UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

FEDERAL TRADE COMMISSION, Plaintiff, v. NATIONAL UROLOGICAL GROUP, INC., et al., Defendants.	CIVIL ACTION NO. 1:04-CV-3294-CAP

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 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

[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.

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

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 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 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

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[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).

[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).

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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[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' 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].

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 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

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

that Smith played an integral part in Hi-Tech's marketing 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

[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.

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.

[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.hitechpharma.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.hitechpharma.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.hitechpharma.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.hitechpharma.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.hitechpharma.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,

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

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both injunctions are still binding, and the parties are reminded of their continuing obligations thereunder.

VII,[10] they posit two primary arguments: the FTC 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

[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.

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] 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)

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

(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."

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.*

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

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 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 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

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

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 "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 about the very real

[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].

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].

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.

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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.")).

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

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

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 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 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

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

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 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 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*.

[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.").

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

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

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]

[20] The court notes that Wheat does posit an inability defense when explaining his noncompliance. At this stage of the contempt framework, however, 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

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court focuses on the FTC's burden and it has convincingly demonstrated that the defendants had the ability to comply. The court will address Wheat's and the other defendants' explanations of their noncompliance below.

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, 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,[21] 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 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

[21] 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.

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]

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

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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.

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 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

[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.

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 clear and unambiguous because the defendants evidently

[26] Doc. No. 390, pp.6-7.

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.

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

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, 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

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

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 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]

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

[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.

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]

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

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

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 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

[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.

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 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

[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

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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.

totals $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

[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.").

proper distribution to the affected consumers, the court will then make a determination of the appropriate distribution of those funds.

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.

[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.

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. 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