UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

FEDERAL TRADE COMMISSION, Plaintiff, v. NATIONAL UROLOGICAL GROUP, INC., *et al.*, Defendants.	1:04-CV-3294-CAP

PLAINTIFF FEDERAL TRADE COMMISSION'S POST-TRIAL BRIEF

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I. Introduction

From January 1, 2009 through November 10, 2014, Contempt Defendants Hi-Tech Pharmaceuticals, Jared Wheat, and Stephen Smith (collectively, "Contempt Defendants") widely disseminated marketing claims that Fastin, Lipodrene, Benzedrine, and Stimerex-ES caused rapid and substantial weight and fat loss, increased metabolism, and reduced body fat and appetite, including through the expert endorsement of Dr. Terrill Mark Wright. For example, Contempt Defendants told consumers that Fastin was an "extreme fat burner," promised that Lipodrene "will cause rapid fat and weight loss with usage," bragged that Benzedrine would "annihilate fat," and boasted that Stimerex-ES would "light them up all day as their pounds melt away!"

Contempt Defendants made these product-specific, unqualified, and causal claims without competent and reliable scientific evidence ("CRSE") that the claims were true, in violation of this Court's orders. At the same time, Contempt Defendants omitted this Court's required health-risk warning for their yohimbine-containing products. Through these order violations, Contempt Defendants caused consumers tens of millions of dollars in harm.

II. Contempt Defendants Have Violated The Hi-Tech And Wright Orders With Unsubstantiated, Unqualified, Causal Efficacy Claims.

Section II of the Hi-Tech Order prohibits Hi-Tech, Wheat, and Smith from claiming that their weight loss products cause rapid or substantial weight or fat loss, or affect body fat, metabolism, or appetite unless they possess CRSE that substantiates (i.e., proves the truth of) those claims. *See* FOF, ¶ 75. Similarly, Section II of the Wright Order prohibits Wright from endorsing such products with unsubstantiated claims. FOF, ¶ 123.[1] Section VII of the Hi-Tech Order prohibits Contempt Defendants from making unsubstantiated comparative benefit claims about any weight-loss product or dietary supplement. FOF, ¶ 77.

> "Competent and reliable scientific evidence" is defined as
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> 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.

FOF ¶¶ 80, 125. As this Court has recognized, what constitutes CRSE "depend[s] on what pertinent professionals would require for the particular claim made." *See Fed. Trade Comm'n v. Nat'l Urological Grp.*, 645 F. Supp. 2d 1167, 1186 (N.D. Ga. 2008), *aff'd*, 356 F. App'x 358 (11th Cir. 2009).

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[1] The Wright Order also requires that, for "any representation made as an expert endorser," Wright must engage in "an actual exercise of his represented

A. The FTC Has Established The Level Of CRSE Necessary To Substantiate Contempt Defendants' Claims.

The expert testimony of Dr. Louis J. Aronne establishes by clear and convincing evidence that, for Contempt Defendants' causal claims, experts in the fields of obesity, weight loss, and body weight regulation require:

> appropriately analyzed results of independent, well-designed, well-conducted, randomized, double-blind, placebo-controlled, clinical trials that test the product at the recommended dosage, and which involve an appropriate sample population in which reliable data on appropriate endpoints is collected over an appropriate period of time.

("Product-specific RCTs"). *See* FOF, ¶¶ 283-88, 291, 294, 298-303, 317-26, 335-38, 342-48, 350-55, 362-75, 383-94, 397-98, 413-19, 425-29, 433-39, 449-55.[2] Dr. Aronne's testimony establishes the scientific basis for each element outlined above, and that each element is well-accepted among experts in the field and rooted in the scientific and academic literature. *See id.*

1. Contempt Defendants Do Not Possess Product-Specific RCTs That Substantiate Their Claims.

By Contempt Defendants' own admission there are no double-blind, placebo-controlled tests of Fastin, Lipodrene, Benzedrine, or Stimerex-ES of any duration or measuring any endpoint. FOF, ¶¶ 467-71, 665-67. Thus, clear and

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expertise, in the form of an examination or testing of the product." FOF, ¶ 123.

[2] Critically, "clear and convincing evidence" need not be uncontroverted. COL, ¶¶ 4-6.

convincing evidence establishes that Contempt Defendants did not possess and rely upon CRSE sufficient to substantiate their claims that the products cause rapid or substantial loss of weight and fat, and affect body fat, metabolism, and appetite. Nor did Contempt Defendants possess CRSE that Stimerex-ES provides benefits equal to those of supplements containing the ephedrine alkaloids banned by the FDA. *Id.*; *see also* FOF, ¶¶ 628-34.

2. Contempt Defendants' Purported Substantiation Does Not Meet The CRSE Standard In Key Ways.

Three flaws permeate Contempt Defendants' purported substantiation: (1) the studies are not of the products at issue, and, thus, cannot be extrapolated to them, *see, e.g.*, FOF, ¶¶ 383-424; (2) the studies involve metabolic endpoints, and, thus, cannot be extrapolated to substantiate weight-loss, fat loss, or appetite claims, *see, e.g.*, FOF, ¶¶ 425-43; and (3) the studies are acute studies (usually spanning three or six hours) and, thus, cannot be extrapolated to longer time periods, *see, e.g.*, FOF, ¶¶ 362-82. In fact, Contempt Defendants' own experts confirm that each of these concepts is well-accepted in the field. *See* FOF, ¶¶ 376-82, 396, 402-07.

First, Dr. Aronne explained that product-specific studies are necessary to substantiate product-specific claims because, even where the effects of an ingredient are known, it is not possible to predict what will happen when

various ingredients are combined. *See* FOF, ¶¶ 385-94, 397-98.[3] Dr. Richard van Breemen concurred, explaining, "mixtures of ingredients can have very different effects than those of individual ingredients," particularly in dietary supplements because plant-derived chemicals are so diverse. FOF, ¶¶ 399-401. Thus, clear and convincing evidence demonstrates that scientists who study dietary supplements require product-specificity.

Moreover, Contempt Defendants' expert Hoffman admitted that "when you have a combination product, you cannot draw conclusions unless you're testing the combination product itself." FOF, ¶¶ 403-04; *see also* FOF, ¶ 407. Contempt Defendants' expert Gaginella also admitted "to know whether there are antagonistic effects in a combination of ingredients, you need to test that combination." FOF, ¶ 396. He further admitted that "ingredients in a product might interfere with each other even though that hadn't been predicted." *Id.*; *see also* FOF, ¶ 402.

Second, Dr. Aronne explained that the results of studies of metabolic endpoints cannot be extrapolated to substantiate weight loss, fat loss, or appetite

[3] Dr. Aronne also explained that scientists cannot simply assume certain ingredients will work synergistically (i.e., better than the ingredients alone) based on their mechanisms of action. FOF, ¶¶ 397-98; *see also* FOF, ¶¶ 396, 402. Indeed, one of the studies on which Contempt Defendants rely demonstrates this principle. *See* FOF, ¶¶ 409-12 (discussing Lean System 7 study).

claims for two reasons. FOF, ¶¶ 425-29, 433-39. First, when metabolism increases, the body quickly triggers counter-regulatory mechanisms that increase appetite and slow metabolism, rendering the effects transient, and preventing weight or fat loss. FOF, ¶¶ 366-68, 427.[4] Second, in studies of caffeine-based products (like the Hi-Tech products at issue), the body quickly habituates to caffeine, requiring more caffeine to achieve the same effects. FOF, ¶¶ 605-10; *see also* FOF, ¶¶ 577-78. Tellingly, Contempt Defendants' experts Hoffman and Gaginella concurred that an increase in metabolism does not support a weight or fat loss claim. FOF, ¶¶ 431-32.

Third, Dr. Aronne explained that studies need to last at least six months to substantiate unqualified claims because shorter durations may only demonstrate transient effects. FOF, ¶¶ 364-70. For example, Prozac and Zoloft were thought to cause weight loss and showed promising results in short term studies, but in longer-term studies subjects regained weight even with continued use. FOF, ¶ 372. Similarly, metabolism studies that occur only over a few hours cannot be extrapolated to longer periods of time. FOF, ¶¶ 373, 427.

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[4] Dr. Aronne explained that the body will consume ingested food, then stored carbohydrates before stored body fat. FOF, ¶¶ 435-39. Thus, fat burning only accompanies increased metabolism in the fasting state. *Id.*; *see also* FOF, ¶¶ 440-43. Critically, Hi-Tech's advertising claims are not limited to the fasting state, and the product instructions do not direct consumers to fast. FOF, ¶¶ 444-48.

Contempt Defendants' experts Hoffman and Gaginella again agreed. FOF, ¶¶ 378-81; *see also* FOF, ¶ 382. Specifically, Gaginella admitted that "to evaluate the effect of a product beyond the acute time frame . . . [requires] test[s] beyond the acute time period." FOF, ¶ 378. Otherwise, Gaginella explained, "you can only ***hypothesize***" that an effect seen in an acute test will continue over time. *Id.* (emphasis added). Hoffman explained, "if you have an acute study that measures metabolism over a few hours, you couldn't extrapolate as to the effect on metabolism ***beyond a few hours***." FOF, ¶ 379 (emphasis added). He further admitted, "one reason you can't extrapolate is because things might happen physiologically that could reduce the effect of a substance over time." *Id.*

B. Contempt Defendants' Defenses Are Baseless.

Without Product-specific RCTs to substantiate their claims, Contempt Defendants instead raise five defenses that lack a basis in fact or law: (1) the Hi-Tech Order is unenforceable because it does not comply with Rule 65, *see, e.g.*, 4/6/17 Trial Tr. at 138-39, 162; (2) the Court is prohibited from interpreting CRSE to require Product-specific RCTs, *see, e.g., id.* at 161-62; (3) Dr. Aronne applied the incorrect substantiation standard, *see, e.g., id.* at 160-61; (4) their claims are substantiated by ingredient-specific studies, *see, e.g., id*. at 152-53; and

(5) their claims are substantiated by studies of three other products, Meltdown, Fastin-XR, and Fastin-RR, *see, e.g., id.* at 155-56, 160.

1. The Definition Of "Competent And Reliable Scientific Evidence" Is Clear, Definite, And Unambiguous.

Contempt Defendants claim that the CRSE standard is too uncertain to enforce. *See, e.g.*, 4/6/17 Trial Tr. at 138-39, 162. However, under controlling Eleventh Circuit law, an order is enforceable if "an ordinary person reading the court's order should be able to ascertain from the document itself exactly what conduct is prescribed." *Eastern Air Lines, Inc. v. Air Line Pilots Ass'n*, 920 F.2d 722, 730 (11th Cir. 1990). This Court applied essentially the same standard in rejecting the defendants' constitutional vagueness challenge to the CRSE standard, finding that the standard was sufficient to "give people of ordinary intelligence a reasonable opportunity to understand what evidence is required to substantiate their health-related claims." *Nat'l Urological Grp.*, 645 F. Supp. 2d at 1186; *see also* COL, ¶¶ 11-14. The Court further found that the need to resolve issues of fact in the application of the standard did not make it too indefinite. *Nat'l Urological Grp.*, 645 F. Supp. 2d at 1186-87.[5] That reasoning applies with

[5] Contempt Defendants mischaracterize Dr. Aronne's testimony to argue that his opinion about the appropriate size for a trial is "arbitrary," and, thus, the CRSE requirement is unenforceable. *See, e.g.*, 4/6/17 Trial Tr. at 141-42. Although Dr. Aronne estimated that 30 subjects per arm were necessary, he explained that

equal force here.

Moreover, in determining whether an order is clear and unambiguous, courts look to whether the parties "understand their obligations under the order." *Planetary Motion v. Techsplosion, Inc.*, 261 F.3d 1188, 1203-04 (11th Cir. 2001); *United States v. Sarcona*, 457 F. App'x 806, 811 (11th Cir. 2012). Here, the clear and convincing evidence establishes that Contempt Defendants understood their obligation to substantiate their advertising claims with Product-specific RCTs. *See* FOF, ¶¶ 87-121.[6] Moreover, Wheat also told Smith that they risked contempt by making claims such as "rapid fat burner" and "increasing the metabolic rate." FOF, ¶¶ 94-97.

2. The Court May Find Contempt Defendants Are Required To Substantiate Their Claims With Product-Specific RCTs.

Contempt Defendants blatantly misstate a trio of rulings to argue that the

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researchers determine the appropriate size of a study through a "power calculation." *See* FOF, ¶¶ 344-47, 353-55. Similarly, Dr. van Breemen opined that the number of subjects required is determined based on the results of a power calculation. FOF, ¶¶ 356-58. Nor has Dr. Aronne's testimony changed over time. Indeed, Dr. Aronne's expert reports in this case consistently have stated that studies of product efficacy may include 20-40 subjects. FOF, ¶ 355.

[6] These included communications between Wheat and his counsel, including Art Leach and Vic Kelley, introduced at the January 2014 contempt hearing. *See* FOF, ¶¶ 91-93, 98-114, 118-21. At trial, the Court once again ruled that the communications were not privileged, *see* Dkt. No. 935, and their relevance to Contempt Defendants' understanding of the Order's requirements is manifest. *See Planetary Motion*, 261 F.3d at 1203-04.

Court cannot require Product-specific RCTs. *See, e.g.*, 4/6/17 Trial Tr. at 142, 161-62. In reality, each case was determined on its unique facts and expert testimony, and reaffirms the Court's discretion to make factual determinations.

In *Basic Research*, the court rejected expert testimony by the United States because the expert failed to articulate a standard employed by experts in the field. *See Basic Research, LLC v. Fed. Trade Comm'n*, 2014 WL 12596497, at *10-11 (D. Utah Nov. 25, 2014). In contrast, Dr. Aronne's testimony establishes that weight loss experts require Product-specific RCTs to substantiate Contempt Defendants' claims. *See* Section II.A, *supra*.

In *Bayer,* the Court weighed the credibility and reliability of expert testimony and ruled that the United States did not prove that Bayer lacked CRSE to substantiate claims relating to the effect of probiotics on the digestive system. *See United States v. Bayer*, 2015 WL 5822595, at *16-18 (D.N.J. Sept. 24, 2015). Like *Basic Research*, and unlike this case, the *Bayer* court found that the plaintiff's expert testimony was not the view of experts in the field. *See id.* at *18.[7]

[7] The *Bayer* court also improperly purported to apply the FDA's regulatory scheme under Dietary Supplement Health and Education Act ("DSHEA"). *See id.* at 16 (critiquing expert for failing to consider FDA scheme). As this Court correctly recognized, DSHEA is irrelevant to the Hi-Tech Order's substantiation requirements. *See* 4/4/17 Trial Tr. at 62:8-63:12 (sustaining relevance objection to testimony concerning requirements under DSHEA); *see also* Dkt. No. 433 at 2.

Finally, *Garden of Life* affirms the Court's broad discretion to make factual determinations based on its assessment of the expert testimony. There, the Eleventh Circuit held that the district court's resolution of conflicting expert testimony was "a quintessentially factual determination" not to be disturbed absent clear error. *See Fed. Trade Comm'n v. Garden of Life*, 516 F. App'x 852, 856-57 (11th Cir. 2013).[8]

3. Dr. Aronne Applied The Correct Substantiation Standard.

Contempt Defendants argue that the CRSE standard applied by Dr. Aronne is incorrect for two reasons. First, they claim that Product-specific RCTs are inconsistent with the FTC's Dietary Supplements: An Advertising Guide for Industry (the "Guide"). *See* 4/6/17 Trial Tr. at 160-61. Second, they argue that Product-specific RCTs are only required for substances marketed to obese and overweight populations, but they ***only*** targeted young, healthy populations. *See, e.g.*, 3/30/17 Trial Tr. at 146-147. Neither argument has a basis in fact.

First, the Guide is necessarily general and does not address any specific type of dietary supplement or any particular claim. However, Example 19 – the

[8] Indeed, in the most recently litigated case involving weight-loss claims for a dietary supplement, the court found that such claims required "well-designed, well-executed, well-analyzed" studies that included, among other things, "placebo control, double blinding . . . , and the same ingredients and dose as the product making the efficacy claim." *See Fed. Trade Comm'n v. NPB Advertising,*

only Guide example that refers to weight loss – specifically references double-blind, placebo-controlled clinical trials. *See* FOF, ¶ 857.[9] Indeed, a court recently rejected Contempt Defendants' argument that the Guide sets an across-the-board CRSE standard short of clinical trials. *See* COL, ¶ 33.[10]

Contempt Defendants' second argument fails for two reasons. First, no evidence supports their bald contention that a different standard applies to weight loss claims made to an overweight or obese population than a young, healthy population. *See* FOF, ¶¶ 759, 761. Indeed, Hoffman, the only defense expert to testify on the issue, could not articulate a basis for his opinion. *See* FOF, ¶¶ 760, 762-64.

Inc., 218 F. Supp. 3d 1352, 1359 (M.D. Fla. 2016).

[9] Citing Example 24 in the Guide, Contempt Defendants have also claimed that product-specific testing can only be required where there is a question about product safety. 3/27/17 Trial Tr. at 20. This again misstates the Guide, which clearly explains that the level of substantiation necessary for a particular claim will depend on the testimony of experts in the relevant area, *see* Defendants' Ex. 3 at 10. In any event, there is ample evidence in the record that the Hi-Tech products at issue are not safe. *See* FOF, ¶¶ 675-712.

[10] Contempt Defendants also complain that Dr. Aronne did not consider the mechanisms of action of the individual ingredients or their purported therapeutic ranges. *See* 4/6/17 Trial Tr. at 143-44. However, Dr. Aronne looked at even stronger evidence, the studies of the ingredients themselves. *See* FOF, ¶¶ 584-627. Through that systematic analysis, he concluded that none of the ingredients showed efficacy for weight-loss, fat loss, chronic metabolic enhancement, or appetite suppression. *See id.*

Second, Hi-Tech's advertising specifically targeted overweight and obese populations in three ways, by: (1) targeting consumers of the prescription, anti-obesity medications called Fastin and Benzedrine, *see* FOF, ¶¶ 766-72, 773-74; (2) advertising to the general population, two-thirds of whom are overweight or obese, *see* FOF, ¶¶ 128-33, 171-75, 209-13, 229-33; and (3) employing advertising claims that specifically target overweight and obese populations, such as "Fastin is a pharmaceutical-grade dietary supplement indicated for weight loss in ***extremely overweight individuals***," *see* FOF, ¶ 765 (emphasis added); *see also* FOF, ¶¶ 135-36, 183-84, 191, 216, 235, 239, 242, 771, 774-76.[11]

4. Contempt Defendants' Ingredient Studies Are Not CRSE.

Contempt Defendants argue that various ingredient studies, including animal and *in vitro* studies, are CRSE that substantiate their claims. *See*, *e.g.*, 4/6/17 Trial Tr. at 152-53. This argument fails for two reasons.

a. Industry Standards Are Irrelevant.

Contempt Defendants argue that the "dietary supplement industry" does not require Product-specific RCTs, and, therefore, the Order does not require

[11] Notably, Contempt Defendants are obligated to substantiate all reasonable interpretations of their advertisements. *See Fed. Trade Comm'n v. Washington Data Res.*, 856 F. Supp. 2d 1247, 1272 (M.D. Fla. 2012) ("When a seller's representation conveys more than one meaning to consumers, one of which is false, the seller is liable for the misleading representation."), *aff'd*, 704 F.3d 1323 (11th Cir. 2013).

them. *See* 4/4/17 Trial Tr. at 57:8-58:5 ("So if you look at manufacturers like Hi-Tech, what is the industry standard? That is, what are other companies doing in terms of RCTs of their products and are they relatively rare?"). However, industry standards do not establish "competent and reliable ***scientific*** evidence;" scientists do. Consistent with scientific requirements, several of Contempt Defendants' experts confirmed the need for product-specific testing. *See* FOF, ¶¶ 396, 402-04, 407; *see also* Section II.A, *supra*.[12]

b. Contempt Defendants' Experts Offer Neither Credible Nor Reliable Opinions.

Contempt Defendants' expert opinions about ingredient studies are incredible and unreliable for at least three reasons. First, five of their six substantiation "experts" do not opine on the claims at issue. Specifically, they do not opine that the products ***cause*** rapid or substantial weight or fat loss or affect body fat. *See* FOF, ¶¶ 635-64. In fact, Jacobs testified that use of the word

[12] Contrary to Contempt Defendants' contention, neither "feasibility" nor "reasonableness" are part of the CRSE standard contained in the Orders. Rather, they are part of the *Pfizer* factors, which are used by courts in cases to determine the appropriate level of substantiation needed to support a claim in cases where – unlike here – the Court has not previously determined that CRSE is necessary. *See* COL, ¶ 52. However, even if such requirements did apply, Contempt Defendants' own experts establish that Product-specific RCTs are both reasonable and feasible. *See* FOF, ¶¶ 717-720. Of course, Contempt Defendants could have complied with the Orders by not making causal efficacy claims without Product-specific RCTs. COL, ¶ 49.

"cause" was not appropriate for any dietary supplement. FOF, ¶¶ 660-61. Instead, they opine that the products "aid" in fat and weight loss as part of a program of diet or exercise. FOF, ¶¶ 636-37, 649-51, 657, 662. But these were not Contempt Defendants' claims. *See* FOF, ¶¶ 134-63, 169, 176-208, 214-28, 234-54 (challenged advertising claims).

Heuer is the only expert who opines that the causal claims are substantiated. *See* 4/4/17 Trial Tr. at 99-106, 107-113. But he admitted that he did not apply any particular criteria in forming his opinions – explaining that "whether there is specific evidence or not, it doesn't matter." FOF, ¶ 841. He further admitted that he does not know of anyone who applies the criteria and methods he used to reach his conclusions in this case. *See* FOF, ¶¶ 842, 850.

Heuer also predicates his opinion on his view that the claims are largely "puffery." *See* FOF, ¶ 851. However, claim interpretation is the exclusive province of the Court, and puffery, where combined with concrete statements about a product's benefits, cannot shield a party from liability for deceptive advertising. *See* COL, ¶¶ 53-54. Thus, Heuer's opinions are little more than impermissible legal opinion. *See Wilson v. Pepsi Bottling Grp., Inc.*, 609 F. Supp. 2d 1350, 1360 (N.D. Ga. 2009); *see also* COL, ¶ 65.

Second, Contempt Defendants' experts offer contradictory opinions in several areas. *See* FOF, ¶¶ 805, 809, 815, 853. For example, their experts disagreed about which ingredients in the Hi-Tech products were "key ingredients" and whether studies of such ingredients alone are sufficient to substantiate Contempt Defendants' claims. *See, e.g.*, FOF, ¶¶ 802, 809, 815, 849. Similarly, Heuer and La Puma disagree about whether obesity is a relevant field and whether Wheat is a "professional in the relevant field." FOF, ¶¶ 853-54.

Third, Contempt Defendants' experts repeatedly changed their testimony at trial and omitted unfavorable information from their expert reports. *See* FOF, ¶¶ 490, 500-01, 508, 512, 519, 645-47, 794, 796, 801-04, 807-08, 816-17, 820-23, 843-44, 848. For example, Jacobs considered numerous studies that showed results unfavorable to Contempt Defendants, yet mentioned none of them in his expert report. FOF, ¶¶ 820-27. Moreover, he misrepresented facts concerning his own studies, including the adverse events experienced by their participants and that the results when he tested Fastin-XR on himself were significantly different than when he tested other study subjects. FOF, ¶¶ 482-83, 487-92, 500-01, 505-20. Heuer misquoted one of the primary sources he relied on for the proposition that studies of key ingredients were sufficient to substantiate product-specific claims,

omitting that the source actually instructs advertisers ***not*** to base product claims on ingredient studies. *See* FOF, ¶¶ 858-60.[13]

5. The Meltdown, Fastin-XR, And Fastin-RR Studies Do Not Substantiate Contempt Defendants' Claims.

Finally, Contempt Defendants claim that acute studies of three other products, Meltdown, Fastin-XR, and Fastin-RR, substantiate their advertising claims. *See, e.g.*, 4/6/17 Trial Tr. at 155-56, 160. However, none of the studies constitute CRSE.

a. The Meltdown Studies

Contempt Defendants rely on five studies of Meltdown, a competing dietary supplement.[14] Each is acute (with durations ranging from 90 minutes to 6 hours), and small (having between 10 and 20 participants). *See* FOF, ¶¶ 576-81. Moreover, these studies do not constitute CRSE for three additional reasons.

First, Meltdown has a different formulation from the Hi-Tech products. Specifically, there are a number of ingredients in Meltdown not present in any of

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[13] Moreover, at least three of Contempt Defendants' experts (Gaginella, Lee, and Hoffman) have no expertise in the area of weight loss. *See* FOF, ¶¶ 777-80, 789-92, 811. In addition, Contempt Defendants identify both Gaginella and Jacobs as Hi-Tech officers, and their close ties to the company belie their credibility. *See* FOF, ¶¶ 782-87, 834-37.

[14] Heuer alone relies on a sixth Meltdown study. *See* 4/4/17 Trial Tr. at 92:11-93:16. This five-person, three-hour metabolism study was unblinded, lacked a placebo-control, and did not measure results to statistical significance. FOF, ¶ 583.

the Hi-Tech products, including tetradecylthioacetic acid ("TTA") and yerba mate. FOF, ¶¶ 542-67. The inclusion of these ingredients is not trivial. *See* FOF, ¶¶ 543-48. Indeed, in his Meltdown study, Contempt Defendants' expert Hoffman concluded that Meltdown's apparent transient efficacy was due to the combination of "yohimbine, yerba mate, and [TTA]." FOF, ¶ 549.[15]

Second, they do not measure weight loss, fat loss, or appetite. FOF, ¶¶ 568-73. Hoffman admitted that even the longest of the studies – the six-hour Bloomer study — could not substantiate weight or fat loss claims for Meltdown, let alone the Hi-Tech products. FOF, ¶ 569. The authors of the Meltdown studies similarly explained that the results of their studies could not be used to draw conclusions about Meltdown's effects on weight or fat. *See* FOF, ¶ 572.[16]

Third, the acute Meltdown metabolism studies cannot be extrapolated beyond their time frames, even for metabolism claims. *See, e.g.*, FOF, ¶ 577.

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[15] Contempt Defendants claim there are only trace amounts of these additional ingredients. *See* 4/6/17 Trial Tr. at 147. The only support for their contention is a document Wheat produced on the eve of trial. *See* FOF, ¶¶ 556-57. However, Wheat's ingredient list is suspect at best, as it has a discrepancy of 42 mg of yerba mate and TTA with the FDA-mandated supplement facts label. *See* FOF, ¶¶ 545, 564-67. Moreover, none of Contempt Defendants' experts reviewed that document or opined on those additional ingredients. *See* FOF, ¶¶ 558-63.

[16] Notably, the Meltdown studies were conducted in the fasting state. FOF, ¶ 574. As discussed above, fasting-state studies cannot support "fat loss" or "fat burning" claims. *See* Section II.A.2, *supra*; *see also* FOF, ¶¶ 435-43.

Once again, Hoffman, one of the Meltdown studies' authors, provides dispositive testimony, admitting that it would be "incorrect" to extrapolate the results of the six-hour Meltdown studies to six days, six weeks, or six months. FOF, ¶ 381.

b. The Fastin-XR Metabolism Study

Numerous deficiencies destroy Contempt Defendants' claim that the Fastin-XR acute metabolism study conducted by Jacobs substantiates their claims. First, Fastin-XR has a different formula than all of the products at issue. Not only does Fastin-XR contain additional ingredients, but the common ingredients are not present in the same amounts as in the four products at issue. FOF, ¶¶ 475-76. Again, these differences are not trivial.[17]

Second, the Fastin-XR metabolism study lasted only three hours and did not measure weight loss, fat loss, or appetite. FOF, ¶ 479. Third, even Jacobs admitted that the study is too acute to determine the chronic effect of Fastin-XR on metabolism. *See* FOF, ¶ 481. Fourth, the study is riddled with methodological flaws that belie its reliability. It is underpowered, only reporting the results for ten participants even though the power calculation called for

[17] Indeed, Hi-Tech touted the differences in its Fastin-XR advertising, calling Fastin-XR "even more potent than Fastin" and explaining that the increased potency resulted from Fastin-XR's different formulation. *See* FOF, ¶ 477.

twelve. FOF, ¶ 482.[18] Similarly, Jacobs concealed that he self-enrolled in the study and that his results were less favorable than the other study participants. FOF, ¶¶ 487-92.[19]

c. The Fastin-RR Studies

Contempt Defendants also rely on two studies of Fastin-RR conducted by Jacobs. The first is an eleven-subject, six-hour, acute metabolism study. The second is a short-term, eight-week, weight loss study that enrolled 72 participants but concluded with 59 subjects. Neither constitutes CRSE.

As an initial matter, the formulation of Fastin-RR differs from that of the four Hi-Tech products at issue. Once again, Fastin-RR contains additional ingredients and common ingredients in additional amounts. FOF, ¶¶ 495-97. Importantly, Jacobs admitted that he did not design the studies to isolate the effect of the differences in formulation. FOF, ¶ 498.

Moreover, the Fastin-RR metabolism study did not measure weight loss, fat loss, or appetite and, therefore, cannot substantiate such claims. FOF, ¶ 499.

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[18] In reports of the study's results, Jacobs claimed that the power calculation only called for ten participants despite admitting that he did not redo the power calculation to determine whether ten subjects were sufficient. FOF, ¶ 483.

[19] Jacobs disputed that he enrolled himself in the study, but he completed a consent to participate, conducted the testing on himself at the same time as other subjects were undergoing testing, and assigned himself a subject number (Subject 12). FOF, ¶¶ 484-89.

Similarly, Jacobs concedes the effects of Fastin-RR on metabolism cannot be extrapolated beyond the test's six-hour duration. *See* FOF, ¶ 504; *id.* ¶ 376.

In addition, the Fastin-RR metabolism study is so riddled with methodological flaws that it is not reliable. First, Jacobs' power calculation called for at least 12 participants, but only 11 completed the study. FOF, ¶¶ 499, 505. Once again, Jacobs did not redo the power calculation but merely restated it to make it appear as though the calculation required only ten participants. *Id.* Second, Jacobs attempted to institute a "hunger scale" designed to measure the effect of Fastin-RR on appetite. FOF, ¶ 500. However, Jacobs discarded the scale mid-experiment because "nothing too dramatic came out of it." *Id.* Jacobs never included the hunger scale in any written description of the Fastin-RR metabolism study's results, including in his expert report. FOF, ¶ 501. Third, Jacobs admitted in his deposition that he broke the blind and readministered dosages of the test substances when the results of the study did not meet his expectations. FOF, ¶¶ 507-09. Fourth, Jacobs did not accurately report the side effects experienced by the study participants. FOF, ¶¶ 511-20. Specifically, even though one of the study subjects experienced chest pressure, nausea, and coughed up fluids during the test, Jacobs repeatedly misreported those

symptoms, including to the Independent Review Board overseeing the study and the Court in his expert report. *Id*. ¶¶ 511-12.

Jacobs' eight-week Fastin-RR weight loss study fares no better. As discussed above, Fastin-RR has a significantly different formulation than the products at issue. Moreover, the eight-week study is too short to substantiate Contempt Defendants' unqualified, causal weight and fat loss claims, *see* FOF, ¶¶ 525-26, and there is no evidence that the study was properly conducted, *see* FOF, ¶¶ 531-39.[20] For example, Jacobs' study protocol does not report that a power calculation was even performed, let alone what the results were. FOF, ¶¶ 535-36. Similarly, in a departure from good clinical practice, Jacobs did not report the manner in which he randomized the study. FOF, ¶ 537. Finally, as Dr. Aronne opined, due to Jacobs' flagrant breaches of protocol and repeated instances of misreporting the facts of his studies, Jacobs is not "a person in the field qualified" to conduct these types of studies. FOF, ¶¶ 521-22, 533.

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[20] Contempt Defendants claim that eight weeks is sufficient because they caution consumers not to use the product beyond eight weeks. *See* 4/6/17 Trial Tr. at 151. However, none of Contempt Defendants' ads contain an eight-week qualification. *See* FOF, ¶¶ 528-30. Instead, the language only appears on the safety warning on some of the products' labels and packaging, often on the part of the label that requires consumers to peel it away to read. FOF, ¶ 530. Small print, non-proximate disclaimers are insufficient to overcome the net impression of an advertisement. *See Fed. Trade Comm'n v. Cyberspace.com, LLC*, 453 F.3d 1196, 1200-01 (9th Cir. 2006) (collecting cases); COL, ¶ 24.

III. Contempt Defendants' Liability For Violating Section VI Of The Hi-Tech Order Is Uncontested.

Section VI of the Order required Contempt Defendants to clearly and prominently include the health-risk warning on each package and label that contains efficacy claims for yohimbine-containing products. *See* FOF, ¶ 76. There is no dispute that Contempt Defendants failed to place the required yohimbine health-risk warning on any of their product packaging or labels from 2009 through 2012, in violation of Section VI of the Order. *See* FOF, ¶¶ 861-76.[21]

IV. The Evidence Demonstrates That Gross Revenues Less Refunds And Returns Is The Only Appropriate Compensatory Sanction.

Gross revenues less refunds and returns is the appropriate compensatory baseline. The purpose of compensatory contempt sanctions is to provide those harmed by the defendants' conduct with "full remedial relief." *See McComb v. Jacksonville Paper Co.*, 336 U.S. 187, 193 (1949). The Eleventh Circuit has repeatedly and consistently held that where, as here, defendants have made material, widespread misrepresentations or omissions, the FTC is entitled to a presumption that each and every consumer relied on those misrepresentations or omissions. COL, ¶¶ 74, 84-85. Once this baseline is established, Contempt Defendants bear the burden of proving offsets because ***individual*** consumers

were not injured by the contumacious conduct. COL, ¶¶ 90-94.

A. Contempt Defendants Caused $40.1 Million In Harm Through Their Unsubstantiated Efficacy Claims.

For the violations of the Hi-Tech Order related to their unsubstantiated claims, Contempt Defendants' own sales data establishes that between January 1, 2009, and August 31, 2013, they took in $40.1 million from the sale of Fastin, Lipodrene, Benzedrine, and Stimerex-ES. *See* FOF, ¶ 920. With respect to Wright, Contempt Defendants' compliance reports establish that, for the period Contempt Defendants used his unsubstantiated Fastin endorsement, Fastin sales equaled approximately $21.4 million. FOF, ¶¶ 930-32.[22]

Contempt Defendants make no effort to meet their burden to show individual transactions should be offset. Instead, they argue that the Court should ignore the law and award profits. But, as this Court has recognized, an award of profits requires consumers to bear the costs of Contempt Defendants' deception. COL, ¶ 95; *see also id.* ¶¶ 74, 85. Moreover, even if such an award were ever appropriate, the profits analysis Contempt Defendants advance rests

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[21] Contempt Defendants conceded that they did not challenge this Court's previous finding of contempt liability for Section VI. *See* FOF, ¶¶ 875-76.

[22] The compensatory sanction should be entered in the form of an "order to pay." Such an order would require Contempt Defendants to disgorge all assets and allow the Court to coerce Contempt Defendants' compliance if they attempt to evade the sanction.

on a series of spoon-fed assumptions that are contrary to fact, rendering that analysis unreliable and unhelpful to the Court. *See* FOF, ¶¶ 933, 937-80; COL, ¶¶ 62-63.[23] Accordingly, Hi-Tech, Wheat, and Smith[24] are jointly and severally liable in the amount of $40,120,950.00, and Wright is jointly and severally liable with them for $21,493,557.64, the amount necessary to compensate consumers for the period during which his endorsement was used to sell Fastin. *See* COL, ¶ 86.

B. Contempt Defendants Caused $34.4 Million In Harm Through Their Failure To Provide The Required Health-Risk Warning.

Contempt Defendants omitted the required health-risk warning from all of their product packaging and labels from January 1, 2009 through at least

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[23] Contempt Defendants also previously argued for a reduction of the compensatory sanction on a laches theory. This argument fails for two reasons. First, laches is not a legally cognizable defense in an action by the government to enforce a public right. COL, ¶ 51. Second, the argument is ludicrous in the face of overwhelming evidence that Contempt Defendants repeatedly lied to the FTC about the content and scope of their advertising. FOF, ¶¶ 1041-78.

[24] At trial, Wheat and Smith bizarrely argued that they were not individually liable for their own order violations. *See, e.g.*, 3/27/17 Trial Tr. at 31**.** However, Wheat and Smith are both individually under order. *See* FOF, ¶¶ 67-71. Accordingly, any of their activities relating to the manufacturing, labeling, advertising, sale and distribution of any weight loss product must comply with the Order. *See* FOF, ¶¶ 75-77. Moreover, the evidence clearly and convincingly establishes not only that Wheat and Smith engaged in those activities in connection with the marketing and sale of the Hi-Tech products at issue, but also directed others in carrying out those activities. *See* FOF, ¶¶ 8-54.

December 31, 2012. *See* FOF, ¶¶ 861-68.[25] The omission is material because, as this Court has recognized, "when a customer makes a decision to purchase a health product that he or she will ingest for purported health benefits . . . any claims regarding the safety of the product will be presumed material." COL, ¶ 79.[26] Widespread, material omissions, like widespread, material misrepresentations, trigger the presumption of reliance, and set gross revenues as the compensatory baseline. COL, ¶¶ 74-76. Based on Hi-Tech's sales data, gross revenues – less consumer remittances – for January 1, 2009 through December 31, 2012 equal $34,441,227.00. FOF, ¶¶ 981-86.[27]

The burden therefore shifts to Contempt Defendants to demonstrate offsets because "***individual*** transactions were atypical and resulted in a lower-

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[25] This period is conservative because the evidence establishes that violative packages of Fastin, Hi-Tech's top selling weight-loss product, were available in CVS – a large retailer – until at least August 2013. *See* FOF, ¶ 874.

[26] Contempt Defendants cherry-pick certain statements from materials contained in FTC rebuttal expert Dr. Susan Blalock's literature search in an effort to show that consumers do not seek warning information from product labels. *See* 4/6/17 Trial Tr. at 128-29. However, those statements showed, at most, that consumers sometimes do not read warnings that are difficult to read and placed on the back or inside of labels. This has no relevance to consumers' understanding of clear and prominent warnings like those required by Section VI.

[27] This $34.4 million is a subset of the $40.1 million in consumer harm caused by Contempt Defendants' failure to substantiate their advertising claims. However, the FTC respectfully requests that the Court enter a separate finding as to the harm caused by Contempt Defendants' failure to include the required warning.

than expected gain to the wrongdoer." *See Fed. Trade Comm'n v. Bronson Partners, LLC*, 654 F.3d 359, 369 (2d Cir. 2011) (emphasis original); *see also* COL, ¶¶ 91-94 (collecting cases). Contempt Defendants failed to do so for two reasons.

1. Gilbert's Survey Is Irrelevant And Unreliable.

Contempt Defendants rely on the Gilbert survey, which is entitled to no weight for four reasons. First, the survey does not attempt to ascertain the understanding of actual Hi-Tech product purchasers. *See* FOF, ¶ 988. Thus, as a matter of law, it cannot rebut the presumption of reliance. *See* COL, ¶¶ 91-94.

Second, by her own admission, Gilbert is not an expert in survey design and analysis. *See* FOF, ¶ 1019. That fact alone demonstrates that her survey is entitled to little to no weight. *See, e.g., Trilink Saw Chain, LLC v. Blount, Inc.*, 583 F. Supp. 2d 1293, 1304 (N.D. Ga. 2008) (Pannell, J.); *see also* COL, ¶ 64.

Third, Gilbert's admission that the survey was not designed to determine "why people believed what they did, so we weren't looking for any sort of causality," FOF, ¶ 1040, renders the survey irrelevant. Because the lack of the safety warning is presumed to have "tainted the customer's purchasing decisions," *see McGregor v. Chierico*, 206 F.3d 1378, 1388 (11th Cir. 2000), a survey

that does not demonstrate the effect of the Contempt Defendants' non-compliant warnings on those decisions has no bearing on the issues before the Court.[28]

Fourth, the survey's design is fundamentally flawed and entitled to no weight. *See Smith v. Wal-Mart Stores, Inc.*, 537 F. Supp. 2d 1302, 1322, 1327 (N.D. Ga. 2009); *see also* COL, ¶ 67. As Dr. Kenneth L. Bernhardt explained, the survey had numerous, major methodological flaws that rendered it unreliable. FOF, ¶¶ 1027-40. Chief among them, Gilbert did not even show the survey respondents the actual, non-compliant warnings. *See* FOF, ¶¶ 1029-31. Instead, she used excerpted language, presented in isolation from the rest of the label's block print language, and in an easier-to-read format. FOF, ¶ 1032. Gilbert admitted that she made these changes to render the language "more readable" and to "focus consumers' attention on those things we felt were most important." *Id.* Moreover, Dr. Bernhardt explained that by focusing respondent's attention on certain statements and then asking true/false questions, Gilbert turned the survey into a flawed "open-book reading comprehension test" rather than an appropriate test of how the consumers

[28] Notably, Gilbert's assertion at trial that the survey was not designed to determine causality directly conflicts with her report, in which she claims that the survey was designed to demonstrate a causal connection. *See* FOF, ¶ 1040. Gilbert's stark reversal reflects her lack of credibility.

would understand warnings from having actually experienced them. *See* FOF, ¶ 1033.

2. Goldhaber's Unsupported Testimony Is Neither Reliable Nor Credible.

Contempt Defendants also rely on faulty opinions from Gerald Goldhaber, a purported warnings expert. First, like Gilbert, Goldhaber does not testify about the purchasing decisions of any actual Hi-Tech product purchaser. FOF, ¶ 1007. Thus, as a matter of law, none of his opinions can rebut the presumption of reliance. *See* COL, ¶¶ 91-94. Second, this Court has already found that his opinions regarding the "state of the art" are irrelevant. *See* Dkt. No. 470 at 8.

Third, without support, Goldhaber claims that consumers would understand the non-compliant warning to have the same meaning as the Court-ordered warning. This claim rests on Goldhaber's conclusory assertion that consumers obtain information from what he terms the "information environment," including the product's print ads and websites. *See* 3/31/17 Trial Tr. at 14. However, Goldhaber's *ipse dixit* is contradicted both by the facts of the case and by his own testimony.

Goldhaber's opinion assumes that consumers could find the correct information through Hi-Tech's print advertisements and webpages. *See* FOF,

¶ 1008. However, from January 1, 2009 through at least September 2010, Contempt Defendants had no webpage, and the only print ads they ran (in their Hi-Tech Health & Fitness catalog) did not contain any yohimbine warning at all (let alone the Court-ordered warning). FOF, ¶ 1009. Moreover, even after September 2010, the Court-ordered warning did not appear on all print ads and webpages for the products in question. *See* FOF, ¶ 1010. Contempt Defendants disclosed none of these facts to Goldhaber, but his failure to consider them renders his opinions unreliable. COL, ¶¶ 62-63.[29]

V. Conclusion

Clear and convincing evidence proves that Contempt Defendants are liable for violating the Hi-Tech and Wright Orders. Accordingly, the FTC respectfully requests that the Court enter a finding of contempt and an order to pay compensatory sanctions of $40,120,950 jointly and severally against Hi-Tech, Wheat, and Smith, with Wright jointly and severally liable for $21,493,557. The FTC also requests that the Court separately find that Hi-Tech, Wheat, and Smith caused $34,441,227 in consumer harm through their violation of Section VI of the Hi-Tech Order. *See* COL, ¶¶ 101-03.

[29] Moreover, Goldhaber conceded that warnings targeted to a particular subgroup (e.g., those with high blood pressure) may suggest to people who are not in that group that "they are not at risk." FOF, ¶¶ 1001-04.

CERTIFICATION PURSUANT TO LOCAL RULE 7.1(D)

Pursuant to Local Rule 7.1(D), I hereby certify that this motion was prepared in Microsoft Word 2010 using 13-point Book Antiqua font.

/s/ Amanda C. Basta
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Dated: June 19, 2017

Respectfully submitted,

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