accuracy or efficacy of each such weight loss product, erectile dysfunction

product, or covered product, program, or service; and

H. Records accurately reflecting the name, address, and telephone number of each manufacturer or laboratory engaged in the development or creation of any testing obtained for the purpose of manufacturing, labeling, advertising, promoting, offering for sale, selling, or distributing any weight loss product, erectile dysfunction product, or covered product, program, or service; and

I. Copies of all contracts concerning the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any weight loss product, erectile dysfunction product, or covered product, program, or service.

XIII.

DISTRIBUTION OF ORDER BY DEFENDANTS

IT IS FURTHER ORDERED that, for a period of five (5) years from the date of entry of this Order, Defendants shall deliver copies of the Order as directed below:

A. Corporate Defendant: Each Corporate Defendant must deliver a copy of this Order to all of its principals, officers, directors, and managers. Each Corporate Defendant also must deliver copies of this Order to all of its employees, agents, and representatives who engage in conduct related to the subject matter of the Order. For current personnel, delivery shall be within (5) days of service of

this Order upon Defendant. For new personnel, delivery shall occur prior to them assuming their responsibilities.

B. Individual Defendant as Control Person: For any business that each Individual Defendant controls, directly or indirectly, or in which he has a majority ownership interest, Individual Defendant must deliver a copy of this Order to all principals, officers, directors, and managers of that business. Each Individual Defendant must also deliver copies of this Order to all employees, agents, and representatives of that business who engage in conduct related to the subject matter of the Order. For current personnel, delivery shall be within (5) days of service of this Order upon Individual Defendant. For new personnel, delivery shall occur prior to their assuming their responsibilities.

C. Individual Defendant As Employee or Non-Control Person: For any business where each Individual Defendant is not a controlling person of a business but otherwise engages in conduct related to the subject matter of this Order, each Individual Defendant must deliver a copy of this Order to all principals and managers of such business before engaging in such conduct.

D. The Corporate and Individual Defendants each must secure a signed and dated statement acknowledging receipt of the Order, within thirty (30) days of delivery,

from all persons receiving a copy of the Order pursuant to this Part.

XIV.

ACKNOWLEDGMENT OF RECEIPT OF ORDER

IT IS FURTHER ORDERED that each Defendant, within five (5) business days of receipt of this Order as entered by the Court, must submit to the Commission a truthful sworn statement, in the form of Attachment A to this Order, acknowledging receipt of this Order.

XV.

RETENTION OF JURISDICTION

IT IS FURTHER ORDERED that this Court shall retain jurisdiction of this matter for purposes of construction, modification, and enforcement of this Order.

SO ORDERED, this 16th day of December, 2008.

/s/ Charles A. Pannell, Jr.
HON. CHARLES A. PANNELL, JR.
United States District Judge

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

Civil Action No. 1:04-CV-3294-CAP

FEDERAL TRADE COMMISSION,
Plaintiff,

v.

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

Filed June 4, 2008
ECF Document 219

ORDER

This matter is before the court on the following motions: (1) the defendants' motion for summary judgment [Doc. No. 168]; (2) defendant Hi-Tech Pharmaceuticals, Inc.'s ("Hi-Tech") motion for summary judgment [Doc. No. 170]; (3) the plaintiff's motion for summary judgment [Doc. No. 172]; and (4) the defendants' motion to strike the declaration of Jennifer A. Thomas [Doc. No. 214].

I. Case Overview

A. The Plaintiff

The Federal Trade Commission ("FTC") is an independent agency of the United States Government created by statute. 15 U.S.C. §§ 41-58. The FTC is

tasked with enforcement of the Federal Trade Commission Act (the "FTC Act"). The FTC Act prohibits unfair or deceptive acts or practices in or affecting commerce. 15 U.S.C. § 45(a). The FTC Act also prohibits false advertisements for food, drugs, devices, services, or cosmetics in or affecting commerce. 15 U.S.C. § 52.

To aid its enforcement of the FTC Act, the FTC has promulgated regulations that require advertisements: (1) to be truthful and not misleading, and (2) to be supported by adequate substantiation for product claims prior to dissemination. The FTC refers to a violation of the former as a "falsity claim," while a violation of the latter requirement is a "lack of reasonable basis ("LORB") claim."

B. The Defendants

Defendants National Urological Group ("NUG"), National Institute for Clinical Weight Loss ("NICWL")[1] and Hi-Tech (collectively, the "corporate defendants") are corporations that are or were marketing, distributing and selling weight loss and/or erectile performance dietary supplements under the brand names Thermalean, Lipodrene, and/or Spontane-ES. Defendants Jared Wheat and Thomasz Holda are or were officers and shareholders of NUG and Hi-Tech, and were officers and shareholders of NICWL prior to its dissolution. Defendant Stephen Smith is or was an officer and shareholder of NUG, and was an officer and shareholder of NICWL before its dissolution. Defendant Terrill Mark Wright, M.D.,

[1] NICWL dissolved in 2004.

is a medical doctor who promoted the dietary supplements at issue in this case.

C. Brief Synopsis of Facts

According to the defendants, the FTC began investigating their advertising practices in May of 2002. During the course of the investigation, the FTC requested from the defendants the substantiation for their advertising. The defendants allegedly complied and provided the FTC with substantiation based on each individual active ingredient in their dietary supplements ("ingredient-specific substantiation"), as opposed to substantiation based on the product as a whole.

While the FTC investigation was ongoing, the United States Food and Drug Administration[2] ("FDA") filed a complaint for injunctive relief against the corporate defendants and Wheat in his individual capacity (collectively, the "FDA defendants"), alleging that they introduced misbranded drugs into commerce. Not long after the suit was filed, the FDA defendants entered into a consent decree with the FDA (the "Consent Decree"). The Consent Decree regulates the FDA defendants' behavior along three pertinent veins. First, before the FDA defendants can sell a dietary supplement that is not considered a

[2] The FTC and the FDA work together under an agreement governing the division of responsibilities between the two agencies. As applied to dietary supplements, the FDA has primary responsibility for claims on product labeling, including packaging, inserts, and other promotional material distributed at the point of sale. The FTC has primary responsibility for claims in advertising, including print and broadcast ads, infomercials, catalogs, and similar direct marketing materials.

drug, the Consent Decree requires them to retain an independent expert to inspect their product labeling, including their promotional materials and internet web sites, and certify to the FDA that the FDA defendants are not making drug claims for their products. In addition to the independent expert's report, the FDA defendants must submit to the FDA a written report that details, among other things, the actions they have taken to comply with the FDA Consent Decree. After this, the FDA defendants must await the FDA's approval to resume or initiate operations. After resuming sales, the FDA defendants are prohibited from "directly or indirectly introduc[ing] or deliver[ing] for introduction into interstate commerce, or directly or indirectly caus[ing] the introduction or delivery for introduction into interstate commerce of, any misbranded or unapproved new drug." Consent Decree, ¶ 4(A) [Doc. No. 168, Ex. I]. Finally, the Consent Decree permits FDA representatives to make unannounced inspections of the FDA defendants' facilities, during which the FDA is allowed to investigate, among other things, all equipment, finished and unfinished drugs and dietary supplements, and all labeling, including promotional materials and internet site information. If the FDA determines that the FDA defendants are not in compliance with the Consent Decree, the FDA may take any other reasonable measures to monitor and ensure the FDA defendants' continuing compliance.

On November 10, 2004, months after the defendants entered into the Consent Decree, the FTC filed the instant suit pursuant to Section 13(b) of the

Act, 15 U.S.C. § 53(b),[3] to secure injunctive and other equitable relief against the defendants. In its complaint, the FTC asserts that the defendants have violated Section 5 of the Act, 15 U.S.C. § 45(a)[4], and Section 12 of the Act, 15 U.S.C. § 52.5 Specifically, the FTC claims that the defendants have made deceptive representations to the public in their advertisements for the dietary supplements Thermalean, Lipodrene, and Spontane-ES. The FTC has petitioned this court for injunctive relief as well as relief in the form of consumer redress and disgorgement of profits.

On August 24, 2007, the defendants, defendant Hi-Tech, individually, and the FTC filed cross motions for summary judgment [Doc. Nos. 168, 170, and 172]. On December 13, 2007, the defendants filed a motion to strike the affidavit of Jennifer Thomas [Doc. No. 214].

II. The Defendants' Motion to Strike the Affidavit of Jennifer Thomas [Doc. No. 214]

Before considering the parties' motions for summary judgment, the court will address the defendants' motion to strike the declaration of Jennifer A. Thomas [Doc. No. 214]. Thomas is Director of the Division of Enforcement in the Center for Food Safety and Applied Nutrition at the FDA. The FTC filed Thomas's declaration in response to the defendants' motion for summary judgment and Hi-Tech's motion for summary judgment on November 5, 2007. Prior to filing Thomas's declaration, the FTC did

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[3] Section 13(b) enables the FTC to seek equitable relief from the district court.

[4] Section 5 prohibits unfair or deceptive acts or practices.

not disclose Thomas to the defendants as a party likely to have discoverable information. The defendants contend that the FTC's failure to identify Thomas at an earlier date was prejudicial to their case and a violation of the Federal Rules of Civil Procedure. Accordingly, the defendants request that the court strike her affidavit.

A. The Defendants' Motion to Strike Is Denied.

The courts in this district have repeatedly found that it is improper to strike an affidavit attached to a summary judgment brief. *Lentz v. Hospitality Staffing Solutions, LLC*, No. 1:06-cv-1893-WSD, 2008 U.S. Dist. LEXIS 6291, at *30–31 (N.D. Ga. Jan. 28, 2008) (noting that Federal Rule of Civil Procedure 12(f) permits the court to strike a pleading, not an affidavit attached to a motion for summary judgment). As this court stated in *Lentz*, "the proper method to challenge such an affidavit is to challenge the admissibility of the evidence contained in the affidavit." *Id.*; *see also Pinkerton & Laws Co. v. Roadway Express, Inc.*, 650 F. Supp. 1138, 1141 (N.D. Ga. 1986) (concluding that a party should file a notice of objection rather than a motion to strike to challenge the admissibility of evidence in an affidavit).

Because a motion to strike is a procedurally improper vehicle for challenging Thomas's affidavit, the court must deny the defendants' motion. However, the court "may only consider admissible evidence when deciding a motion for summary judgment," and the defendants' motion raises important questions regarding the admissibility of the Thomas affidavit. *Id.* Accordingly, the court, "in the interest of efficiency," will "proceed to assess the admissibility of

the challenged affidavit." *Spratlin Outdoor Media, Inc. v. City of Douglasville*, No. 1:04-cv-3444-JEC, 2006 U.S. Dist. LEXIS 20797, at *13 (N.D. Ga. Mar. 27, 2006).

B. The Thomas Declaration is Inadmissible.

Federal Rule of Civil Procedure 26(a)(1) requires parties to provide initial disclosures including "the name and, if known, the address and telephone number of each individual likely to have discoverable information . . . that the disclosing party may use to support its claims or defenses, unless the use would be solely for impeachment." By rule, the obligation to disclose pertinent parties is continuing, so that a party must supplement its disclosures or discovery responses "in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing." Fed. R. Civ. P. 26(e)(1)(A). If a party does not "provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1).

It is undisputed that the FTC neither initially disclosed Thomas as a potential witness nor listed her as a witness in response to pertinent interrogatories. Although the FTC supplemented its initial disclosures in February 2006 to note that an "as yet unknown" FDA representative may have information relevant to the case, the FTC did not further supplement its

disclosures in April 2006 when it identified Thomas as the FDA representative that it intended to use as a witness. FTC's First Am. Initial Disclosures, ¶ 3(N) [Doc. No. 118]. In fact, the FTC did not notify the defendants of Thomas or indicate in any other way that it had identified a FDA witness until it filed her declaration at the end of 2007.

The FTC does not offer justification for its substantial delay in disclosing Thomas as a witness, but instead simply contends that her declaration should be admitted because the defendants were neither surprised nor prejudiced by its failure to disclose her as a witness at an earlier date. Essentially, the FTC contends that its disclosure in February 2006 that it was looking for a witness was enough to put the defendants on notice of Thomas's potential role in this case. Moreover, the FTC contends that it was not required to disclose Thomas because she was a "witness used solely for impeachment," and thus was not subject to Federal Rule of Civil Procedure 26. Fed. R. Civ. P. 26(a)(1).

The FTC's arguments are unconvincing. First, the fact that the FTC notified the defendants that they were looking for a witness in 2006, without more, does not mean that the defendants were not surprised when such a witness suddenly appeared on the record a year and a half later. Moreover, the court is convinced that the FTC's failure to disclose Thomas's identity was prejudicial to the defendants. Thomas's declaration addresses the meaning and effect of the Consent Decree, a topic of critical importance to the defendants' summary judgment briefs. The FTC's failure to disclose Thomas as a potential witness

prevented the defendants from deposing her or anticipating her testimony before expending the significant resources required to file their dispositive motions. Such a failure can hardly be considered harmless.

Similarly, this court cannot conclude that the FTC presented Thomas's declaration "solely for impeachment." Impeachment evidence is evidence that is "offered to discredit a witness . . . to reduce the effectiveness of her testimony by bringing forth evidence which explains why the jury should not put faith in her or her testimony." *Chiasson v. Zapata Gulf Marine Corp.*, 988 F.2d 513, 517 (5th Cir. 1993). Although Rule 26(a)(1) does not require a party to disclose a witness that it intends to use "solely for impeachment," the Eleventh Circuit has indicated that this is a narrow exception that should be limited to circumstances where the evidence offered by the witness plays no role other than impeachment. *See Cooley v. Great Southern Wood Preserving*, 138 Fed. Appx. 149, 161 (11th Cir. 2005) (affirming a district court's decision to exclude affidavits because the plaintiff failed to show that the evidence was offered solely for impeachment).

Here, Thomas's declaration does not simply discredit one particular witness or even a group of witnesses; rather, it is substantive evidence supporting the FTC's defense to one of the defendants' key summary judgment contentions. In their motion for summary judgment, the defendants have argued that the FTC's action is not in the public interest because all of the relief the FTC seeks has already been achieved by the FDA's Consent Decree. Thomas's

declaration, which the FTC offered "to clarify many of the facts surrounding the FDA consent decree," provides substantive evidence that the relief the FTC seeks is not redundant and that the action the FTC pursues is in the public interest. FTC's Resp. to Defs.' Mot. for Summ. J., p. 52 [Doc. No. 195]. This evidence was provided to preserve the FTC's case by demonstrating that there is a genuine issue for trial. Accordingly, it cannot simply be considered impeachment evidence offered solely "to discredit" the defendants.

The FTC's reliance on *Sessoms v. Ghertner & Co.*, C.A. No. 3:05-0257, 2006 U.S. Dist. LEXIS 29863 (M.D. Tenn. April 25, 2006), is misplaced. In *Sessoms*, the defendant, in response to a summary judgment motion, sought to impeach specific deposition testimony by filing declarations of individuals not previously disclosed in interrogatories or initial disclosures. *Id.* at *9. That is not the situation here, where Thomas's declaration is offered to rebut legal arguments and interpret the Consent Decree rather than to simply impeach deposition testimony.

The court concludes that Thomas's declaration was not offered solely for impeachment, and thus holds that the FTC was not exempt from disclosing her as required by Federal Rule of Civil Procedure 26. The FTC has offered no justification for its year and a half delay in disclosing Thomas to the defendants, and the court concludes that this delay was harmful and inexcusable. Consequently, the court will not consider Thomas's declaration or its supporting exhibits in any summary judgment proceeding currently before the court.

III. Summary Judgment Motions

On August 24, 2007, defendant Hi-Tech individually filed a motion for summary judgment [Doc. No. 170],[6] the defendants collectively filed a motion for summary judgment [Doc. No. 168] and the FTC filed a motion for summary judgment [Doc. No. 172]. These summary judgment motions will be addressed in turn.

A. Summary Judgment Standard

Summary judgment is proper where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party bears the initial burden of showing that there is no genuine issue of material fact. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). This may be accomplished by showing that the nonmoving party will be unable to "establish the existence of an element essential to [the nonmoving] party's case, and on which [the nonmoving] party will bear the burden of proof at trial." *Id.* at 322.

Once the moving party has met its burden, the burden shifts to the nonmoving party to "designate specific facts showing that there is a genuine issue for trial." *Id.* at 324 (internal quotation marks omitted). There is a genuine issue if the combined body of evidence, viewed in the light most favorable to the

[6] Hi-Tech also joined in the defendants' collective motion for summary judgment, but filed an individual motion to address a liability defense not shared by its co-defendants.

nonmoving party, would allow a reasonable jury to find in favor of the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In other words, the relevant inquiry is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Id.* at 251–52. When, as here, a district court is presented cross motions for summary judgment on the same issues, "[t]he court must rule on each party's motion on an individual and separate basis, determining, for each side, whether a judgment may be entered in accordance with the Rule 56 standard." 10A Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, *Federal Practice and Procedure* § 2720, at 335–36 (3d ed. 1998) (footnote omitted).

B. Hi-Tech's Motion for Summary Judgment [Doc. No. 170]

Hi-Tech premises its motion for summary judgment on one simple contention: it claims that it did not manufacture, advertise, or market the Lipodrene product at issue in this case and, thus, is not liable on the FTC's allegations. Although Hi-Tech admits that it has produced and marketed multiple products under the name Lipodrene, it claims that these products are "completely different in look and formulation" from the Lipodrene that its co-defendant, NUG, marketed in the advertisements targeted in this action. Hi-Tech's Resp. to FTC's Statement of Additional Facts, ¶ 9 [Doc. No. 202, Ex. 1]. Hi-Tech contends that it did not participate in or fund the advertisements for the old Lipodrene or any other product, and thus, cannot be held liable for them.

The FTC argues that Hi-Tech is not entitled to summary judgment because Hi-Tech participated in all of the advertising at issue in this case, particularly the Lipodrene advertisements. Specifically, the FTC contends that Hi-Tech, NUG, and NICWL acted as a common enterprise. Accordingly, the FTC contends that Hi-Tech should be jointly and severally liable with its corporate codefendants for all of the advertising at issue in this case.

1. Legal Standard for Finding a Common Enterprise

"The general rule is that, absent highly unusual circumstances, the corporate entity will not be disregarded." *Collier & Son Corp. v. FTC*, 427 F.2d 261, 266 (6th Cir. 1970). However, "where the public interest is involved, as it is in the enforcement of Section 5 of the Federal Trade Commission Act, a strict adherence to common law principles is not required . . . where strict adherence would enable the corporate device to be used to circumvent the policy of the statute." *Id.* at 267 (making this statement in the context of determining whether a parent should be held liable for the acts of its subsidiary). Thus, in situations where corporations are so entwined that a judgment absolving one of them of liability would provide the other defendants with "a clear mechanism for avoiding the terms of the order," courts have been willing to find the existence of a common enterprise. *See Delaware Watch Co. v. FTC*, 332 F.2d 745, 746–47 (2d Cir. 1964) (affirming a FTC order holding a company liable because it was part of a "maze of interrelated companies" through which "the same individuals were transacting an integrated business").

When corporations act as a common enterprise, each may be held liable for the deceptive acts and practices of the other. *CFTC v. Wall Street Underground, Inc.*, 281 F. Supp. 2d 1260, 1271 (D. Kan. 2003) (citing *Sunshine Art Studios, Inc. v. FTC*, 481 F.2d 1171, 1175 (1st Cir. 1973)).

When determining whether a common enterprise exists, "the pattern and frame-work of the whole enterprise must be taken into consideration." *Delaware Watch Co.*, 332 F.2d at 746 (citations omitted). Some of the factors that courts evaluate to determine whether a common enterprise exists include common control; the sharing of office space and officers; whether business is transacted through a maze of interrelated companies; the commingling of corporate funds and failure to maintain separation of companies; unified advertising; and evidence that reveals that no real distinction exists between the corporate defendants. *FTC v. Wolf*, No. 94-8119-CIV-FERGUSON, 1996 U.S. Dist. LEXIS 1760, at *22–23 (S.D. Fla. Jan. 30, 1996) (citations omitted).

2. Application of Legal Standard to Facts

In this case, it is clear that all three companies at issue operated as a common enterprise. First, all three companies were under the common control of Wheat and Holda, and were at least influenced by Smith. Wheat served as the president and primary decision maker of all three companies. He developed all of the products at issue in this case, owned all of their trademarks, developed all of their advertising (or at least provided the information for all of the advertisements), wrote checks for all three companies, made deposits and withdrawals on behalf of all three

companies, and had the authority to enter into contracts and terminate contracts for all three companies.

Holda likewise served as an officer of all three companies. In that role, he participated in business decisions. Holda also ran the shipping operations for each of the companies and testified that he reviewed the advertisements for errors before they were disseminated.

Smith served as an officer of NICWL and NUG, and served as an independent contractor for Hi-Tech beginning in 2003. In all three companies, Smith served as the employee/independent contractor manager. Smith, like Holda, testified that he reviewed all of the advertisements for errors.

Wheat, Holda, and Smith ran the three companies out of the same office space in an integrated fashion. For instance, Hi-Tech—the only company with its name on the door—assumed the duty of leasing the office space, often served as the addressee and mail distributor for the other companies, and ordered goods on behalf of the other companies so that all of the companies could save money.[7] Similarly, NICWL served as the payroll manager for itself, NUG, and other affiliated, non-party companies. All three companies shared in the allocation of a number of indirect costs and expense items, including bank charges, credit card fees, depreciation, and—most

[7] Purportedly, Wheat reimbursed each company for the expenditures that it made on behalf of the other companies. However, it does not appear that the companies were compensated for the services that they performed on the other companies' behalf.

importantly—consulting fees for the Thermalean and Lipodrene products. Significantly, the defendants' own expert identified NUG, NICWL, and Hi-Tech as among "five companies [that] have overlapping ownership and [which] incur costs and expenses in relation to [Thermalean, Lipodrene, and Spontane-ES]." Abernathy Expert Report, attached as Ex. 2 to Knight Decl. [Doc. No. 172, Ex. 7].

In addition, the companies worked together to develop and advertise their products. For example, in a related trademark infringement action, Hi-Tech alleges that it worked for years with now-dissolved United Metabolic Research Center, Inc. ("UMRC"), which it ultimately equates with NUG, to develop the original Lipodrene product.[8] Trademark Compl.,

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[8] Although Hi-Tech does not directly state that NUG and UMRC are the same entity, it essentially concedes this point over the course of its briefing. As noted above, Hi-Tech alleges in a related trademark infringement case that it and its self-described "sister company," UMRC, spent years developing the original Lipodrene product. Trademark Compl., ¶¶ 14–17, attached as Ex. 1 to Knight Decl. [Doc. No. 195, Ex. 30]. Hi-Tech then states, in that complaint, that UMRC marketed the original Lipodrene through mail order until the product was reformulated. *Id.* at ¶ 17.

Confusingly, in its brief in support of its motion for summary judgment [Doc. No. 170, Ex. 1, p. 11] and its corresponding statement of facts [Doc. No. 171, ¶ 25], Hi-Tech unambiguously asserts that Warner Laboratories, a division of NUG, marketed the original Lipodrene product and transmitted the income to NUG. This is consistent with the Lipodrene advertisements attached to the complaint, which reflect that Warner Laboratories was the generating entity [Doc. No. 1, Exs. C–E]. However, this is obviously inconsistent with Hi-Tech's allegations in the trademark infringement complaint and with Hi-Tech's expert's report, which notes that Lipodrene was

¶¶ 14–17, attached as Ex. 1 to Knight Decl. [Doc. No. 195, Ex. 30]. Hi-Tech goes on to represent that NUG/UMRC marketed the original Lipodrene through mail order until the product was reformulated. At that point, Hi-Tech, using some of the same advertising materials for the original Lipodrene, began to market the new Lipodrene through wholesale and retail outlets. Hi-Tech later used—almost verbatim—NICWL's Thermalean brochure to market its new Lipodrene. Similarly, Hi-Tech also used claims, language, and artwork from NUG's Spontane-ES advertisement to market its male potency product, Stamina-RX.

When the operations of the companies are considered as a whole, it is clear that they functioned as a common enterprise. All were controlled by the same primary parties, all used and/or shared advertising generated by these controlling

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produced, marketed, and sold by UMRC between January 1, 2001, and March 31, 2004. Abernathy Expert Report, attached as Ex. 2 to Knight Decl., at NUG 0006331 [Doc. No. 172, Ex. 7].

In the defendants' statement of disputed material facts [Doc. No. 198, ¶ 19], in which Hi-Tech joins, they again confuse the companies, this time noting that NUG sold the original Lipodrene product under the corporate name of Warner Laboratories, which they identify as a division of UMRC.

Finally, Hi-Tech begins to refer to NUG and UMRC as "NUG/UMRC" in its reply brief [Doc. No. 202, p. 5, n.3]. Similarly, Hi-Tech begins to use NUG and UMRC's names interchangeably throughout its Response to the FTC's Statement of Additional Facts [Doc. No. 202, Ex. 1]. If Hi-Tech cannot maintain any distinction between UMRC and NUG in its own briefs, then the court must conclude that the companies functioned as a single entity.

individuals, all worked together to achieve profitability, and all shared costs and expenses in relation to the same products. Most importantly, if one of these companies escaped liability, it would afford all three a means for continuing their operations. The few distinctions between the corporations (i.e., the fact that they maintained separate bank, merchant, and UPS accounts and filed their taxes separately) are superficial in nature and would not, when considered in light of the overwhelming evidence of the corporations' interrelated functions, provide a reasonable jury with a basis to reject the application of the common enterprise theory here. The evidence compels that the court find a common enterprise; thus, NUG, NICWL, and Hi-Tech should share liability for the advertisements at issue. Accordingly, Hi-Tech is not entitled to summary judgment here.

C. The Defendants' Motion for Summary Judgment [Doc. No. 168]

The defendants' summary judgment argument is two-pronged. First, the defendants contend that the court should not use the FTC's standards in applying the FTC Act because it argues that those standards are unconstitutional. Second, the defendants contend that they are entitled to summary judgment because the FTC is not eligible for injunctive relief under Section 13(b) of the FTC Act. Because the defendants have requested that the court consider their arguments regarding injunctive relief in the FTC's motion for summary judgment, the court will defer a discussion on these arguments until it addresses that motion. Accordingly, the court need only address the defendants' constitutional arguments at this juncture.

The defendants dedicate a large portion of their briefing to an argument that the FTC's standards in applying the FTC Act are unconstitutional. Using a test articulated in *Central Hudson Gas & Electric Corporation v. Public Service Commission*, 447 U.S. 557 (1980), the defendants argue that many of the standards that the TC uses to determine whether advertising is deceptive violate the First Amendment. In addition, the defendants contend that the standards that the FTC uses to review advertisements for violations of the FTC Act are unconstitutionally vague and overbroad. The court will address these arguments separately below.

1. The Defendants' Central Hudson Arguments

In *Central Hudson*, 447 U.S. 557 (1980), the Supreme Court articulated a four-part analysis for reviewing whether a regulation governing commercial speech violates the First Amendment. The court stated,

> At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.

Id. at 566. Focusing on the last three elements of this analysis, the defendants claim that the following standards that the FTC uses in determining whether advertising is false or deceptive violate the First Amendment:

- The FTC does not consider proof of intent to deceive or permit a good faith defense when an advertisement is challenged as deceptive;
- The FTC relies on its own facial analysis of an advertisement, rather than extrinsic evidence of consumer perceptions, to determine what implicit claims an advertisement promotes;
- The FTC has not promulgated a trade rule to define what misleading implications flow from specified product claims or descriptions, particularly with respect to advertising containing ingredient specific substantiation; and
- The FTC requires all advertising claims that pertain to a supplement's health related benefits to be substantiated by competent and reliable scientific evidence but does not define "competent and reliable scientific evidence."

The court concludes that the defendants have misapplied the *Central Hudson* test in this situation. The test the Court articulated in *Central Hudson* was promulgated to assist courts in determining whether a regulation that limits protected commercial speech is constitutional. Here, the defendants do not attack any particular regulation restricting speech; instead, the defendants attack the guidelines the FTC uses to determine whether speech is protected. *See Bristol-Myers Co. v. FTC*, 738 F.2d 554, 562 (2d Cir. 1984)

("[D]eceptive advertising enjoys no constitutional protection."). Thus, the defendants employ circular logic: they contend that the court must use the *Central Hudson* test—which only applies to protected speech—to determine whether or not speech is protected.

The court is unpersuaded by this confusing and illogical argument. Whether or not the advertisements are deceptive, and thus unprotected speech, is a matter that is in the sound discretion of the court. *Kraft, Inc. v. FTC*, 970 F.2d 311, 316 (7th Cir. 1992) (citing *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 385 (1965)) ("[T]he words 'deceptive advertising' set forth a legal standard that derives its final meaning from judicial construction."). Accordingly, the court finds that Central Hudson does not apply in this situation.

2. The Defendants' Vagueness and Overbreadth Challenges

In addition to the *Central Hudson* concerns presented above, the defendants allege that the FTC's standards regulating advertising are vague and overbroad. As an initial matter, the defendants' arguments regarding the overbreadth doctrine are unsustainable. The Supreme Court has explicitly held that the overbreadth doctrine cannot be used to challenge regulations of commercial speech. *Village of Hoffman Estates v. Flipside*, 455 U.S. 489, 497 (1982) ("the over-breadth doctrine does not apply to commercial speech."). All of the standards challenged by the defendants in this case concern commercial speech; accordingly, the overbreadth doctrine does not apply.

The defendants' vagueness challenges center around the standards the FTC uses to determine whether claims that an advertisement makes regarding health and/or safety are adequately substantiated. The FTC requires advertising claims that pertain to a health benefit to be substantiated by competent and reliable scientific evidence. The defendants argue that this standard is unconstitutionally vague because it does not provide sufficient certainty about the criteria the FTC uses to evaluate the scientific support for ingredient-specific claims,[9] does not establish requirements for size, duration, or protocol of a scientific study, does not provide any single fixed formula for the number or type of scientific studies required to substantiate a claim, and does not specify the proper mechanism for extrapolating results of a study.

The defendants' arguments are not persuasive. As the defendants point out, "A statute can be impermissibly vague for either of two independent reasons. First, if it fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits. Second, if it authorizes or even encourages arbitrary and discriminatory enforcement." *Hill v. Colorado*, 530 U.S. 703, 732 (2000). Here, the defendants have not demonstrated that the FTC's standard fails for either of these reasons. "Competent and reliable scientific evidence"

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[9] As a preliminary matter, the court notes that whether the FTC's standards provide sufficient certainty about the criteria the FTC uses to evaluate the scientific support for ingredient-specific claims is not at issue here, as none of the claims targeted by the FTC are ingredient-specific.

has been defined in various contexts, including in guidelines promulgated by the FTC, as "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." Bureau of Consumer Protection, Federal Trade Commission, *Dietary Supplements, An Advertising Guide for the Industry* (2001), p. 9, attached as Ex. H to Defs.' Mot. for Summ. J. [Doc. No. 168]. The court can find 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. Obviously, this definition 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. Thus, the size, duration or protocol of a scientific study, the number or type of scientific studies required to substantiate a claim, and the proper mechanism for extrapolating results from studies will obviously vary from circumstance to circumstance depending upon the expert evidence presented. However, the standard by which these issues of fact are resolved is clear, and an advertiser can be reasonably certain of what substantiation will be required by conferring with appropriate professionals or experts. The fact that different scientific evidence is required for different claims impacting different products does not mean that the FTC can enforce its act arbitrarily; instead, it simply means that different claims require different

substantiation. As Judge Dimock wrote in his concurring opinion in *United States v. Shackne*, 333 F.2d 475, 488 (2nd Cir. 1964), "Statutes are not . . . void for vagueness because they raise difficult questions of fact. They are void for vagueness only where they fail to articulate a definite standard." Here the FTC has articulated a definite standard; accordingly, the issues of fact that it generates do not render it unconstitutionally vague.

The defendants have failed to demonstrate that the FTC's standards at issue in this case are unconstitutional and, thus, are not entitled to summary judgment on this issue.

D. The FTC's Motion for Summary Judgment [Doc. No. 172]

In the FTC's motion for summary judgment, the FTC argues that it is entitled to summary judgment on all of its claims because the defendants' advertisements violate the FTC Act. The defendants respond to the FTC's motion by first asserting that the FTC is legally precluded from litigating its claims by the doctrines of res judicata and collateral estoppel. The defendants then argue the merits of the case, contending that the FTC does not have sufficient evidence to demonstrate that the advertising was false and misleading and that most of the challenged advertising was nonactionable puffery. The court will first address the defendants' affirmative defenses before turning to the merits of the case.

1. The Defendants' Affirmative Defenses

The defendants allege that the doctrines of res judicata and collateral estoppel preclude the FTC's claims. Specifically, they argue that the Consent

Decree that the defendants entered into with the FDA resolved the claims and issues presented in the current action.

Collateral estoppel and res judicata are affirmative defenses. Fed. R. Civ. P. R. 8(c). Eleventh Circuit courts have held that the "failure to include an affirmative defense in the answer or have it included in the pre-trial order of the district court, which supersedes the pleadings, will normally result in waiver of the defense." *Jackson v. Seaboard C.L.R. Co.*, 678 F.2d 992, 1012 (11th Cir. 1982); *see also Palmer v. Braun*, 376 F.3d 1254, 1257 n.2 (11th Cir. 2004) (finding that the defendant waived his affirmative defense when he failed to include it in either his answer or the pretrial order). While parties may raise the res judicata and collateral estoppel defenses in a summary judgment motion if the motion is filed in place of an answer, *Concordia v. Bendekovic*, 693 F.2d 1073, 1075 (11th Cir. 1982), or if events subsequent to the filing of the answer give rise to the defenses and the assertion of the defenses is not prejudicial to the plaintiff, *In re Air Disaster at Brunswick, Georgia*, 879 F. Supp. 1196, 1200 (N.D. Ga. 1994), a party may not revive an available defense that he failed to assert in his answer by arguing it on summary judgment. *Funding Systems Leasing Corp. v. Pugh*, 530 F.2d 91, 96 (5th Cir. 1976).[10] This is consistent with Supreme Court rulings, which hold that preclusion defenses must be asserted in a timely

[10] Decisions of the former Fifth Circuit issued prior to October 1, 1981, are binding precedent on this court. *See Bonner v. City of Prichard*, 661 F.2d 1206, 1207 (11th Cir. 1981).

manner. *Arizona v. California*, 530 U.S. 392, 410 (U.S. 2000).

In this case, the defendants base their preclusion defenses on a Consent Decree that they entered into with the FDA on September 22, 2003. Although the Consent Decree had been in place for almost sixteen months, the defendants did not assert res judicata or collateral estoppel when they filed their answers on January 18, 2005.[11] In fact, it was not until the defendants filed their response to the FTC's motion for summary judgment on November 5, 2007—over four years after the Consent Decree was signed—that the defendants raised these preclusion defenses.

The court finds the defendants' delay in asserting these defenses inexcusable. The preclusion defenses that the defendants now attempt to assert have been available to them throughout the three plus years that this case has been pending. The defendants cannot assert them at this late point simply because the "light finally dawned" that they might be available. *Arizona v. California*, 530 U.S. at 410 ("We disapprove of the notion that a party may wake up because a 'light finally dawned,' years after the first opportunity to raise a defense, and effectively raise it so long as the party was (though no fault of anyone else) in the dark until its late awakening."). Accordingly, this court

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[11] The defendants did attempt to reserve the right to assert additional defenses that became apparent during discovery; however, the court struck this "reservation of rights" defense in its June 24, 2005, order and noted that "absent permission of the court, the defendants are required to assert every defense in their answer." [Doc. No. 75, pp. 34–35].

concludes that the defendants have waived their right to assert these defenses.

2. Analysis of the Defendants' Advertisements for False and Misleading Claims

As noted above, the FTC has asserted that the defendants violated Sections 5 and 12 the FTC Act by (1) making false claims regarding Thermalean, Lipodrene, and Spontane-ES; (2) making unsubstantiated claims regarding Thermalean, Lipodrene and Spontane-ES; and (3) making false claims regarding research and medical facilities. The FTC has also alleged that Dr. Wright violated the FTC Act by making false and unsubstantiated claims in his role as an expert endorser for Thermalean.

The court will first address the legal framework for analyzing the advertisements for violations of the FTC Act and then will apply that framework to the advertisements at issue. Finally, the court will address the defendants' defense that much of the advertising constitutes non-actionable puffery.

a. Overview of the Law

The FTC's claims are premised on the defendants' alleged violations of Sections 5 and 12 of the FTC Act. Section 5 of the FTC Act prohibits unfair or deceptive acts or practices in or affecting commerce. 15 U.S.C. § 45(a). Section 12 addresses false advertising and provides that the dissemination of false advertisements—defined as advertisements that are misleading in a material respect—is an unfair or deceptive practice in commerce. 15 U.S.C. §§ 52(b) and 55. "Thus, a violation of Section 12, dissemination of false advertising, constitutes a violation of Section

5(a)." *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 957 (N.D. Ill. 2006).

To establish liability under Sections 5 and 12 of the FTC Act, the FTC must prove: (1) that there was a representation; (2) that the representation was likely to mislead customers acting reasonably under the circumstances; and (3) that the representation was material. *FTC v. Tashman*, 318 F.3d 1273, 1277 (11th Cir. 2003); *see also Kraft, Inc.*, 970 F.2d at 314 (citing Sections 5 and 12 to state that "an advertisement is deceptive under the Act if it is likely to mislead customers, acting reasonably under the circumstances, in a material respect"); *QT, Inc.*, 448 F. Supp. 2d at 957 (using this three part test to find violations of Sections 5 and 12). The court will address each of these elements in depth.

i. Was the Representation Made?

The first step that the court must take to analyze whether the defendants violated the FTC Act is to determine whether the advertisements made the claims asserted by the FTC in the complaint. *QT, Inc.*, 448 F. Supp. 2d at 957. The meaning of an advertisement, the claims or net impressions communicated to reasonable consumers, is fundamentally a question of fact. *See, e.g.*, *id.* at 957–58 (citing *National Bakers Services, Inc., v. FTC*, 329 F.2d 365, 367 (7th Cir. 1964)). This question of fact may be resolved by the terms of the advertisement itself or by evidence of what consumers interpreted the advertisement to convey.

When assessing the meaning and representations conveyed by an advertisement, the court must look to the advertisement's overall, net impression rather

than the literal truth or falsity of the words in the advertisement. *FTC v. Peoples Credit First, LLC*, No. 8:03-cv-2353-T-TBM, 2005 U.S. Dist. LEXIS 38545, at *20–25 (M.D. Fla. Dec. 18, 2005) (finding that an advertisement was implicitly deceptive by looking at the net impression that it was likely to make on the general public). If the advertisement explicitly states or clearly and conspicuously implies a claim, the court need not look to extrinsic evidence to ascertain whether the advertisement made the claim. *See In re Thomson Med. Co., Inc.*, 104 F.T.C. 648, 311–12 (1984) (noting that when an advertisement unequivocally states a claim, "it is reasonable to interpret the ads as intending to make [it]"); *QT, Inc.*, 448 F. Supp. 2d at 958 ("Where implied claims are conspicuous and reasonably clear from the face of the advertisements, extrinsic evidence is not required.") (internal citations omitted). However, if the advertisement faintly implies a claim, the court may certainly decline from concluding that the advertisement makes such a representation without extrinsic evidence of consumer perceptions. As another district court noted, "implied claims fall along a continuum from those which are so conspicuous as to be virtually synonymous with express claims to those which are barely discernable. It is only at the latter end of the continuum that extrinsic evidence is necessary." *FTC v. Febre, C.A.* No. 94-C-3625, 1996 U.S. Dist. LEXIS 9487, at *14–15 (N.D. Ill. July 2, 1996).

In this case, the FTC has not presented any evidence of what claims consumers perceived the advertisements to make; accordingly, any claims that the FTC contends that the advertisements make must

be clear and conspicuous from the face of the advertisements.[12]

ii. Is the Representation Likely to Mislead?

To demonstrate that a claim is likely to mislead a reasonable customer, the FTC may proceed under a "falsity theory," a "reasonable basis theory," or both. *QT, Inc.*, 448 F. Supp. 2d at 957–58. If the FTC proceeds under a falsity theory, it "must demonstrate either that the express or implied message conveyed by the ad is false." *FTC v. Natural Solutions, Inc.*, C.A. No. 06-6112-JFW, 2007 U.S. Dist. LEXIS 60783, at *10 (C.D. Cal. Aug. 7, 2007). If the FTC proceeds under a "reasonable basis" theory, it must demonstrate that the advertiser lacked a reasonable basis - or adequate substantiation—for asserting that the message was true. *Id.* As discussed in the defendants' motion for

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[12] Despite established case law to the contrary, the defendants argue that the court "cannot reliably or accurately ascertain the meaning of the advertisements." Defs.' Resp. Br., p. 33 [Doc. No. 196]. Citing the FTC's expert's testimony, the defendants contend that only the recipients of the advertising can ascertain the content and meaning of the advertisements and the claims which influenced their purchase decision. *Id.* at pp. 32–33.

The court is not persuaded by the defendants' argument. As the above case law indicates, the court is well-equipped to discern express claims or clear and conspicuous implied claims from the face of the advertisement. While evidence of consumer perceptions is always welcomed by the court, it is only necessary when the asserted claims fall on the "barely discernable" side of the continuum. The court concludes that imposing a legal requirement on the FTC to survey the exact consumer group that the defendants solicited is both unduly burdensome and unnecessary, particularly when the claims are apparent from the face of the advertisement.

summary judgment, in the case of health-related claims or claims concerning the efficacy or safety of dietary supplements, this reasonable basis must, at a minimum, consist of competent and reliable scientific evidence. *QT, Inc.*, 448 F. Supp. 2d at 961.

All of the products at issue in this case are dietary supplements and/or drugs that are marketed as promoting health benefits in the form of weight loss and sexual enhancement. Not surprisingly, all of the unsubstantiated representations that the FTC claims the advertisements make are related to the safety and/or efficacy of the dietary supplements and, correspondingly, implicate health concerns. Thus, all of the lack of reasonable basis claims discussed in this case must be supported by "competent and reliable scientific evidence."

As noted in the discussion of the defendants' motion for summary judgment [Doc. No. 168], the FTC has defined competent and reliable scientific evidence as "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." *Dietary Supplements, An Advertising Guide for the Industry*, *supra*, at 9. The court adopts this definition. Thus, what constitutes competent and reliable scientific evidence in this case is a question of fact for expert interpretation. *Id.*

iii. Is the Representation Material?

"A representation or omission is material if it is the kind usually relied on by a reasonably prudent

person." *FTC v. Windward Marketing*, No. 1:96-cv-615, 1997 U.S. Dist. LEXIS 17114, at *27 (N.D. Ga. Sept. 30, 1997); *see also QT, Inc.*, 448 F. Supp. at 960 ("A claim is considered material if it involves information that is important to consumers and, hence, likely to affect their choice of, or conduct regarding, a product.") (internal citations omitted). "Express claims, or deliberately made implied claims, used to induce the purchase of a particular product or service are presumptively material." *Windward Marketing*, 1997 U.S. Dist. LEXIS 17114, at *28. In addition, other courts have also found claims that "significantly involve health, safety, or other issues that would concern reasonable customers" to be presumptively material. *QT, Inc.*, 448 F. Supp. 2d at 960, 965–66.[13]

As noted above, all of the representations that the FTC claims the ads make are related to health and/or safety. As a matter of practicality, this court finds it hard to imagine that any reasonable customer would find claims regarding how a product affects his or her health or safety immaterial, but the court need not reach that question at this juncture. For purposes of this case, it is sufficient to state that when a customer makes a decision to purchase a health product that he or she will ingest for purported health benefits, any claim on the label regarding the health benefits (i.e., any product efficacy claims) or any claims regarding

[13] As both *QT, Inc.* and *Windward Marketing* suggest, the court may presume that some claims are material absent evidence to the contrary. The defendants' argument that the court may not ascertain the materiality of such claims is unavailing and contradicted by the cited case law.

the safety of the product can be presumed material. Thus, the court will presume that all of the asserted claims in this case, if made, were material to the customers' purchasing decisions.

b. Application of the Law to Product Claims and False Endorsement Claims

The FTC asserts that the defendants' advertising violates the FTC Act by making false and unsubstantiated claims regarding Thermalean, Lipodrene, and Spontane-ES. The FTC also alleges that Dr. Wright made false claims and claims without a reasonable basis in his endorsement of Thermalean. The court will examine the advertisements on a product-by-product basis to determine whether the claims were made. The court will then address (1) whether the claims are likely to mislead a reasonable consumer; and (2) whether the claims are material.

i. Do the Advertisements Make the Claims?

(A) Thermalean Claims and Wright False Endorsement Claims

As a basis for its allegations, the FTC attached to the complaint a nine-page Thermalean brochure and a two-page letter "from the desk of Dr. Mark Wright, M.D., Chief of Staff, NICWL" ("the Wright letter") endorsing Thermalean. [Doc. No. 1, Exs. A and B]. Based on these advertisements, the FTC has asserted that the defendants made the following false and deceptive claims:

Falsity Claim 1:	Thermalean is clinically proven to be an effective treatment for obesity;
Falsity Claim 2:	Thermalean causes rapid and substantial weight loss, including as much as 30 pounds in 2 months;
Falsity Claim 3:	Thermalean is clinically proven to cause rapid and substantial weight loss, including as much as 30 pounds in 2 months;
Falsity Claim 4:	Thermalean is clinically proven to enable users to lose 19% of their total body weight, lose 20–35% of abdominal fat, reduce their overall fat by 40–70%, decrease their stored fat by 300%, and increase their metabolic rate by 76.9%; and Falsity Claim 5: Thermalean is clinically proven to inhibit the absorption of fat, suppress appetite, and safely increase metabolism without dangerous side effects.

Compl., ¶¶ 21–22 [Doc No. 1]. The FTC has also asserted that the defendants made the following representations ("Lack of Reasonable Basis ("LORB") Claims") without possessing or relying upon a reasonable basis to substantiate the claims:

LORB Claim 1:	Thermalean is an effective treatment for obesity;
LORB Claim 2:	Thermalean causes rapid and substantial weight-loss, including as much as 30 pounds in two months;
LORB Claim 3:	Thermalean causes users to lose 19% of their total body weight, lose 20–35% of abdominal fat, reduce their overall fat by 40–70%, decrease their stored fat by 300%, and increase their metabolic rate by 76.9%;
LORB Claim 4:	Thermalean inhibits the absorption of fat, suppresses appetite, and safely increases metabolism without dangerous side effects;
LORB Claim 5:	Theramalean is equivalent or superior to the prescription weight loss drugs Xenical, Meridia, and Fastin in providing weight loss benefits; and
LORB Claim 6:	Thermalean is safe.

Id. at ¶¶ 23–24. In addition, the FTC has used the two Thermalean advertisements as the basis for its expert endorsement claims against Dr. Wright. The FTC asserts that Dr. Wright made the following false endorsements regarding Thermalean:

False Endorsement Claim 1:	Thermalean is clinically proven to be an effective treatment for obesity;
False Endorsement Claim 2:	Thermalean is clinically proven to cause rapid and substantial weight loss, including as much as 30 pounds in two months;
False Endorsement Claim 3:	Thermalean is clinically proven to enable users to lose 20–35% of abdominal fat, reduce their body fat by 42%, decrease their stored fat by 300%, and increase their metabolic rate by 76.9%; and
False Endorsement Claim 4:	Thermalean is clinically proven to inhibit the absorption of fat, suppress appetite, and safely increase metabolism without dangerous side effects.

Id. at ¶¶ 34-35. The FTC also claims that Dr. Wright made the following claims without a reasonable basis:

Wright LORB Claim 1:	Thermalean is an effective treatment for obesity;
Wright LORB Claim 2:	Thermalean causes rapid and substantial weight loss, including as much as 30 pounds in 2 months;

Wright LORB Claim 3:	Thermalean causes users to lose 20–35% of abdominal fat, reduce their body fat by 42%, decrease their stored fat by 300%, and increase their metabolic rate by 76.9%;
Wright LORB Claim 4:	Thermalean inhibits the absorption of fat, suppresses appetite, and safely increases metabolism without dangerous side effects;
Wright LORB Claim 5:	Thermalean is equivalent or superior to the prescription weight loss drugs Xenical, Meridia, and Fastin in providing weight loss benefits; and
Wright LORB Claim 6:	Thermalean is safe.

The court will analyze the advertisements for each of these claims. Where the claims are closely linked and supported by the same or similar evidence, the court will examine the claims in tandem.

(1) Falsity Claim 1, LORB Claim 1, False Endorsement Claim 1, and Wright LORB Claim 1

The FTC argues that the advertisements and Dr. Wright falsely represent that Thermalean is clinically proven to be an effective treatment for obesity and represent, without a reasonable basis, that Thermalean is an effective treatment for obesity. The court has surveyed the advertisements, and has

identified the following express statements related to obesity:

- Introducing Thermalean (575 mg Capsule)[-] [t]hree specific causes linked to obesity with one solution Thermalean [Doc. No. 1, Ex. A-2];
- At the National Institute for Clinical Weight Loss, [o]ur research and development team has developed a non-prescription formulation that incorporates a naturally occurring equivalent and substitute for Meridia, Xenical, and Fastin.[14] Thermalean is the most complete, omni-faceted nutriceutical ever developed for the diet industry! After four full years of product development and feedback from hundreds of thousands of clients, we are very proud to announce that Thermalean is the **FIRST** over-the-counter (OTC) nutriceutical to incorporate all three aspects of obesity into one amazing product called Thermalean [*Id.*];
- Why Thermalean? Why now? Thermalean is a product of decades of research and development in the field of weight loss. Thermalean was designed to help the person only needing to los[e] 5 or 10 pounds, as well as the person needing to lose 100 or more pounds. Pharmaceutical "mega-firms" would have you believe that their product is the only product to fight obesity. If this were true then why is America the most overweight society in the

[14] These three products are identified earlier in the advertisement as pharmaceuticals that each "address one aspect of obesity." [Doc. No. 1, Ex. A].

history of the world? With an estimated 75 million Americans clinically considered obese the question should be, Why not now? [Doc. No. 1, Ex. A-7];

- With 75 million Americans clinically considered "obese" [sic] Thermalean could not have come at a better time [Doc. No. 1, Ex. A-6, Wright Endorsement Section];
- Try Thermalean today and win the battle against obesity [Wright Letter, Doc. No. 1, Ex. B-2].

After reviewing these express statements in light of the advertisements in full, the court is persuaded that the defendants' advertisements, including Dr. Wright's endorsement, clearly imply that Thermalean is an effective treatment for obesity. However, the court is not convinced that the advertisements clearly and conspicuously imply that Thermalean is *clinically proven* to treat obesity. Throughout the advertisements, the defendants heavily imply that Thermalean is clinically proven to cause weight loss. However, the defendants have presented evidence that the disease of obesity is different from general weight loss; thus, the court will not presume, without extrinsic evidence, that a recipient of these advertisements would infer that Thermalean is clinically proven to treat obesity from the clinical weight loss claims. Since the FTC has presented no extrinsic evidence, the court concludes that the advertisements do not represent that Thermalean is clinically proven to treat obesity and thus do not make Falsity Claim 1 or False Endorsement Claim 1.

(2) Falsity Claims 2 and 3, LORB Claim 2, Wright False Endorsement Claim 2 and Wright LORB Claim 2

The FTC contends that the Thermalean advertisements and defendant Wright as an endorser falsely and without a reasonable basis represent that Thermalean causes rapid and substantial weight-loss, including as much as 30 pounds in two months. In addition, the FTC contends that the advertisements and Wright falsely represent that Thermalean is clinically proven to cause rapid and substantial weight-loss, including as much as 30 pounds in two months. The court has reviewed the advertisements, and concludes that they, through Wright's endorsements, make the asserted representations. The Wright letter states, "Thermalean is the most complete product on the market today for rapid[,] sustainable weight loss . . . Whether you need to lose 10, 20, 100 pounds or more, Thermalean will work for you." [Doc. No. 1, Ex. B]. Obviously, this portion of the letter expressly states that Thermalean delivers fast, significant weight loss. However, the court need not hang its hat on this statement alone, as the brochure also unambiguously makes the claims at issue here. In the "Questions for Dr. Mark Wright, M.D." portion of the brochure, the advertisement states:

Q: How much weight can I expect to lose with Thermalean?

A: Clinical trials based on Thermalean's proprietary components have yielded weight loss to nearly 15% of beginning body weight within the first two months

Example: (to put this statistic in perspective)

Starting Date	June 1
Starting Weight	200 lbs
Weight after 60 days	170 lbs
Weight loss in 60 days	30 lbs

[Doc. No. 1, Ex. A].

This question and answer segment establishes that Thermalean causes rapid, significant weight loss, and the example given indicates that a consumer can lose up to thirty pounds in two months. In addition, the answer is purportedly based on "clinical trials," providing support for the falsity claims at issue here.[15] Although the defendants have highlighted the language regarding "proprietary components" and argued that the clinical trials and the results thereof were explicitly referring to the ingredients rather than the product as a whole, the court is not persuaded by this argument. The question part of the segment asks about the overall Thermalean product, and the answer, though phrased as an answer regarding the proprietary components, was clearly meant to respond to the query regarding the benefits of the product as a

[15] Confusingly, the defendants' expert, Dr. Richey, indicated in his report that study participants who were shown a copy of the Lipodrene and Thermalean advertisements did not feel that the marketer did a clinical test. However, in parentheses beside this statement, Dr. Richey indicates that the average participant slightly agreed with the statement, "The company who developed this advertisement did a clinical test of this specific branded product." [Doc. No. 198, Ex. 7, pp. 7 and 35]. Because the court concludes that no reasonable consumer would rely upon an expert's conclusion that is directly contradicted by the expert's own study results, the court will disregard this evidence.

whole. The advertisement's generic reference to "Thermalean's proprietary components" emphasizes not the unnamed ingredients but the overall product, and thus achieves the advertisement's goal of promoting the product the defendants are attempting to sell. The unambiguous intent and meaning of the advertisement is that Thermalean—not its "proprietary components"—causes rapid and substantial weight loss, including as much as thirty pounds in two months; thus, the court concludes that the advertisements make the representations alleged by the FTC.[16]

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[16] In their brief, the defendants cite a survey conducted by their expert for the proposition that "consumer intent to purchase the products at issue was driven by the claims in the advertisements about the ingredients of the product and not the product itself." [Doc. No. 196, p. 37]. The court notes that even if this statement was supported by the evidence, it pertains to the materiality of claims rather than the question of whether claims were made. However, the portions of the study upon which this statement is based do not provide a foundation for the statement. The study simply reflects that participants mildly agreed with the following statements:

> (1) I am able to think systematically about information that is given to me about a product, and make my own judgments about the effectiveness of a product; and
>
> (2) I believe that information about the components of a product is useful to me when deciding whether or not to purchase the product.

Richey Report, p. 13 [Doc. No. 198, Ex. 7]. In the survey results, the court can find no basis for the expert's cited conclusion that consumer intent to purchase the products at issue was not driven by claims about the products themselves.

(3) Falsity Claim 4 and LORB Claim 3

The FTC asserts that the advertisements falsely convey that Thermalean is clinically proven to enable users to lose 19% of their total body weight, lose 20–35% of abdominal fat, reduce their overall fat by 40–70%, decrease their stored fat by 300%, and increase their metabolic rate by 76.9%. The FTC also asserts that the advertisements, without a reasonable basis, represent that Thermalean causes users to accomplish these same statistical results.

The Thermalean brochure states,

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

[Doc. No. 1, Ex. A-2].

Similarly, the brochure also states,

> In their precise ratios, the thermogenic components used in Thermalean have achieved the following results in University-sponsored clinical trials (all of these statistics have been reported in such professional journals as the International Journal of Obesity, American Journal of Clinical Nutrition, and The New England Journal of Medicine):

- 300% decrease in stored fat vs. placebo
- 29% greater weight loss vs. REDUX
- 600% increase in total weight loss vs. placebo
- 42% reduction in body fat in a specified time period

Id. at A-3.

A quick analysis of the language above demonstrates that the Thermalean brochure conveys the asserted claims. The brochure unequivocally states that Thermalean's "active components" and "thermogenic components" enable users to lose 19% of their total body weight, lose 20–35% of abdominal fat, reduce their overall fat by 40–70%, decrease their stored fat by 300%, and increase their metabolic rate by 76.9%. It also unequivocally represents that these results are backed by clinical studies and independent, university-sponsored clinical trials. Although the defendants go to great lengths to establish that this express language is language about the ingredients rather than language about the Thermalean product, the court is not persuaded by such meaningless distinctions. The brochure does not define these active and/or thermogenic components by name or proportion; instead, it simply uses these references to mysterious ingredients as synonyms for "Thermalean." The obvious implication from the brochure is that Thermalean—as a whole—is scientifically and clinically proven to yield the touted results; accordingly, the court concludes that it makes the alleged claims.

(4) Wright False Endorsement Claim 3 and Wright LORB Claim 3

The FTC also contends that Dr. Wright, without a reasonable basis, represents that Thermalean causes users to lose 20-35% of abdominal fat, reduce their body fat by 42%, decrease their stored fat by 300%, and increase their metabolic rate by 76.9%. In addition, the FTC contends that Dr. Wright falsely represents that Thermalean is clinically proven to cause users to achieve these same results.

Under the "Questions for Dr. Mark Wright, M.D." section, the Thermalean brochure states, "Thermalean's scientifically proven formula has yielded the following results in independent university-sponsored trials: 42% reduction in body fat - 300% decrease in stored fat - 6.9% elevation in basal metabolic rate - 20–35% reduction in abdominal fat - 600% greater fat burning capabilities than placebo." *Id.* at A-6. This language almost explicitly states that Thermalean causes users to achieve a 20–35% loss of abdominal fat, a 42% reduction in total body fat, a 300% decrease in stored fat, and a 76.9% increase in metabolic rate. Although this portion of the brochure does not specifically state that Thermalean has been *clinically* proven to yield these results, it does state that Thermalean is a scientifically proven formula that has yielded the desired results in independent university-sponsored trials. The court concludes that this language clearly implies that the results were "clinically proven," and is satisfied that Wright made both of the asserted claims.

(5) Falsity Claim 5, LORB Claims 4 and 5, Wright False Endorsement Claim 4, and Wright LORB Claims 4 and 5

The FTC claims that Dr. Wright and the advertisements falsely represent that Thermalean is clinically proven to inhibit the absorption of fat, suppress appetite, and safely increase metabolism without dangerous side effects. In addition, the FTC claims that the advertisement and Wright, without a reasonable basis, represent that Thermalean inhibits the absorption of fat, suppresses appetite, and safely increases metabolism without dangerous side effects. Because the advertising language supporting these claims also supports the representation that Thermalean is equivalent or superior to the prescription weight loss drugs Xenical, Meridia, and Fastin in providing weight loss benefits, all claims will be discussed together.

On the second page, the Thermalean brochure states:

> The pharmaceutical drugs Xenical, Meridia, and Fastin all address one aspect of obesity and only one aspect:
>
> 1.) Xenical — Inhibits the absorption of dietary fats
>
> 2.) Meridia — Suppresses the appetite by blocking the re-uptake of serotonin
>
> 3.) Fastin — Burns fat by increasing the metabolic rate

> Each of these novel pharmaceuticals attack one aspect of obesity, but neglect to address the other causes of obesity.
>
> At the National Institute for Clinical Weight Loss, Our research and development team has developed a non-prescription formulation that incorporates a naturally occurring equivalent and substitute for Meridia, Xenical, and Fastin. *Thermalean* is the most complete, omni-faceted nutriceutical ever developed for the diet industry! After four full years of product development and feedback from hundreds of thousands of clients, we are very proud to announce that Thermalean is the ***FIRST*** over-the-counter (OTC) nutriceutical to incorporate all three aspects of obesity into one amazing product called Thermalean and the results have been extraordinary—*without side effects*!

[Doc. No. 1, Ex. A-2]. Similarly, Dr. Wright's letter states, "Thermalean is a pharmaceutical-grade nutriceutical containing naturally occurring equivalents and substitutes for Sibutramine (Meridia), Orlistat (Xenical), and Phentermine (Fastin) in Thermalean's Core Pharmaceutical Composition and Formulation." *Id.* at Ex. B-1. A few paragraphs down, the letter goes on to state,

> Thermalean's proprietary components have been proven to accomplish the following:
>
> - Inhibit Lipase for obesity management by inhibiting the absorption of dietary fats.

- Slows the rate at which the body 'metabolizes' serotonin therefore suppressing the appetite.
- Safely increasing the metabolic rate without dangerous side-effects associated with prescription drugs.

Thermalean was engineered upon cutting-edge *scientific* and *clinical* data which supports our claim that Thermalean is unmatched by any other prescription or non-prescription diet aid currently available.

Id. The above language clearly supports the claim that Thermalean is equivalent or superior to Meridia, Xenical, and Fastin and the claim that Thermalean inhibits the absorption of fat, suppresses appetite, and safely increases metabolism without dangerous side effects.[17] The court also finds that the advertisements represent that Thermalean is *clinically proven* to inhibit fat absorption, suppress appetite, and increase metabolism. The Wright letter is printed on National Institute for Clinical Weight Loss letterhead and claims to be "From the desk of: Dr. Mark Wright M.D. Chief of Staff, NICWL." *Id.* The letter states that Thermalean's proprietary components have been *proven* to accomplish the functions that are the subject of these claims. *Id.* Immediately beneath this

[17] Although the Wright letter incorporates the use of the term "proprietary components," the court is not persuaded by the defendants' arguments that the statement refers to Thermalean's individual ingredients rather than the product as a whole. As previously noted, the generic reference to all of a product's ingredients, without more, essentially functions as a synonym for the product's name.

statement, the letter states that Thermalean was engineered upon cutting-edge scientific and clinical data. *Id.* These different components, when read as a whole, create the impression that Thermalean was proven to accomplish the asserted functions through clinical studies and/or trials. Moreover, the brochure repeatedly emphasizes that Thermalean achieves clinically proven weight loss by blocking the absorption of dietary fats, suppressing the appetite, and increasing the metabolism. This creates the impression that Thermalean has been clinically proven to achieve its three touted functions.

(6) LORB Claim 6 and Wright LORB Claim 6

Finally, the FTC claims that the Thermalean advertisements and Dr. Wright represent that Thermalean is safe without adequate substantiation. For this claim, the court need look no further than the express language of the advertisements. For example, the Thermalean brochure states, "New Thermalean is safe and natural" and "New Safe Alternative Just Released – Thermalean." [Doc. No. 1, Ex. A-8]. Likewise, the Wright letter states "the introduction of Thermalean reflects the cumulative efforts of many top bariatric (weight loss) physicians and researchers to bring the public a safe and effective, scientifically-based formulation that will have a significant impact on your weight loss goals." *Id.* at Ex. B-2. Because the advertisements and Dr. Wright expressly state that Thermalean is safe, no additional analysis is necessary.

(B) Lipodrene Claims

The FTC attached three Lipodrene advertisements as exhibits to the complaint. The first exhibit is a one-page advertisement placed in Cosmopolitan Magazine that states—in large, underlined letters across the top—"Clinically PROVEN Weight Loss." [Doc. No. 1, Ex. C]. The second exhibit is a more detailed, two-page direct mail insert prepared on Warner Laboratories letterhead that provides an overview of Lipodrene's Phase I Review and announces the launch of Phase II. *Id.* at Ex. D. The third exhibit attached to the complaint is a one-page print of an internet web page. *Id.* at Ex. E. It clearly refers to Lipodrene, and states in prominent print, "Clinically PROVEN to be SAFE AND EFFECTIVE!" *Id.*

Based on the these advertisements, the FTC contends that the defendants made the following false claims:

Falsity Claim 1:	Lipodrene causes substantial weight loss, including as much as 125 pounds;
Falsity Claim 2:	Lipodrene is clinically proven to enable users to lose up to 42% of total body fat and 19% of total body weight, and to increase their metabolic rate by up to 50%;
Falsity Claim 3:	Lipodrene is clinically proven to be safe; and

Falsity Claim 4: Lipodrene is clinically proven to cause virtually no side effects.

[Doc. No. 1, ¶¶ 25–26]. In addition, the FTC also argues that the defendants made the following representations regarding Lipodrene without adequate substantiation:

LORB Claim 1: Lipodrene causes substantial weight loss, including as much as 125 pounds;

LORB Claim 2: Lipodrene enables users to lose up to 42% of total body fat and 19% of total body weight, and to increase their metabolic rate by up to 50%; and

LORB Claim 3: Lipodrene is safe.

Id. at ¶¶ 25–26. Each of these claims will be discussed below.

(1) Falsity Claim 1 and LORB Claim 1

The FTC claims that the Lipodrene advertisements falsely and without a reasonable basis represent that Lipodrene causes substantial weight loss, including as much as 125 pounds. The court has reviewed the advertisements and concludes that the first advertisement does make the asserted representation. First, the advertisement clearly represents that Lipodrene causes substantial weight loss. Directly beneath the "Clinically PROVEN Weight Loss!" banner at the top of the page, the ad states: "Lose up to 42% of your total body fat! Lose up to 19% of your total body weight!" [Doc. No. 1, Ex. C].

Underneath this segment, the ad touts an overall 88% success rate. *Id.* The court concludes that, when read together, this ad suggests that Lipodrene is a tried and tested way to lose substantial weight—even up to 19% of one's total body weight. However, the advertisement does not stop with these assertions. The ad, in a section "*from Dr. Mark Wright, M.D. – Medical Director for Warner Laboratories*," states, "Lipodrene is a product you simply MUST TRY if you are having trouble losing weight—whether your weight loss goals involve 5 lbs, 25 lbs, or even 125 lbs." *Id.* This statement from a doctor clearly implies that Lipodrene can help patients meet their weight loss goals - even if that goal is 125 pounds. Accordingly, the court finds that the advertisement makes the asserted representation.[18]

(2) Falsity Claim 2 and LORB Claim 2

The FTC contends that the Lipodrene advertisements falsely represent that Lipodrene is clinically proven to enable users to lose up to 42% of their total body fat and 19% of their total body weight and to increase their metabolic rate by up to 50%. In addition, the FTC contends that the Lipodrene advertisements, without a reasonable basis, represent that Lipodrene enables users to accomplish these goals.

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[18] The other two advertisements do not contain any language specifying 125 pounds, but they do expressly claim that Lipodrene causes significant weight loss. Each of the advertisements note that Lipodrene can reduce a consumer's total body fat by 42% and total body weight by 19%. Thus, this court finds that they provide additional support for the asserted claim.

All three of the advertisements contain language indicating that Lipodrene enables users to accomplish these asserted statistical goals and that such results are clinically proven. For example, the first advertisement sandwiches statements that a consumer can "Lose up to 42% of your total body fat! Lose up to 19% of your total body weight! Increase your metabolic rate up 50%!" directly underneath a "Clinically proven weight loss" banner and directly beside a segment that states that "Lipodrene technology is backed by volumes of Independent Research and hundreds of published studies by the most prominent Universities and Medical Journals in the world." [Doc. No. 1, Ex. C]. When read in context, the only logical conclusion is that these statistical representations have clinical and scientific support.

The court need not even engage in an analysis of the second advertisement, because that ad, citing Warner Laboratories' Chief of Staff, Dr. Timothy Gaginella, explicitly states that the Lipodrene technology accomplished the statistical results in clinical trials. [Doc. No. 1, Ex. D-2].

The third advertisement is much like the first advertisement in that it squeezes these statistical results beneath a larger statement that Lipodrene is "Clinically PROVEN to be SAFE AND EFFECTIVE!" and above a segment that states, "The Lipodrene technology is backed by Volumes of Independent Research and hundreds of Published studies by the most prominent Universities and Medical Journals in the world . . . ." [Doc. No. 1, Ex. E]. As was the case with the first ad, this positioning conveys the impression that Lipodrene is clinically proven to

accomplish the ambitious statistical results set forth therein.

(3) Falsity Claim 3 and LORB Claim 3

The FTC asserts that the Lipodrene advertisements represent that Lipodrene is clinically proven to be safe or, more simply, that Lipodrene is safe. To find these claims, the court need look no further than the express language in the short, one-page internet print out attached to the complaint that states, in reference to Lipodrene, "***Clinically PROVEN to be SAFE AND EFFECTIVE!***" [Doc. No. 1, Ex. E]. As this language is expressly stated, no further analysis is needed.

(4) Falsity Claim 4

The FTC asserts that the advertisements falsely represent that Lipodrene is clinically proven to cause virtually no side effects. Under a header entitled Lipodrene: PHASE I REVIEW, the first advertisement states, "Upon review of 25,000 participants in the Phase I trials, Lipodrene has been shown to yield an 88% SUCCESS RATE with virtually no side effects." [Doc. No. 1, Ex. C]. As previously discussed, this advertisement begins with the "Clinically PROVEN weight loss" banner and contains a caption noting that the Lipodrene technology is backed by volumes of respected studies and research *Id.* In the second advertisement, the ad recaps the Phase I results and notes that there was "an extremely low incidence of side effects." *Id.* at Ex. D-2. The advertisement further cites Dr. Gaginella for the observation that Lipodrene appears to be void of significant or problematic side effects. *Id.* The third advertisement, as just discussed, contains the

statement that Lipodrene is "[c]linically PROVEN to be SAFE AND EFFECTIVE!" *Id.* at Ex. E.

Although none of these advertisements expressly state that Lipodrene is clinically proven to have virtually no side effects, the claim that Lipodrene is "clinically proven to be safe" in the third ad heavily implies that clinical studies have shown that Lipodrene has no or negligible side effects. *Id.* at Ex. E. Moreover, the second ad, which involves a doctor ratifying Lipodrene because of its "near-negligible rate of side effects," heavily implies some sort of clinical backing. *Id.* at Ex. D-2. Finally, both the first and second advertisements attribute side-effect claims to the mysterious and undefined "Phase I trials." *Id.* at Exs. C and D. In light of the repeated references to clinical studies and studies published in medical journals, the overall impression that the advertisements promote is that this "Phase I trial" is a clinical endeavor. Accordingly, the court finds that the advertisements make the asserted representation.

(C) Spontane-ES claims

The FTC attached a two-page Spontane-ES advertisement to the complaint [Doc. 1, Ex. F]. On the basis of this advertisement, the FTC has asserted that the defendants made the following false and deceptive claims:

Falsity Claim 1:	Spontane-ES is clinically proven to be effective in treating 90% of men with erectile dysfunction;

Falsity Claim 2:	Spontane-ES is clinically proven to be effective in treating men with erectile dysfunction; and
Falsity Claim 3:	Spontane-ES is clinically proven to cause no harmful side-effects.

[Doc. No. 1, ¶¶ 29–30]. In addition, the FTC argues that the defendants made the following LORB claims for Spontane-ES:

LORB Claim 1:	Spontane-ES is effective in treating erectile dysfunction in 90% of users; and
LORB Claim 2:	Spontane-ES is safe.

Id. at ¶¶ 31-32.

(1) Falsity Claims 1 and 2 and LORB Claim 1

The FTC contends that the Spontane-ES advertisement falsely represents that Spontane-ES is clinically proven to be effective in treating men with erectile dysfunction and that Spontane-ES is clinically proven to be effective in treating 90% of men with erectile dysfunction. The FTC also contends that the advertisement, without a reasonable basis, represents that Spontane-ES is effective in treating erectile dysfunction in 90% of users.

The advertisement clearly represents that Spontane-ES is effective in treating erectile dysfunction. The conspicuous, introductory phrase of the brochure states that Spontane-ES is "THE RIGHT MOVE AGAINST SEXUAL DYSFUNCTION." [Doc. No. 1, Ex. F-1]. On another "Question and

Answer" flap of the brochure, the advertisement discusses the causes of erectile dysfunction ("ED"). *Id.* Two questions later, the advertisement indicates that Spontane-ES will increase libido, "even if you don't have ED." *Id.* The obvious express and implied meaning of these phrases is that Spontane-ES treats erectile dysfunction, but can be used to enhance the sexual experience "even if you don't have [erectile dysfunction]."

The advertisement also unambiguously states that Spontane-ES has enjoyed a 90 percent success rate among users. [Doc. No. 1, Exs. F-1 and F-2] (stating that Spontane-ES has had "success rates as high as 90%" and "in preliminary testing, Spontane-ES's active components have been shown to be effective in nearly 90% of all men who have taken it.").[19] Moreover, since the advertisement promotes Spontane-ES as treating erectile dysfunction and enhancing the sexual experience, the obvious, overall implication of the advertisement is that Spontane-ES has a 90% success rate of accomplishing these goals.

Finally, the advertisement also clearly represents that Spontane-ES's success rates were achieved in clinical trials. As noted above, the advertisement states that Spontane-ES has achieved a 90% success rate in "preliminary testing." *Id.* at F-1. This language follows references to the "research and development" conducted by the "pharmacological staff at Warner

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[19] Although one of the references to Spontane-ES's success rates mentions "Spontane-ES's active ingredients," the court concludes that the overall impression conveyed by the advertisement is that Spontane-ES—rather than its individual components—enjoys a 90% success rate.

Laboratories." *Id.* Moreover, the testing language is right next to a "Letter from the Doctor," which indicates that Dr. Wright "review[ed]" Spontane-ES. Id. Taken together, the obvious implication from the advertisement is that the success rates were the result of clinical testing.

When the advertisement is read as a whole, it clearly represents that Spontane-ES is clinically proven to be effective in treating men with erectile dysfunction, is clinically proven to be effective in treating 90% of men with erectile dysfunction, and is effective in treating erectile dysfunction in 90% of users. Accordingly, the advertisement makes all three of the claims at issue here.

(2) LORB Claim 2 and Falsity Claim 3

The FTC contends that the Spontane-ES advertisement represents that Spontane-ES is safe and that it is clinically proven to cause no harmful side-effects. In the question and answer segment, the advertisement states:

> Q: "Is Spontane-ES safe?
>
> A: Extremely. With five years worth of research and development in each component going into Spontane-ES by the pharmacological staff at WARNER LABORATORIES we have not experienced any harmful side effects to date."

[Doc. No. 1, Ex. F-1]. This segment of the advertisement expressly states that Spontane-ES is safe; therefore, no further analysis of that claim is needed. In addition, this segment of the advertisement

also conveys that Spontane-ES has resulted in no harmful side-effects after years of clinical study.[20] Accordingly, the court concludes that the advertisement unambiguously makes both claims as alleged.

ii. Are the Representations Regarding the Products Likely to Mislead?

Having concluded that the advertisements make 22 of the 23 claims targeted by the FTC and that Dr. Wright made 9 of the 10 claims alleged, the court must now determine whether these claims were "likely to mislead" consumers. The court will address the lack of reasonable basis claims before moving on to the falsity claims.

(A) Lack of Reasonable Basis Claims

The FTC has alleged that the lack of reasonable basis claims are likely to mislead consumers because they are unsubstantiated. As indicated above, all of these claims regard the safety and efficacy of dietary supplements; thus, they must be substantiated with competent and reliable scientific evidence. In this case, the FTC has presented expert testimony to

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[20] In a column entitled "Final Considerations," the advertisement states,

> CAN I TAKE Spontane-ES WITHOUT RISK TO MY HEALTH? The incidence of side effects is less than 3%!
>
> * The only side effect ever reported is mild nervousness, dizziness, or heart palpitations. If these occur, discontinue use of Spontane-ES.

[Doc. No. 1, Ex. F-2]. By characterizing the side-effects as rare and mild, this statement merely supports the advertisement's overall representation that Spontane-ES has no *harmful* side effects.

establish what constitutes "competent and reliable scientific evidence" for purposes of these claims. The FTC's expert, Dr. Aronne, stated that the type of evidence required to substantiate weight loss claims for any product, including a dietary supplement, is appropriately analyzed results of 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. Dr. Aronne also stated that to scientifically establish the truth of a claim that a product such as Thermalean or Lipodrene has been clinically proven to be efficacious or safe, a reliable clinical study showing that outcome must have been conducted on the product itself. Dr. Aronne further clarified that anecdotal evidence (i.e. reports from patients) are insufficient to prove the efficacy of a product.

In regard to the Spontane-ES claims, the FTC presented Dr. Melman's expert report. In his report, Dr. Melman states that, to support claims that Spontane-ES is effective in treating erectile dysfunction in 90% of users and is safe, experts in the field of erectile dysfunction would require well-designed, placebo-controlled, randomized, double-blind clinical trials involving an appropriate sample population in which reliable data on the subject's ability to maintain an erection rigid enough and for a sufficient length of time to achieve sexual satisfaction is collected over an appropriate period of time. Dr. Melman stated in his expert report that a study that uses higher doses of the active ingredients or a different combination of active ingredients would not

be sufficient to support the efficacy of another product that used lower doses of the active ingredients or a different combination of the ingredients.

The defendants have not countered the testimonies of the FTC's experts regarding what level of substantiation is required for the claims made in this case.[21] Accordingly, the court concludes that there is no issue of fact regarding the requisite levels of substantiation, and will rely upon the standards set forth by Dr. Aronne and Dr. Melman. Both Dr. Melman and Dr. Aronne establish that some form of clinical trial must have been conducted on the product itself or an exact duplicate of the product to substantiate the defendants' claims regarding the overall product. The defendants have admitted that the products themselves have not been clinically or scientifically tested; accordingly, the court finds that the product LORB claims are unsubstantiated and likely to mislead.

(B) Falsity Claims

The FTC has alleged that a number of the defendants' advertising claims are likely to mislead consumers because they are false. The majority of these "falsity claims" assert that a clinical test was performed on the products. All of these claims are inherently false because the defendants have

[21] Instead, the defendants have simply argued that the claims were not made and have maintained that the numerous studies regarding the products' ingredients that they relied upon support their ingredient-specific claims. This argument is unavailing because the defendants did, in fact, make the majority of the contested claims.

admitted that the products have not been clinically tested.

This leaves only two claims for the court to address on an individual basis. First, the FTC contends that the Thermalean advertisements falsely represent that Thermalean causes rapid and substantial weight loss, including as much as 30 pounds in 2 months. Second, the FTC contends that the Lipodrene advertisements falsely assert that Lipodrene causes substantial weight loss, including as much as 125 pounds.

To demonstrate that both of these claims are false, the FTC cites its expert's testimony that there is no evidence that the active ingredients used in Thermalean and Lipodrene can provide anything more than two pounds per month of weight loss. The defendants dispute this fact; however, rather than specifying the nature of their dispute, they simply point the court to their statement of disputed material facts numbers 370–420. The court concludes that the defendants' ambiguous reference to 50 statements of fact, without more, is not a proper citation to evidence as required by Local Rule 56.1(B). Even after reviewing these 50 statements of fact, the court can find no concise statement facially countering the FTC's expert testimony. The court is persuaded that the defendants' failure to combat the FTC's expert testimony with anything more than a vague reference to 50 paragraphs is the equivalent of sending the court on a snipe hunt through the defendants' evidence. It is not the role of the court to pinpoint the defendants' evidence for them; accordingly, the court concludes that there is no factual dispute and that the two

representations at issue are false and likely to mislead.

iii. Are the Representations Regarding the Products Material?

Having concluded that all of the claims at issue are likely to mislead, the court must determine whether the claims were material to consumer purchasing decisions. As noted at the outset, these health and safety claims are presumed material; however, the defendants may rebut this presumption with extrinsic evidence.

In an effort to do just that, the defendants have presented results from two surveys measuring the impact of the Lipodrene and Thermalean advertisements. These surveys were conducted by the defendants' expert, Dr. Richey. In the first study, Dr. Richey concluded that the advertising as a whole was ineffective in promoting the products and, thus, was not likely a strong driver of consumer intent to purchase the products. In the second survey, Dr. Richey concluded that many claims in the advertisements would not significantly impact a consumer's decision to purchase a weight loss product.

The court finds that the defendants' evidence is insufficient to create an issue of fact regarding the materiality of the health, safety, and efficacy claims at issue here. First, the FTC has presented evidence that Lipodrene and Thermalean, marketed through the advertisements at issue in this case, generated in excess of $10.6 million in sales between 2001 and 2004. Based on these figures, the court concludes that no reasonable jury could find that the advertisements were ineffective and immaterial to consumers as a

whole. Clearly, the advertising appealed to many people and whetted their desire to purchase the Thermalean and Lipodrene products.

Second, the court concludes that Dr. Richey failed to survey the impact of any of the advertising claims at issue in this case, and thus failed to establish that these claims were immaterial. Rather than testing the claims that serve as the basis for the complaint, the study tested small portions of these claims, misstatements of these claims, or claims wholly irrelevant to the case. What survey participants thought of the representations in the survey is irrelevant, as this case concerns only the claims set forth in the complaint. Accordingly, the defendants have failed to present evidence that the claims at issue in this case are immaterial, and the court concludes that there is no basis for this issue to proceed to a trier of fact.

iv. Conclusion Regarding the Product Claims

As described in depth above, the court is satisfied that—with the exception of Thermalean Falsity Claim 1—the advertisements made all of the asserted claims. The court is likewise satisfied that Dr. Wright made all of the deceptive endorsement claims except for False Endorsement Claim 1. The court has concluded that all of the claims made were material and likely to mislead. Accordingly, the court holds that the defendants have violated Sections 5 and 12 of the FTC Act.

c. Application of the Law to the Defendants' Medical and Research Facility Claims

In addition to the product claims, the FTC alleges that the defendants' advertising for all three products falsely represented that Warner Laboratories and NICWL are bona-fide research or medical facilities that engage in scientific medical research and product testing at on-site facilities. The FTC argues that the names of the entities alone—"Warner Laboratories" and "National Institute for Clinical Weight Loss"—implies that they are research or medical facilities. In addition, the FTC argues that the defendants used the following excerpts from the advertisements to advance the perception that NICWL and Warner Laboratories were medical or research establishments:

> At the National Institute for Clinical Weight Loss, Our research and development team has developed a non-prescription formulation that incorporates a naturally occurring equivalent and substitute for Meridia®, Xenical®, and Fastin®. Thermalean™ is the most complete, omni-faceted nutriceutical ever developed for the diet industry!
>
> * * *
>
> Q. Is Spontane-ES safe? A. Extremely. With five years worth of research and development in each component going into Spontane-ES by the pharmacological staff at WARNER LABORATORIES we have not experienced any harmful side effects to date.
>
> * * *

> SYNOPSIS: Upon review of 25,000 women and men participating in the PHASE I Trials, Lipodrene™ has been shown to yield an 88% SUCCESS RATE with virtually no side effects.
>
> * * *
>
> On March 1, 1999, the professional staff and Medical Board at WARNER Laboratories aligned with one of the nation's largest manufacturing facilities to begin Phase I testing of Lipodrene, an advanced, pharmaceutical-grade nutriceutical engineered to help women and men lose weight quickly and safely.
>
> * * *
>
> *From the desk of*: Dr. Mark Wright M.D. Chief of Staff, NICWL
>
> * * *
>
> [F]rom Dr. Mark Wright, M.D. – Medical Director for Warner Laboratories

Pl.'s Br., pp. 29–30, attached as Ex. 1 to Pl.'s Mot. for Summ. J. [Doc. No. 172].

The court has reviewed the advertisements, and concludes that they represent that NICWL and Warner Laboratories are entities that engage in scientific medical research and on-site product testing. The court need not even address whether the companies' names imply that they are medical or science research companies because the language of the advertisements—as highlighted above—clearly represents that these companies engage in the scientific activities alleged.

The FTC argues that the claims are false because neither NICWL nor NUG ever operated a facility that engaged in clinical testing of dietary supplement products. The defendants assert that they did engage in scientific research, and point the court to their statement of material facts nos. 372–422 and 453–461. As noted above, the defendants' citation to more than fifty statements of fact does not constitute an appropriate response. Upon review of these statements, however, the court has determined that they do not represent that NICWL or NUG engaged in on-site research[22] or clinical testing of the weight loss products as the advertisements suggest. Because neither NICWL nor NUG ever performed any clinical tests on the products themselves or conducted any independent research regarding the products, the court concludes that the representations conveyed by the advertisements are false and, therefore, likely to mislead. Moreover, because the representation that NUG and NICWL conducted clinical tests and engaged in scientific research before dispensing the products conveys that the products are safe, the court concludes that the claims are entitled to the presumption of materiality. The defendants have offered no evidence to rebut this presumption; accordingly, the court concludes that these medical and research facility claims violate the FTC Act.

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[22] The statements of fact do represent that NICWL and NUG reviewed the research efforts of independent entities regarding some of the ingredients that were ultimately used in Lipodrene, Thermalean and Spontane-ES. However, this secondary research does not provide support for the advertisements' overall message that NUG and NICWL conducted clinical trials and other types of primary research.

d. The Defendants' Puffery Defense

As the above analysis indicates, the FTC has demonstrated that the advertisements make false and unsubstantiated claims. Accordingly, the FTC should be entitled to summary judgment. However, the defendants argue that summary judgment is precluded because most of the advertising claims challenged by the FTC constitute non-actionable puffery, and thus, cannot be considered violations of Sections 5 or 12.

Although courts have defined puffery in numerous ways, "'[p]uffing' refers generally to an expression of opinion not made as a representation of fact." *FTC v. US Sales Corp.*, 785 F. Supp. 737, 746 (N.D. Ill. 1992); *see also In re Sterling Drug, Inc.*, 102 F.T.C. 395, 749 (1983) ("Puffing claims are usually either vague or highly subjective and, therefore, incapable of being substantiated."). While the law affords a seller "some latitude in puffing his goods . . . he is not authorized to misrepresent them or to assign to them benefits they do not possess. Statements made for the purpose of deceiving prospective purchasers cannot properly be characterized as mere puffing." *US Sales Corp.*, 785 F. Supp. at 746; *see also United States v. Simon*, 839 F.2d 1461, 1468 (11th Cir. 1988) (citing *United States v. New South Farm & Home*, 241 U.S. 64 (1916)) ("[W]hen a proposed seller goes beyond [exaggerating the qualities which the article has and] assigns to the article qualities it does not possess, [when the seller] does not simply magnify in opinion the advantages [but] falsely asserts their existence, he transcends the limits of 'puffing' and engages in false representations and pretenses."). Thus, the Eleventh

Circuit has concluded that when an advertiser places "otherwise general assertions about the value [of a product] into a concrete factual setting," the advertiser creates representations that are either true or false, not mere puffery. *Simon*, 839 F.2d at 1468.

The advertisements at issue in this case are indisputably riddled with puffery and, thus, create many overall impressions that could not serve as the basis for Section 5 or Section 12 violations. To demonstrate the rampant use of puffery, the defendants go through the advertisements sentence by sentence and sometimes even phrase by phrase to point out any language that could fit—even in the remotest sense—within the definition of puffery. By deconstructing the advertisements, the defendants attempt to create the overall impression that substantive claims could not arise from such vague, subjective statements.

Despite the defendants' focus on the words and phrases of the advertisements, the focus of this case is on the claims derived from each of the advertisements as a whole. All of the claims that the FTC articulates in the complaint are phrased as factual statements that can be verified by research and science. As discussed in-depth above, the court has reviewed the advertisements, and has concluded that they clearly and conspicuously make the majority of these claims. To be sure, some of the advertisements' direct language supporting these claims contains puffery; however, the combination of this puffery with the concrete, factual statements and phrases that also comprise the advertisements results in the claims highlighted in the complaint. The fact that puffery is

present cannot serve as a shield for the advertisements' deceptive, factual representations. Accordingly, the court concludes that puffery is not a justifiable defense, and the FTC is entitled to summary judgment.

e. The Defendants' Liability

In this case, the FTC seeks to hold all of the defendants liable for the deceptive advertising of Thermalean, Lipodrene, and Spontane-ES. In addition, the FTC seeks to hold Dr. Wright liable for his deceptive endorsements. The parties' respective liability is analyzed below.

i. NUG, NICWL, and Hi-Tech's Liability

As noted in the discussion of Hi-Tech's motion for summary judgment, NUG, NICWL, and Hi-Tech operated as a common enterprise and thus are jointly liable for any deceptive advertising attributable to any of them individually. Since the defendants do not dispute that NUG disseminated the Lipodrene and Spontane-ES advertisements and that NICWL disseminated the Thermalean advertisements, each of the corporate defendants are jointly liable for the FTC Act violations contained in these deceptive advertisements.

ii. Liability of Defendants Wheat, Smith, and Holda

In a case brought by the FTC, individual defendants:

> are liable for the corporate defendant's violations if the FTC demonstrates that (1) the corporate defendant violated the FTC Act; (2) the individual defendants

> participated directly in the wrongful acts or practices or the individual defendants had authority to control the corporate defendants; and (3) the individual defendants had some knowledge of the wrongful acts or practices.

Windward Marketing, 1997 U.S. Dist. LEXIS 17114, at *38; *see also FTC v. Gem Merchandising Corp.*, 87 F.3d 466, 470 (11th Cir. 1996)("[T]he FTC must show that the individual defendants participated directly in the practices or acts or had authority to control them . . . . The FTC must then demonstrate that the individual had some knowledge of the practices."). If a defendant was a corporate officer of a small, closely-held corporation, that individual's status gives rise to a presumption of ability to control the corporation. *FTC v. Transnet Wireless Corp.*, 506 F. Supp. 2d 1247, 1270 (S.D. Fla. 2007). To establish the knowledge requirement, the FTC need not demonstrate actual knowledge of material misrepresentations; instead, the FTC may meet this element by "showing that [an] individual had 'actual knowledge of material misrepresentations, reckless indifference to the truth or falsity of such misrepresentations, or an awareness of a high probability of fraud along with an intentional avoidance of truth.'" *Transnet*, 506 F. Supp. 2d at 1270 (citing *FTC v. Army Travel Services, Inc.*, 875 F.2d 564, 574 (7th Cir. 1989). "A defendant's participation in corporate affairs is probative of knowledge." *FTC v. Wilcox*, 926 F. Supp. 1091, 1104 (S.D. Fla. 1995).

In this case, Wheat, Holda, and Smith were all corporate officers, owners, and/or independent contractors or employees of NUG, NICWL, and Hi-Tech. In these roles, these individuals clearly had the

ability to control the corporate defendants. Many of the examples in the record of Wheat, Holda, and Smith's involvement with the companies indicate that they knew of, or at least were recklessly indifferent to, the misrepresentations the advertisements made.[23] Rather than repeating each of those instances here, the court finds it sufficient to note that the defendants, in their motion for summary judgment, do not even dispute the individual defendants' knowledge of the advertisements' misrepresentations. Accordingly, this court finds that the individual defendants are liable for the violations of the FTC Act promulgated by the corporate defendants.

iii. Dr. Wright's Liability

The FTC petitions this court to hold Dr. Wright individually liable for his participation in marketing Thermalean. Here, the record is clear that Dr. Wright participated directly in the advertising and knew that the advertisements made material misrepresentations regarding the product claims or at least was recklessly indifferent to the truth or falsity of the advertisements. Dr. Wright helped develop the products, reviewed the substantiation regarding the ingredients in the products, and reviewed and edited the advertisements before they were disseminated. He allowed himself to be called "Chief of Staff" and "Medical Director" in the advertisements. He knew that no clinical trials had ever been conducted on the products and conducted no such trials himself. He was aware that none of the studies that he reviewed were

[23] Significantly, each of the individual defendants testified that he had a hand in creating the advertisements or reviewing them prior to dissemination.

conducted on any of the products sold by the defendants. Most importantly, Dr. Wright does not contest his individual liability for the corporate defendants' wrongs; instead, he simply joins the corporate defendants in arguing that no violations occurred. As discussed above, the corporate defendants did engage in violations of the FTC Act; accordingly, Dr. Wright is individually liable for his participation in those violations.

The FTC also seeks to hold Dr. Wright liable for his deceptive endorsements of Thermalean. The FTC guidelines state that an expert's endorsement:

> must be supported by an actual exercise of his expertise in evaluating product features or characteristics with respect to which he is expert and which are both relevant to an ordinary consumer's use of or experience with the product and also are available to the ordinary consumer. This evaluation must have included an examination or testing of the product at least as extensive as someone with the same degree of expertise would normally need to conduct in order to support the conclusions presented in the endorsement.

Guides Concerning Use of Endorsements and Testimonials in Advertising, 16 CFR § 255.3 (2008). The FTC has presented evidence that a physician would require scientific evidence regarding the product itself (rather than its individual components) before making many of the claims that Dr. Wright made, and Dr. Wright has not contested this evidence. Dr. Wright has admitted that he did not rely on any

scientific studies regarding the Thermalean product when making his endorsement; thus, Dr. Wright did not examine or test the product at least as extensively as someone with the same degree of expertise would normally need to examine or test the product before making the conclusions he presented in the endorsement.

Because Dr. Wright did not base his endorsements on the substantiation that a similarly positioned expert in his field would require when making such endorsements, his endorsements were deceptive. Accordingly, the court holds that Dr. Wright is liable for making deceptive endorsements that violate the FTC Act.

f. Relief Requested by the FTC

In its motion for summary judgment, the FTC has requested an award of permanent injunctive relief, as outlined in its proposed order, from ongoing violations by the corporate defendants and defendants Wheat, Smith, and Holda. Moreover, the FTC has requested that the court award equitable monetary relief against the corporate defendants and defendants Wheat, Smith, and Holda, and has further requested that the court hold these parties jointly and severally liable. The FTC has also requested that the court award injunctive and equitable relief against Dr. Wright, as outlined in a proposed final judgment drafted specifically in regard to this defendant.

The defendants contest the FTC's entitlement to the relief requested, and argue that an award of joint and several liability would be unjust. The court will address the defendants' concerns and liability below.

i. The FTC's Entitlement to Permanent Injunctive Relief from the Corporate Defendants and Wheat, Holda, and Smith[24]

Under Section 13(b) of the FTC Act, the FTC may seek, and the court may grant, a permanent injunction to prevent future violations of "any provisions of law enforced by the FTC." 15 U.S.C. § 53(b); *FTC v. Evans Products Co.*, 775 F.2d 1084, 1086 (9th Cir. 1985). As this court concluded it its June 24, 2005, order, the FTC must have reason to believe that the violation is ongoing or likely to recur as a prerequisite to seeking a permanent injunction. Order, June 24, 2005, p. 11 [Doc. No. 75]. Although this court may not grant injunctive relief in favor of the FTC if there is no likelihood that the defendants' violations will recur, "the fact that illegal conduct has ceased does not foreclose injunctive relief." *FTC v. Citigroup Inc.*, 239 F. Supp. 2d 1302, 1306 (N.D. Ga. 2001). If the FTC is able to demonstrate that there is "some cognizable danger of recurrent violation, something more than a mere possibility," then the FTC is entitled to injunctive relief. *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953); *United States v. Realty Multi-List, Inc.*, 629 F.2d 1351, 1388 (5th Cir. 1980) (applying standard for injunction in this circuit). In determining whether there is a "cognizable danger of

[24] The defendants have requested that the court consider here the arguments articulated in their motion for summary judgment on this issue. Accordingly, the court will consider both the defendants' and the FTC's briefing on this issue as found in the documents associated with the defendants' motion for summary judgment.

future violations," this court has previously looked to the nature of the alleged violations, whether the defendants' current occupations position them to commit future violations, and the alleged harm to consumers if the wrongs recur. *Citigroup*, 239 F. Supp. 2d at 1306.

The court concludes that the FTC is entitled to a permanent injunction impacting NUG, Hi-Tech, Wheat, Holda, and Smith.[25] The evidence clearly demonstrates that the corporate defendants' previous violations of the FTC Act were numerous and grave. These parties, acting through their corporate officers, did not engage in a harmless advertising scheme with an isolated incidence of deception; instead, their advertising was chock-full of false, misleading, and unsubstantiated information. This deceptive propaganda was not simply distributed through magazine advertisements and other general circulation media that could easily be "tuned-out" by consumers; rather, it was also sent directly to pre-determined lists of individuals who were especially vulnerable to such targeted advertisement. In short, the defendants dispensed deception to those with the greatest need to believe it, and—not surprisingly—generated a handsome profit for their efforts.

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[25] The defendants have argued that the FTC is not entitled to injunctive relief against NICWL because NICWL is dissolved. The court is persuaded by the defendants' arguments, and concludes that it is unnecessary to enter a permanent injunction against a corporation that is no longer in existence. Accordingly, the court DENIES the FTC's request for injunctive relief from NICWL.

In addition to the gravity of the past violations, the court concludes that the need for a permanent injunction is supported by the evidence on the record of NUG and Hi-Tech's current activities. Although they contend that they no longer advertise or even make the exact formulations of the products at issue, both NUG and Hi-Tech continue to market—through direct mail—dietary supplements similar to the dietary supplements that are discussed in this lawsuit. Significantly, Hi-Tech continues to market a product called Lipodrene, and callously continues to use—almost verbatim—NICWL's old Thermalean brochure to market this product. Thus, it is readily apparent that NUG and Hi-Tech's current business endeavors could serve as a platform for continuing violations of the FTC Act.

If NUG and Hi-Tech's violations recur, the harm to consumers is certain and serious. The advertisements that they disseminated deceived consumers into spending approximately $15.8 million; accordingly, future violations of a similar nature will almost certainly result in financial harm to consumers. More concerning, however, is the physical harm that these types of deceptive claims could foreseeably inflict on consumers' health. It is easy to imagine that a consumer, relying upon false and unsubstantiated advertising about a dietary supplement's safety, efficacy, and ability to conquer health threatening circumstances, could forgo a much needed medical appointment. Moreover, it is also easy to imagine the physical harm that a consumer, relying upon a product's assertions of safety and clinical testing, might experience when suddenly struck by a violent side effect. These are but two examples of

many that this discussion could generate. Thus, it is clear to the court that the recurrence of the corporate defendants' violations could cause significant harm to consumers.

Although a permanent injunction is clearly proper under these circumstances, the defendants make one last argument against it. They claim that the Consent Decree they entered into with the FDA requires them to submit all advertising efforts to the FDA prior to dissemination and, thus, makes it extremely unlikely that they will violate the FTC Act. Because the FDA applies "a standard that is 'consistent with' the FTC's approach" when reviewing advertisements, the defendants argue that "any oversight remedy sought by the FTC in this case" is redundant and not in the public interest. [Doc. No. 168, p. 48].

Upon review of the admissible evidence, the court concludes that the defendants' arguments are groundless. First, the Consent Decree only applies to the FDA defendants; thus, it has no impact on the behavior of Holda, Smith, or Wright. Second, none of the terms of the Consent Decree appear to require the FDA to pre-screen every advertisement issued by the FDA defendants,[26] rendering the defendants'

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[26] The Consent Decree, entered into in 2003, required the FDA defendants to retain an independent auditor to conduct inspection of the defendants' advertising and labeling to ensure that they were no longer making drug claims and that they were appropriately tracking and investigating adverse events. There is no evidence that this auditor was ensuring that the defendants were not disseminating misbranded dietary supplements or engaging in other FTC Act violations. However, even if this auditor did keep a watchful eye for these violations, there is no evidence that the auditor was required to continue to pre-screen

arguments that they are prevented from dispensing deceptive advertising unsubstantiated. Finally, the injunctive relief sought in this case is not identical to the relief achieved by the FDA Consent Decree and, thus, does not present any public interest concerns. The focus of the FDA Consent Decree is unauthorized drug claims, not false or misleading claims regarding dietary supplements. Although the FDA and FTC may attempt to apply consistent standards when evaluating advertisements, nothing in the Consent Decree indicates that the FDA was actively evaluating the defendants' advertisements for all of the issues present here.

Even if there is some overlap between the Consent Decree and the injunctive relief requested here, it does not follow that the injunctive relief is not in the public interest. Generally, any action commenced by the FTC to "stop deception in its incipiency" will be deemed in the public interest. *Regina Corp. v. Federal Trade Commission*, 322 F.2d 765, 768 (3d Cir. 1963) (citing *Progress Tailoring Co. v. Federal Trade Commission*, 153 F.2d 103, 105 (7th Cir. 1946). This action seeks to

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the defendants' products after they were introduced or re-introduced into the market. The Consent Decree did require the FDA defendants to retain an auditor to conduct inspections of their operations at least twice a year for two years after they resumed operations to ensure compliance with the Food, Drug and Cosmetic Act ("FDCA"). Consent Decree, ¶ 11 [Doc. No. 168, Ex. I]. If still ongoing, these bi-annual visits hardly constitute an injunctive prohibition against disseminating deceptive advertising; rather, they seem to function more as a check-in to ensure the defendants have not violated the Consent Decree. Moreover, the defendants have pointed the court towards no evidence establishing that these audits are still ongoing.

prevent the defendants from continuing to violate the FTC Act by: (1) enjoining the defendants from continuing violations, and (2) requiring the defendants to bear the consequences of their previous violations by compensating consumers for money spent on the defendants' deceptively advertised products. Although the public interest is not necessarily served when one agency duplicates the gains that another agency has already achieved, *see* June 24, 2005, Order, p. 49 [Doc. No. 75], an action like this which seeks new, more targeted relief is not against the public interest simply because the injunctive relief requested inadvertently echoes the injunctive relief already achieved in some respects.[27]

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[27] Practically speaking, the court notes that the defendants' real motivation in making their public interest argument appears to be avoiding monetary liability, not injunctive relief. If the Consent Decree really does, as the defendants argue, prohibit and reign in all of the activities that the FTC seeks to enjoin in this case, the defendants would have no reason to contest the injunctive relief here because it creates no new restraints for them. However, the defendants argue that all monetary relief requested is contingent upon the grant of a permanent injunction; therefore, they claim that if the court does not grant a permanent injunction, it cannot award monetary redress. This contention is not correct. Even if the primary injunctive relief is not requested, the court is still entitled to grant other equitable remedies. *See FTC v. Southwest Sunsites, Inc.*, 665 F.2d 711, 717–18 (5th Cir. 1982) ("[It is] indisputably clear that a grant of jurisdiction such as that contained in Section 13(b) carries with it the authorization for the district court to exercise the full range of equitable remedies traditionally available to it.") (internal citations omitted); *In re Evans Products Co.*, 60 B.R. 863, 867 (S.D. Fla. 1986) ("The district court's power under § 13(b) to exercise the full range of equitable remedies, including rescission

As indicated above, there is ample reason for the FTC to believe that the violations are likely to recur. Accordingly, the FTC is entitled to injunctive relief from NUG and Hi-Tech. As Wheat, Holda, and Smith have admitted continuing involvement in these corporations, the FTC is entitled to injunctive relief from these individual defendants as well.

ii. The FTC's Entitlement to Monetary Relief from the Corporate Defendants and Wheat, Holda, and Smith

In addition to injunctive relief, the FTC has requested monetary relief from the corporate defendants and Wheat, Holda, and Smith. "A corporation is liable for monetary relief under Section 13(b) if [the FTC] shows that the corporation engaged in misrepresentations or omissions of a kind usually relied on by reasonably prudent persons and that consumer injury resulted." *Natural Solutions, Inc.*, 2007 U.S. Dist. LEXIS 60783, at *19. "To demonstrate reliance and resulting consumer injury, [the FTC] must prove that [the] 'defendant made material representations, that they were widely disseminated, and that consumers purchased the defendant's product.'" *Id.* (citing *FTC v. Figgie International, Inc.*, 994 F.2d 595, 606 (9th Cir. 1993)).

As established in detail above, the advertisements made many material misrepresentations. Moreover, the FTC has conclusively demonstrated that the

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and restitution, is not diminished by the fact that primary injunctive relief might not be granted.").

advertisements were widely disseminated.[28] Finally, the FTC has proven that consumers spent $7,456,010.00 on Thermalean between May 1, 2001, through March 31, 2004; that consumers spent $3,163,073.00 on Lipodrene between January 1, 2001, and March 31, 2004; and that consumers spent approximately $5,263,353.00 on Spontane-ES between January 1, 2001, and March 31, 2004. Defs.' Resp. to FTC's Statement of Facts, ¶¶ 248, 250, and 313 [Doc. No. 197]. Thus, it is clear that consumers purchased the products at issue. Accordingly, the defendants are liable for consumer redress.

In similar Section 13(b) actions, "the proper amount of restitution has been held to be the purchase price of the relevant product or business opportunity, less any refunds." *US Sales Corp.*, 785 F. Supp. at 753; *Transnet Wireless Corp.*, 506 F. Supp. 2d at 1271; *Peoples Credit First*, 2005 U.S. Dist. LEXIS 38545, at *29, n.18. The primary purpose of restitution in the context of deceptive advertising is to restore victims to

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[28] The FTC has established that approximately 10 million copies of the Thermalean advertisements attached to the complaint were mailed to consumers between the first half of 2001 and the first half of 2003. Defs.' Resp. to FTC's Statement of Facts, ¶¶ 114 and 130 [Doc. No. 197]. Similarly, the FTC has demonstrated that approximately 4 million copies of the Lipodrene advertisement attached to the complaint as Exhibit D were mailed to consumers, that the Lipodrene advertisement attached to the complaint as Exhibit C was placed in Cosmopolitan Magazine, and that the Lipodrene advertisement attached to the complaint as Exhibit E was maintained on an internet website. *Id.* at ¶¶ 67, 166, and 188. The FTC has also demonstrated that approximately 4 million copies of the Spontane-ES advertisement in Exhibit F to the complaint were mailed to consumers. *Id.* at ¶ 260.

their position prior to the deceptive sales. Thus, in calculating a refund, the court looks to the price paid by the consumer and does not deduct any value received. *Figgie International*, 994 F.2d at 606.

Using the above formula, the FTC claims that the defendants are jointly and severally liable for $15,882,436.00.[29] The defendants argue that this figure is improper because it represents the amount of the sales to consumers rather than profits made by the defendants. In addition, the defendants argue that the damages should be reduced by the amount of sales to customers who reordered the product. The defendants further argue that this figure presumes joint and several liability, which they contend is improper in this case. Finally, the defendants request that the court allow them to pay consumer redress directly to their customers rather than to the FTC.

The defendants have provided no case law in support of their position that consumer redress should be measured by the profits made by the defendants rather than the expenses incurred by consumers, and the court concludes that this argument does not comport with the theory behind restitution. Restitution is intended to return the injured party to the status quo and is measured by the amount of loss suffered by the victim. *Transnet Wireless Corp.*, 506 F. Supp. 2d at 1271. Requiring the defendants to return the profits that they received rather than the costs

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[29] This figure represents the total of $7,456,010.00 in Thermalean sales between May 1, 2001, and March 31, 2004; $3,163,073.00 in Lipodrene sales between January 1, 2001, and March 31, 2004; and $5,263,353.00 in Spontane-ES sales between January 1, 2001, and March 31, 2004.

incurred by the injured consumer would be the equivalent of making the consumer bear the defendants' expenses. The court will not make the victimized consumers shoulder such a burden.

The court finds the defendants' second argument—that the damages should be reduced by the amount of sales to customers who reordered the product—equally unavailing. Essentially, the defendants argue that they should not be required to compensate customers who reordered the products because "those customers were obviously influenced by their actual experience with the product and not the advertisement." [Doc. No. 196, p. 58]. The defendants do not introduce any evidence of what actually influenced the customers' decisions to reorder the products; instead, they merely speculate that it was the customers' experiences rather than the advertisements.

While it may be logical to infer that the customers who reordered the defendants' products relied to some degree upon their experience with the products, the fact that the customers' experiences played a role in their purchasing decisions does not mean or even imply that the customers did not also rely upon the representations in the advertisements when making their subsequent purchases.[30] The FTC has

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[30] Indeed, the advertisements contain several express statements that indicate that consumers who reorder the products and use them long term will see favorable results. *See* Doc. No. 1, Ex. A-4 (noting that Thermalean recipients can expect to lose a whopping 73 pounds in a year); *Id.* at Ex. A-6 ("Thermalean users can expect to lose 30 pounds in 60 days"); *Id.* at Ex. C (noting that Lipodrene can help customers achieve their weight loss goal of 125 pounds and can also help customers

demonstrated that the defendants made material representations, that the misrepresentations were widely disseminated, and that consumers purchased the defendants' products; thus, the court may presume that the consumers actually relied upon the advertisements, even when making subsequent purchases. *See Figgie International*, 994 F.2d at 605–06. To rebut this presumption, the defendants must introduce evidence demonstrating that the repeat customers did not rely on the advertisements. *Id.* at 606. The defendants have presented nothing more than mere speculation in this regard and, thus, have failed to meet their burden. Accordingly, the court will not reduce the defendants' monetary liability by the amount of the sales to consumers who reordered the products.

Next, the defendants argue that they should not be held jointly and severally liable because the advertisements were promulgated by different companies, albeit companies with overlapping but not identical ownership. In short, the defendants seem to argue that they are not all liable for the same violations and, thus, should not be held jointly and severally liable as if they were.

The FTC has demonstrated that the corporate defendants acted as a common enterprise.

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lose up to 42% of their total body fat). In addition, the Spontane-ES advertisement indicates that the product is in short supply and encourages customers to purchase it quickly before it is no longer available [*Id.* at Ex. F-1]. This type of advertisement could have encouraged multiple orders and rapid re-orders from customers who were particularly vulnerable to the extreme promises made by the advertisement.

Consequently, each corporation may be held liable for the actions of the other corporations. Because all of the individual defendants are liable for the corporations' actions, joint and several liability is appropriate here.

Finally, the defendants request that the court allow them to pay consumer redress directly to the purchasers of its products rather than to the FTC. The defendants propose contacting every single customer and providing or offering to provide each customer with a complete refund. The FTC, on the other hand, has proposed that all funds earmarked for consumer redress be deposited into a fund in its name to be used for consumer redress and any attendant expenses for the administration of such equitable relief. If the FTC determines that consumer redress is wholly or partially impracticable or if funds remain after redress is completed, the FTC has proposed using any remaining funds for such other equitable relief as it determines to be related to the defendants' practices as alleged in the complaint. The FTC proposes depositing any additional funds into the United States Treasury as disgorgement.

The court has ample discretion to grant the FTC's requested relief, and the defendants have offered no compelling reason why they, the purveyors of the deception, should be charged with competently and honestly reimbursing the consumers. Hence, the court denies the defendants' request.

The FTC has demonstrated that it is entitled to the consumer redress requested. Accordingly, the court finds NUG, NICWL, Hi-Tech, Wheat, Holda, and Smith jointly and severally liable for $15,882,436.00.

iii. Remedy Against Dr. Wright

The FTC has requested that this court enter a permanent injunction against Dr. Wright. The FTC has also requested that the court order disgorgement of ill-gotten gains from Dr. Wright in the amount of $15,454.00 for his participation in the deceptive marketing of the products.

Dr. Wright contends that the FTC is not entitled to injunctive relief from him because the FTC can show no "cognizable danger" that he will violate the law again. Dr. Wright contends that, if the FTC is not entitled to a permanent injunction, it is barred from recovering any ancillary damages from him.

Dr. Wright's arguments are unpersuasive. As detailed above, Dr. Wright's previous violations of the FTC Act were significant. In the Thermalean advertisement alone, he made numerous false and unsustainable endorsements that afforded the product an air of clinical safety that it otherwise may not have had.[31] Moreover, the FTC has demonstrated that Dr. Wright is still making endorsements for the defendants. Indeed, in a recent Lipodrene brochure, Dr. Wright makes some of the very same claims at issue in this case. While the FTC has not attacked the new Lipodrene brochure in this action, Dr. Wright's continuing endorsements indicate, at the very least, that he is positioned to commit future violations of the FTC Act. Finally, any future FTC Act violations on the

[31] Although the FTC only pursues this action against Dr. Wright for his involvement in the Thermalean advertising campaign, his participation in the deceptive Lipodrene and Spontane-ES advertisements is obvious.

part of Dr. Wright will likely result in monetary and physical harm similar to that discussed in regard to future violations on the part of the corporate defendants. Thus, it is clear that injunctive relief is warranted against Dr. Wright.

Other than arguing that the FTC is not entitled to a permanent injunction against him, Dr. Wright does not contest the monetary damages that the FTC seeks. Accordingly, the court finds that the FTC is entitled to the monetary relief requested.

iv. Entry of the Proposed Orders

The FTC has provided the court with two proposed orders in this case. In these proposed orders, the FTC sets forth the injunctive relief that it seeks from the defendants, the monetary relief requested, and monitoring and other provisions.

The defendants have requested that the court grant them further opportunity to address issues raised by the proposed orders before the court adopts them. Citing "space limitations," they contend that they were unable to fully address the "numerous deficiencies" in the proposed orders. Defs.' Resp. Br., p. 58 [Doc. No. 196].

In the interest of justice, the court will grant the defendants' request. However, the court cautions the defendants that it is persuaded by case law that "injunctive relief may be broader than the violations alleged in the complaint as long as the relief is reasonably related to the violations of the FTC Act which occurred, and is not too indefinite." *United States v. Vend Direct, Inc.*, C.A. No. 06-cv-02423, 2007 U.S. Dist. LEXIS 83759, at *6 (D. Colo., July 26, 2007); *see also SlimAmerica*, 77 F. Supp. 2d at 1275 ("Broad

injunctive provisions are often necessary to prevent transgressors from violating the law in a new guise."). Thus, the defendants are instructed to concisely frame their objections with this standard in mind.

IV. Conclusion

Pursuant to the reasons stated herein, the court DENIES the defendants' motion to strike the declaration of Jennifer Thomas [Doc. No. 214], DENIES Hi-Tech's motion for summary judgment [Doc. No. 170], and DENIES the defendants' motion for summary judgment [Doc. No. 168]. The court GRANTS the FTC's motion for summary judgment [Doc. No. 172]. The court concludes that the FTC is entitled to a permanent injunction against all parties, with the exception of NICWL. In addition, the court concludes that defendants NUG, NICWL, Hi-Tech, Wheat, Holda, and Smith are jointly and severally liable for $15,882,436.00 in consumer redress, and that Dr. Wright is liable for $15,454.00.

The defendants are hereby ORDERED to submit to the court, within 15 days, any objections they have to the proposed orders presented by the FTC. The FTC will then have 15 days to file any response to the defendants' objections. Both parties are INSTRUCTED to limit their response to **ten (10) pages**. In addition, both parties are INSTRUCTED to include any citations to the record in their briefs, and are further INSTRUCTED to cite directly to any supporting evidence that they wish the court to consider.

SO ORDERED, this 4th day of June, 2008.

/s/ Charles A. Pannell, Jr.
CHARLES A. PANNELL, JR.
United States District Judge

Appendix E

15. U.S.C. § 45. Unfair methods of competition unlawful; prevention by Commission

(a) Declaration of unlawfulness; power to prohibit unfair practices; inapplicability to foreign trade

(1) Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.

(2) The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations, except banks, savings and loan institutions described in section 57a(f)(3) of this title, Federal credit unions described in section 57a(f)(4) of this title, common carriers subject to the Acts to regulate commerce, air carriers and foreign air carriers subject to part A of subtitle VII of title 49, and persons, partnerships, or corporations insofar as they are subject to the Packers and Stockyards Act, 1921, as amended [7 U.S.C. 181 et seq.], except as provided in section 406(b) of said Act [7 U.S.C. 227(b)], from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce.

(3) This subsection shall not apply to unfair methods of competition involving commerce with foreign nations (other than import commerce) unless—

(A) such methods of competition have a direct, substantial, and reasonably foreseeable effect—

(i) on commerce which is not commerce with foreign nations, or on import commerce with foreign nations; or

(ii) on export commerce with foreign nations, of a person engaged in such commerce in the United States; and

(B) such effect gives rise to a claim under the provisions of this subsection, other than this paragraph.

If this subsection applies to such methods of competition only because of the operation of subparagraph (A)(ii), this subsection shall apply to such conduct only for injury to export business in the United States.

(4)(A) For purposes of subsection (a), the term "unfair or deceptive acts or practices" includes such acts or practices involving foreign commerce that—

(i) cause or are likely to cause reasonably foreseeable injury within the United States; or

(ii) involve material conduct occurring within the United States.

(B) All remedies available to the Commission with respect to unfair and deceptive acts or practices shall be available for acts and practices described in this paragraph, including restitution to domestic or foreign victims.

(b) Proceeding by Commission; modifying and setting aside orders

Whenever the Commission shall have reason to believe that any such person, partnership, or corporation has been or is using any unfair method of competition or unfair or deceptive act or practice in or affecting commerce, and if it shall appear to the Commission that a proceeding by it in respect thereof would be to the interest of the public, it shall issue and serve upon such person, partnership, or corporation a complaint stating its charges in that respect and containing a notice of a hearing upon a day and at a place therein fixed at least thirty days after the service of said complaint. The person, partnership, or corporation so complained of shall have the right to appear at the place and time so fixed and show cause why an order should not be entered by the Commission requiring such person, partnership, or corporation to cease and desist from the violation of the law so charged in said complaint. Any person, partnership, or corporation may make application, and upon good cause shown may be allowed by the Commission to intervene and appear in said proceeding by counsel or in person. The testimony in any such proceeding shall be reduced to writing and filed in the office of the Commission. If upon such hearing the Commission shall be of the opinion that the method of competition or the act or practice in question is prohibited by this subchapter, it shall make a report in writing in which it shall state its findings as to the facts and shall issue and cause to be served on such person, partnership, or corporation an order requiring such person, partnership, or corporation to cease and desist from using such method of competition or such act or

practice. Until the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time, or, if a petition for review has been filed within such time then until the record in the proceeding has been filed in a court of appeals of the United States, as hereinafter provided, the Commission may at any time, upon such notice and in such manner as it shall deem proper, modify or set aside, in whole or in part, any report or any order made or issued by it under this section. After the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time, the Commission may at any time, after notice and opportunity for hearing, reopen and alter, modify, or set aside, in whole or in part any report or order made or issued by it under this section, whenever in the opinion of the Commission conditions of fact or of law have so changed as to require such action or if the public interest shall so require, except that (1) the said person, partnership, or corporation may, within sixty days after service upon him or it of said report or order entered after such a reopening, obtain a review thereof in the appropriate court of appeals of the United States, in the manner provided in subsection (c) of this section; and (2) in the case of an order, the Commission shall reopen any such order to consider whether such order (including any affirmative relief provision contained in such order) should be altered, modified, or set aside, in whole or in part, if the person, partnership, or corporation involved files a request with the Commission which makes a satisfactory showing that changed conditions of law or fact require such order to be altered, modified, or set aside, in whole or in part. The

Commission shall determine whether to alter, modify, or set aside any order of the Commission in response to a request made by a person, partnership, or corporation under paragraph 1 (2) not later than 120 days after the date of the filing of such request.

(c) Review of order; rehearing

Any person, partnership, or corporation required by an order of the Commission to cease and desist from using any method of competition or act or practice may obtain a review of such order in the court of appeals of the United States, within any circuit where the method of competition or the act or practice in question was used or where such person, partnership, or corporation resides or carries on business, by filing in the court, within sixty days from the date of the service of such order, a written petition praying that the order of the Commission be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Commission, and thereupon the Commission shall file in the court the record in the proceeding, as provided in section 2112 of title 28. Upon such filing of the petition the court shall have jurisdiction of the proceeding and of the question determined therein concurrently with the Commission until the filing of the record and shall have power to make and enter a decree affirming, modifying, or setting aside the order of the Commission, and enforcing the same to the extent that such order is affirmed and to issue such writs as are ancillary to its jurisdiction or are necessary in its judgement to prevent injury to the public or to competitors pendente lite. The findings of the Commission as to the facts, if supported by evidence, shall be conclusive. To the

extent that the order of the Commission is affirmed, the court shall thereupon issue its own order commanding obedience to the terms of such order of the Commission. If either party shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Commission, the court may order such additional evidence to be taken before the Commission and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Commission may modify its findings as to the facts, or make new findings, by reason of the additional evidence so taken, and it shall file such modified or new findings, which, if supported by evidence, shall be conclusive, and its recommendation, if any, for the modification or setting aside of its original order, with the return of such additional evidence. The judgment and decree of the court shall be final, except that the same shall be subject to review by the Supreme Court upon certiorari, as provided in section 1254 of title 28.

(d) Jurisdiction of court

Upon the filing of the record with it the jurisdiction of the court of appeals of the United States to affirm, enforce, modify, or set aside orders of the Commission shall be exclusive.

(e) Exemption from liability

No order of the Commission or judgement of court to enforce the same shall in anywise relieve or absolve any person, partnership, or corporation from any liability under the Antitrust Acts.

(f) Service of complaints, orders and other processes; return

Complaints, orders, and other processes of the Commission under this section may be served by anyone duly authorized by the Commission, either (a) by delivering a copy thereof to the person to be served, or to a member of the partnership to be served, or the president, secretary, or other executive officer or a director of the corporation to be served; or (b) by leaving a copy thereof at the residence or the principal office or place of business of such person, partnership, or corporation; or (c) by mailing a copy thereof by registered mail or by certified mail addressed to such person, partnership, or corporation at his or its residence or principal office or place of business. The verified return by the person so serving said complaint, order, or other process setting forth the manner of said service shall be proof of the same, and the return post office receipt for said complaint, order, or other process mailed by registered mail or by certified mail as aforesaid shall be proof of the service of the same.

(g) Finality of order

An order of the Commission to cease and desist shall become final—

(1) Upon the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time; but the Commission may thereafter modify or set aside its order to the extent provided in the last sentence of subsection (b).

(2) Except as to any order provision subject to paragraph (4), upon the sixtieth day after such order is served, if a petition for review has been duly filed;

except that any such order may be stayed, in whole or in part and subject to such conditions as may be appropriate, by—

(A) the Commission;

(B) an appropriate court of appeals of the United States, if (i) a petition for review of such order is pending in such court, and (ii) an application for such a stay was previously submitted to the Commission and the Commission, within the 30-day period beginning on the date the application was received by the Commission, either denied the application or did not grant or deny the application; or

(C) the Supreme Court, if an applicable petition for certiorari is pending.

(3) For purposes of subsection (m)(1)(B) and of section 57b(a)(2) of this title, if a petition for review of the order of the Commission has been filed—

(A) upon the expiration of the time allowed for filing a petition for certiorari, if the order of the Commission has been affirmed or the petition for review has been dismissed by the court of appeals and no petition for certiorari has been duly filed;

(B) upon the denial of a petition for certiorari, if the order of the Commission has been affirmed or the petition for review has been dismissed by the court of appeals; or

(C) upon the expiration of 30 days from the date of issuance of a mandate of the Supreme Court directing that the order of the Commission be affirmed or the petition for review be dismissed.

(4) In the case of an order provision requiring a person, partnership, or corporation to divest itself of stock, other share capital, or assets, if a petition for review of such order of the Commission has been filed—

(A) upon the expiration of the time allowed for filing a petition for certiorari, if the order of the Commission has been affirmed or the petition for review has been dismissed by the court of appeals and no petition for certiorari has been duly filed;

(B) upon the denial of a petition for certiorari, if the order of the Commission has been affirmed or the petition for review has been dismissed by the court of appeals; or

(C) upon the expiration of 30 days from the date of issuance of a mandate of the Supreme Court directing that the order of the Commission be affirmed or the petition for review be dismissed.

(h) Modification or setting aside of order by Supreme Court

If the Supreme Court directs that the order of the Commission be modified or set aside, the order of the Commission rendered in accordance with the mandate of the Supreme Court shall become final upon the expiration of thirty days from the time it was rendered, unless within such thirty days either party has instituted proceedings to have such order corrected to accord with the mandate, in which event the order of the Commission shall become final when so corrected.

(i) Modification or setting aside of order by Court of Appeals

If the order of the Commission is modified or set aside by the court of appeals, and if (1) the time allowed for filing a petition for certiorari has expired and no such petition has been duly filed, or (2) the petition for certiorari has been denied, or (3) the decision of the court has been affirmed by the Supreme Court, then the order of the Commission rendered in accordance with the mandate of the court of appeals shall become final on the expiration of thirty days from the time such order of the Commission was rendered, unless within such thirty days either party has instituted proceedings to have such order corrected so that it will accord with the mandate, in which event the order of the Commission shall become final when so corrected.

(j) Rehearing upon order or remand

If the Supreme Court orders a rehearing; or if the case is remanded by the court of appeals to the Commission for a rehearing, and if (1) the time allowed for filing a petition for certiorari has expired, and no such petition has been duly filed, or (2) the petition for certiorari has been denied, or (3) the decision of the court has been affirmed by the Supreme Court, then the order of the Commission rendered upon such rehearing shall become final in the same manner as though no prior order of the Commission had been rendered.

(k) "Mandate" defined

As used in this section the term "mandate", in case a mandate has been recalled prior to the

expiration of thirty days from the date of issuance thereof, means the final mandate.

(l) Penalty for violation of order; injunctions and other appropriate equitable relief

Any person, partnership, or corporation who violates an order of the Commission after it has become final, and while such order is in effect, shall forfeit and pay to the United States a civil penalty of not more than $10,000 for each violation, which shall accrue to the United States and may be recovered in a civil action brought by the Attorney General of the United States. Each separate violation of such an order shall be a separate offense, except that in a case of a violation through continuing failure to obey or neglect to obey a final order of the Commission, each day of continuance of such failure or neglect shall be deemed a separate offense. In such actions, the United States district courts are empowered to grant mandatory injunctions and such other and further equitable relief as they deem appropriate in the enforcement of such final orders of the Commission.

(m) Civil actions for recovery of penalties for knowing violations of rules and cease and desist orders respecting unfair or deceptive acts or practices; jurisdiction; maximum amount of penalties; continuing violations; de novo determinations; compromise or settlement procedure

(1)(A) The Commission may commence a civil action to recover a civil penalty in a district court of the United States against any person, partnership, or corporation which violates any rule under this subchapter respecting unfair or deceptive acts or practices (other than an

interpretive rule or a rule violation of which the Commission has provided is not an unfair or deceptive act or practice in violation of subsection (a)(1)) with actual knowledge or knowledge fairly implied on the basis of objective circumstances that such act is unfair or deceptive and is prohibited by such rule. In such action, such person, partnership, or corporation shall be liable for a civil penalty of not more than $10,000 for each violation.

(B) If the Commission determines in a proceeding under subsection (b) that any act or practice is unfair or deceptive, and issues a final cease and desist order, other than a consent order, with respect to such act or practice, then the Commission may commence a civil action to obtain a civil penalty in a district court of the United States against any person, partnership, or corporation which engages in such act or practice—

> (1) after such cease and desist order becomes final (whether or not such person, partnership, or corporation was subject to such cease and desist order), and
>
> (2) with actual knowledge that such act or practice is unfair or deceptive and is unlawful under subsection (a)(1) of this section.

In such action, such person, partnership, or corporation shall be liable for a civil penalty of not more than $10,000 for each violation.

(C) In the case of a violation through continuing failure to comply with a rule or with subsection (a)(1), each day of continuance of such

failure shall be treated as a separate violation, for purposes of subparagraphs (A) and (B). In determining the amount of such a civil penalty, the court shall take into account the degree of culpability, any history of prior such conduct, ability to pay, effect on ability to continue to do business, and such other matters as justice may require.

(2) If the cease and desist order establishing that the act or practice is unfair or deceptive was not issued against the defendant in a civil penalty action under paragraph (1)(B) the issues of fact in such action against such defendant shall be tried de novo. Upon request of any party to such an action against such defendant, the court shall also review the determination of law made by the Commission in the proceeding under subsection (b) that the act or practice which was the subject of such proceeding constituted an unfair or deceptive act or practice in violation of subsection (a).

(3) The Commission may compromise or settle any action for a civil penalty if such compromise or settlement is accompanied by a public statement of its reasons and is approved by the court.

(n) Standard of proof; public policy considerations

The Commission shall have no authority under this section or section 57a of this title to declare unlawful an act or practice on the grounds that such act or practice is unfair unless the act or practice causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to

competition. In determining whether an act or practice is unfair, the Commission may consider established public policies as evidence to be considered with all other evidence. Such public policy considerations may not serve as a primary basis for such determination.

15 U.S.C. § 52. Dissemination of false advertisements

(a) Unlawfulness

It shall be unlawful for any person, partnership, or corporation to disseminate, or cause to be disseminated, any false advertisement—

(1) By United States mails, or in or having an effect upon commerce, by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly the purchase of food, drugs, devices, services, or cosmetics; or

(2) By any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase in or having an effect upon commerce, of food, drugs, devices, services, or cosmetics.

(b) Unfair or deceptive act or practice

The dissemination or the causing to be disseminated of any false advertisement within the provisions of subsection (a) of this section shall be an unfair or deceptive act or practice in or affecting commerce within the meaning of section 45 of this title.

28 U.S.C. § 1291. Final decisions of district courts

The courts of appeals (other than the United States Court of Appeals for the Federal Circuit) shall have jurisdiction of appeals from all final decisions of the district courts of the United States, the United States District Court for the District of the Canal Zone, the District Court of Guam, and the District Court of the Virgin Islands, except where a direct review may be had in the Supreme Court. The jurisdiction of the United States Court of Appeals for the Federal Circuit shall be limited to the jurisdiction described in sections 1292(c) and (d) and 1295 of this title.