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 PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

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Plaintiff, Federal Trade Commission ("FTC" or "Commission"), submits these amended proposed findings of fact and conclusions of law to conform its pretrial proposed findings of fact and conclusions of law, Dkt. No. 906, which were submitted in accordance with Paragraph 25 of the December 6, 2016 Pretrial Order, with the evidence as it was presented at the evidentiary hearing, which took place between March 27, 2017 and April 6, 2017.

Proposed Findings of Fact

I. Parties

A. Contempt Defendant Hi-Tech Pharmaceuticals, Inc.

1. Contempt Defendant Hi-Tech Pharmaceuticals, Inc. ("Hi-Tech") is a Georgia corporation with its principal place of business at 6015 Unity Drive B, Norcross Georgia. Plaintiff's Ex. 11 at 4; Plaintiff's Ex. 66 at 3.[1]

2. Hi-Tech describes its products as a "revolutionary line of nutraceutical products . . . at the forefront of the dietary supplement industry." Plaintiff's Ex. 66 at 3.

[1] Cited exhibits identified as Plaintiff's Exs. 1-298 and Defendants' Exs. 1-99 were previously admitted by the Court during the January 21, 2014 through January 24, 2014 evidentiary hearing. *See generally* Dkt. Nos. 700 and 701.

3. Hi-Tech manufactures, labels, advertises, promotes, offers for sale, sells, or distributes 55 to 60 of its own branded dietary supplements, including Fastin, Lipodrene, Benzedrine, and Stimerex-ES. *See* 1/21/14 Trial Tr. at 162:14-24.

4. Fastin, Lipodrene, Benzedrine, and Stimerex-ES are weight-loss products. *See* Plaintiff's Ex. 145.

5. Hi-Tech sells its dietary supplements, including Fastin, Lipodrene, Benzedrine, and Stimerex-ES, to consumers through distributors, Internet retailers, and retailers nationally at over 100,000 locations. Wheat Dep. at 47:21-48-2.[2]

6. Hi-Tech also sells its dietary supplements, including Fastin, Lipodrene, Benzedrine, and Stimerex-ES, directly to consumers through its website and 1-800 number. Wheat Dep. at 45:6-13.

7. The majority of Hi-Tech's business comes from its sales of its dietary supplements made through retail outlets. 1/21/14 Trial Tr. at 157:23-158:3

[2] "Wheat Dep." refers to the August 22, 2012 deposition of Jared Wheat designated at Dkt. No. 880-5. The original transcript of Wheat's August 22, 2012 deposition was lodged with the Court on October 22, 2012. *See* Dkt. Nos. 447-1, 447-2, and 447-3.

(describing direct mail business as "non-existent"); *see also id.* at 158:25-159:12.

B. Contempt Defendant Jared Wheat

1. Wheat Had Control Over Hi-Tech's Marketing Practices And Directly Participated In Those Practices.

8. From January 1, 2009 through November 10, 2014, Jared Wheat controlled Hi-Tech's marketing activities and directly participated in those activities. *See* FOF ¶¶ 9-25.

9. Wheat is Hi-Tech's sole owner, President, Chief Executive Officer, Secretary, and Treasurer. *See* Plaintiff's Ex. 18 at 8; Plaintiff's Ex. 12 at 3; Plaintiff's Ex. 91 at 3.

10. Wheat admits 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. Plaintiff's Ex. 18 at 7.

11. In connection with a criminal prosecution, Wheat was incarcerated from March 16, 2009 to September 2010. *See* 1/21/14 Trial Tr. at 183:18-23.

12. It was Wheat's intention to run Hi-Tech from prison. Wheat Dep. at 199:6-21.

13. While in prison, Wheat communicated by email regarding Hi-Tech's business, including about the contents of the company's print and web advertising, product packaging, and labels for Fastin, Lipodrene, Benzedrine, and Stimerex-ES. Plaintiff's Ex. 109 at 4; *see generally* Plaintiff's Exs. 68-77, 79-92, 94-104, 158, 209-215, 279-282.

14. In or around April 2010, Wheat resumed his role as CEO of Hi-Tech. Plaintiff's Ex. 18 at 8; Plaintiff's Ex. 23 (adopting Plaintiff's Ex. 18).

15. During his deposition on August 21, 2012, Wheat asserted his Fifth Amendment privilege against self-incrimination and refused to answer the question of whether he is compensated for his work at Hi-Tech. Wheat Dep. at 39:17-40:2.

16. Hi-Tech admits that with respect to the labeling and promoting of Fastin, Lipodrene, Benzedrine, and Stimerex-ES, Wheat "is ultimately responsible for the creation of its ad, web verbiage, label, and box. He oversees the manufacturing of the product, and designed the formulation. He also overseas [sic] the sales of the product through approximately 20 sales reps and customer service personnel." Plaintiff's Ex. 18 at 12, 17, 23, 28;

Plaintiff's Ex. 23 (adopting Plaintiff's Ex. 18); *see also* Wheat Dep. at 152:9-153:13.

17. Wheat admits that he formulated advertising claims for Fastin, Lipodrene, Benzedrine, and Stimerex-ES. Plaintiff's Ex. 18 at 35; Plaintiff's Ex. 23 (adopting Plaintiff's Ex. 18); *see also* Plaintiff's Ex. 74 at 3-4.

18. Wheat planned and placed advertisements for Fastin, Lipodrene, Benzedrine, and Stimerex-ES. Plaintiff's Ex. 18 at 35; Plaintiff's Ex. 23 (adopting Plaintiff's Ex. 18); *see also* Plaintiff's Ex. 70 at 3; Plaintiff's Ex. 73 at 3-4, 5-6; Plaintiff's Ex. 75 at 4; Plaintiff's Ex. 76 at 3; Plaintiff's Ex. 79 at 3.

19. Wheat had the authority to give final approval of any marketing budget or advertising campaign. *See* Plaintiff's Ex. 74 at 4.

20. Wheat drafted the webpages at www.hitechpharma.com for Fastin, Lipodrene, Benzedrine, and Stimerex-ES. Plaintiff's Ex. 18 at 35; Plaintiff's Ex. 23 (adopting Plaintiff's Ex. 18).

21. Wheat marketed and promoted Fastin, Lipodrene, Benzedrine, and Stimerex-ES to retailers and distributors. Plaintiff's Ex. 18 at 35; Plaintiff's Ex. 23 (adopting Plaintiff's Ex. 18).

22. Wheat controls the contract terms of retail accounts. Smith Dep. at 49:16-25.[3]

23. Wheat was responsible for obtaining and/or maintaining tests, reports, studies, clinical trials, experiments, demonstrations, scientific literature, written opinions, oral opinions, or other evidence purporting to substantiate claims about the health benefits, absolute or comparative benefits, performance, safety, or efficacy of Fastin, Lipodrene, Benzedrine, and Stimerex-ES. Plaintiff's Ex. 18 at 36; Plaintiff's Ex. 23 (adopting Plaintiff's Ex. 18).

24. In March 2010, Wheat decided to start advertising Hi-Tech products again in print and planned a national advertising campaign for Fastin, Lipodrene, Benzedrine, and Stimerex-ES. *See* Plaintiff's Ex. 68.

25. In the Spring and Summer of 2010, Wheat planned and reviewed proposed advertising materials for Hi-Tech's products, including Fastin, Lipodrene,

[3] Smith Dep. refers to the August 21, 2012 deposition of Stephen Smith designated at Dkt. No. 880-5. The original transcript of Smith's August 21, 2012 deposition was lodged with the Court on October 22, 2012. *See* Dkt. Nos. 447-4, 447-5.

Benzedrine, and Stimerex-ES, and edited them with other Hi-Tech employees. *See generally* Plaintiff's Exs. 68-84.

C. Contempt Defendant Stephen Smith

1. Smith Had Control Over Hi-Tech's Marketing Practices And Directly Participated In Those Practices.

26. From January 1, 2009 through November 10, 2014, Contempt Defendant Stephen Smith had control over Hi-Tech's marketing activities and directly participated in those activities. *See* FOF ¶¶ 27-54.

27. Stephen Smith admits that he is the Senior Vice-President in charge of sales of Hi-Tech products, including Fastin, Lipodrene, Benzedrine, and Stimerex-ES. 1/21/14 Trial Tr. at 63:21-64:3; Plaintiff's Ex. 14 at 3; Smith Dep. at 14:4-15, 43:8-18, 44:15-18; *see also* Plaintiff's Ex. 18 at 12, 16, 22-23, 27, 33; Plaintiff's Ex. 24 (adopting Plaintiff's Ex. 18).

28. Since 2009, Smith has identified himself as Hi-Tech's senior vice president when communicating with retailers. 1/21/14 Trial Tr. at 63:21-64:3.

29. In his role as senior vice president in charge of sales, Smith oversees the sales force that markets Hi-Tech products to retailers, and has the authority to decide which retailers will sell Hi-Tech products. 1/21/14 Trial Tr. at 64:4-17, 80:12-17; Plaintiff's Ex. 14 at 3; Plaintiff's Ex. 18 at 12,

16, 22-23, 27, 33; Plaintiff's Ex. 24 (adopting Plaintiff's Ex. 18); Smith Dep. at 26:17-28:12, 42:19-24; Wheat Dep. at 34:20-35:3.

30. Smith answers directly to Wheat, the President and CEO of Hi-Tech, and in connection with Hi-Tech sales, Smith is the highest in the chain of command except for Wheat. Wheat Dep. at 34:20-35:3.

31. Smith is the head of the Food, Drug, and Mass division at Hi-Tech, where he is responsible for landing retail accounts with food stores, drug chains, and mass merchandisers, including, but not limited to, CVS, Rite Aid, and GNC. 1/21/14 Trial Tr. at 64:15-22; Smith Dep. at 14:4-15; Wheat Dep. at 34:20-35:8.

32. Smith admits that he markets and promotes Hi-Tech products to retailers and distributors by dealing with brokers as intermediaries or by dealing with retailers and distributors directly. Smith Dep. at 42:19-43:4, 58:7-18, 58:25-59:7, 59:13-19, 92:13-22; *see also* Plaintiff's Ex. 18 at 35; Plaintiff's Ex. 24.

33. Brokers act as liaisons between Hi-Tech and Food, Drug, and Mass retailers and their buyers. 1/21/14 Trial Tr. at 80:19-22.

34. Brokers are not Hi-Tech employees. 1/21/14 Trial Tr. at 81:11-12.

35. Brokers are crucial to placing Hi-Tech's products into Food, Drug, and Mass retailers. 1/21/14 Trial Tr. at 81:21-23.

36. Smith admits that he made presentations to brokers in order to "give them the sales tools that they would need to go back to the [Food, Drug and Mass] buyer and" make a sales pitch, including bullet points about the products, pricing structures, projected sales, and images of the product labels. Smith Dep. at 59:13-19.

37. Smith admits that he markets and promotes Hi-Tech products to retail accounts by attending trade shows at which he pitches Hi-Tech products, including Fastin, Lipodrene, and Benzedrine, using JPEG or PDF images of the product labels and packaging. Smith Dep. at 61:11-62:9, 63:2-8, 122:4-9.

38. Smith admits that he lands retail accounts for Hi-Tech through his participation at trade shows, including the ECRM and GNC trade shows. Smith Dep. at 61:11-62:9, 63:2-8, 111:3-112:3.

39. Smith admits that he was responsible for deciding which retailers that sold Fastin, Lipodrene, Benzedrine, and Stimerex-ES would be identified at the bottom of print ads to let consumers know where they could buy the products. 1/21/14 Trial Tr. at 76:15-77:6.

40. Smith admits that he is head of customer service for Hi-Tech, and in that role oversees customer service representatives who provide customer service to retail accounts, including CVS, Rite Aid, GNC, and other large chains. Smith Dep. at 24:8-25:3, 25:25-26:16.

41. While Wheat was in prison, Smith worked to keep Hi-Tech in business by overseeing day-to-day operations, including managing the Food, Drug, and Mass market sales department, landing retail accounts for Hi-Tech products, and providing customer service to retail accounts. Smith Dep. at 47:5-15, 47:25-48:15, 49:16-25; Plaintiff's Ex. 75 at 3 (May 24, 2010, email from Wheat to Smith: "At this time you are the senior officer of HT [Hi-Tech] running day-to-day operations.").

42. Smith admits that while Wheat was incarcerated, it was Smith's job to "hold down the fort" at Hi-Tech. 1/21/14 Trial Tr. at 68:1-69:1.

43. Smith admits that, both before and after Wheat was released from prison, he helped secure Fastin, Lipodrene, Benzedrine, and Stimerex-ES advertising on Hi-Tech's behalf with various publications and advertising agencies, by supplying advertising to media markets, negotiating advertising pricing, developing monthly advertising plans, and signing

insertion orders for ads to appear in magazines, including Plaintiff's Exs. 43, 44, 52, 57, and 61; Smith Dep. at 34:16-35:13, 35:20-35:23, 36:7-9, 36:13-17, 69:24-72:9, 112:4-8, 112:13-19, 112:23-25; Plaintiff's Ex. 18 at 12, 16, 22-23, 27, 33; Plaintiff's Ex. 24.

44. For example, on July 16, 2010, Stephen Smith provided Wheat with the dates that Hi-Tech's Fastin advertisements were due to various magazines as follows:

a. Cosmopolitan: August 25, 2010

b. Redbook: July 23, 2010

c. First: July 20, 2010

d. In Touch: September 3, 2010

e. OK!: August 9, 2010

f. Life & Style: August 27, 2010

g. Woman's World: July 23, 2010

h. Star: August 27, 2010

i. National Enquirer: August 20, 2010

j. Whole Living: July 30, 2010

k. Allure: August 6, 2010.

Plaintiff's Ex. 90 at 3. These magazines all published Contempt Defendants' print advertisements. *See* Plaintiff's Ex. 18 at 10-11.

45. Smith admits that he placed Hi-Tech advertisements in Muscle & Fitness magazine. 1/21/14 Trial Tr. at 72:18-73:14.

46. The unsubstantiated print advertisements for Lipodrene and Stimerex-ES appeared in Muscle & Fitness magazine. Plaintiff's Exs. 18 at 17, 28; 20 at 4.

47. Smith communicated with retailers, directly or through brokers, concerning Fastin, Benzedrine, Lipodrene, and Stimerex-ES, and addressed concerns retailers and brokers had about Hi-Tech's products, including concerns about whether advertising claims were substantiated. *See* Smith Dep. at 105:5-18, 129:13-130:1, 139:1-22, 139:25-140:10, 146:5-12; Plaintiff's Exs. 79 at 3, 86 at 3, 87 at 3-5, 88 at 3, 224 at 2.

48. For example, while Wheat was in prison, Hi-Tech's broker for its GNC and CVS accounts, Dave McDermitt, informed Smith of his concern that the "rapid fat loss" claim on the Fastin packaging was "a problem," and Smith communicated that concern to Wheat. Smith Dep. at 129:13-130:1, 130:5-131:3.

49. Wheat did not make any changes to the Fastin packaging in response to McDermitt's concerns. 1/21/14 Trial Tr. at 87:9-90:8; *see also* Defendants' Ex. 27 at 2; Defendants' Ex. 59 at 1-2; Plaintiff's Exs. 46-51, 146, 274, 290.

50. In 2010, while Wheat was in prison, Smith was involved in trying to substantiate Fastin claims, by helping Wheat find studies to support the claims, sending Wheat ingredient studies when Wheat was in prison, and offering to help Wheat investigate the possibility of conducting a double-blind study of Fastin. Smith Dep. at 118:7-15, 131:4-132:4, 133:16-134:19, 139:1-139:22, 139:25-140:10, Plaintiff's Exs. 86 at 3, 87 at 3-6, 224 at 2.

51. Smith admits that he receives $15,000 per month for his work at Hi-Tech. 1/21/14 Trial Tr. at 65:17-19.

52. Smith admits that in 2012, he received $375,000 in compensation from Hi-Tech. 1/21/14 Trial Tr. at 65:23-24; Defendants' Ex. 60 at 8.

53. At Hi-Tech, Smith uses the email address ssipharma@aol.com. Smith Dep. at 43:15-23.

54. Smith admits that he used the email address hitechsnrvp@gmail.com to communicate with Wheat while Wheat was in prison at FCI Jesup. Smith Dep. at 43:24-44:9.

D. Contempt Defendant Terrill Mark Wright, M.D.

55. Contempt Defendant Terrill Mark Wright, M.D., directly participated in Hi-Tech's marketing activities.

56. Wright is a physician with a primary specialty of internal medicine, with subspecialty training in bariatric medicine. Plaintiff's Ex. 659 at 2.

57. Wright identifies himself as a "weight loss physician," who provided expert endorsements for Hi-Tech's Fastin product. *See* Plaintiff's Ex. 43.

58. In July 2009, Wright informed the FTC that he "[did] not individually engage in any conduct related to the subject matter of the Order and [had] not done so since December 16, 2008." Plaintiff's Ex. 16 at 4.

59. However, since January 1, 2009, Hi-Tech has paid Wright $5,000 a month for, among other things, endorsing Hi-Tech's products, including the products at issue in this contempt proceeding. Plaintiff's Ex. 18 at 33-34; Plaintiff's Ex. 9 at ¶¶ 1, 4; Plaintiff's Ex. 295 at 4; Wheat Dep. at 65:13-67:6, 68:25-69:10.

60. For example, Wright is identified as the author of the following advertisements, which appeared in the April 2009 edition of Hi-Tech Health & Fitness: "Benzedrine™ A Diet Aid That Pushes The

Nutraceutical Envelope!" and "Lose Weight Fastin!" Plaintiff's Ex. 295 at 4, 19-20, 71-73.

61. Similarly, Wright is identified as the author of the following advertisement for Fastin, Lipodrene, and Stimerex-ES, which appeared in the January 2011 edition of Hi-Tech Health & Fitness: "Weight Loss Supplements – What's Hot in the Weight Loss Industry!" Plaintiff's Ex. 296 at 4-6, 8 , 10-12.

62. In 2009, Hi-Tech paid Wright $80,454. Plaintiff's Ex. 22 at 11.

63. In 2010, Hi-Tech paid Wright $55,000. Plaintiff's Ex. 22 at 10.

64. In 2011, Hi-Tech paid Wright $45,000. Plaintiff's Ex. 22 at 12.

65. In total, Hi-Tech paid Wright $180,454 during that time period. Plaintiff's Ex. 22 at 10-12.

II. The Court's Clear And Definite Orders Against Hi-Tech Pharmaceuticals, Inc., Jared Wheat, Stephen Smith, And Terrill Mark Wright.

A. The Court's Summary Judgment Decision

66. On June 4, 2008, this Court granted summary judgment in favor of the FTC, and issued an order, upheld on appeal, finding that Hi-Tech Pharmaceuticals, Inc. ("Hi-Tech"), Jared Wheat ("Wheat"), Stephen Smith

("Smith"), Terrill Mark Wright ("Wright"), and other defendants violated Section 5 of the FTC Act by making product claims and for weight-loss products without having a reasonable basis for those claims and endorsements. *See Fed. Trade Comm'n v. Nat'l Urological Grp.*, 645 F. Supp. 2d 1167 (N.D. Ga. 2008), *aff'd*, 356 F. App'x 368 (11th Cir. 2009).

67. The Court held that both Wheat and Smith were individually liable for Hi-Tech's violations of Section 5. *See Nat'l Urological Grp.*, 645 F. Supp. 2d at 1206-07.

68. The Court specifically found that Wheat and Smith were "corporate officers, owners, and/or independent contractors or employees" of Hi-Tech and that as such "these individuals clearly had the ability to control" Hi-Tech. *Id.* at 1207.

69. The Court further found that Wheat and Smith "knew of, or at least were recklessly indifferent to, the misrepresentations the advertisements made." *Id.*

70. The Court entered the permanent injunction was warranted against Wheat and Smith in their individual capacities because there was a "cognizable

danger" that Wheat and Smith would violate the FTC Act in the future. *Id.* at 1208.

71. The Court specifically found that there was such a cognizable danger because "the corporate defendants' previous violations of the FTC Act were numerous and grave. These parties, ***acting through their corporate officers,*** did not engage in a harmless advertising scheme with an isolated incidence of deception; instead, their advertising was chock full of false, misleading, and unsubstantiated information." *Id.* (emphasis added).

72. The Court also found that Wright was individually liable for his expert endorsements of Thermalean because he "participated directly in the advertising and knew that the advertisements made material misrepresentations regarding the product claims or at least was recklessly indifferent to the truth or falsity of the advertising." *Id.* at 1207.

73. The Court rejected Smith and Wright's argument that a permanent injunction against them as individuals was not necessary because Hi-Tech and Wheat were already bound by a consent decree with the FDA on the grounds that, *inter alia*, the consent decree had "no impact" on their individual behavior. *Id.* at 1210.

B. Final Judgment And Permanent Injunction Against Hi-Tech, Wheat, and Smith

74. On December 16, 2008, this Court entered a Final Judgment and Permanent Injunction Against National Urological Group, Inc., Hi-Tech Pharmaceuticals, Inc., Jared Wheat, Thomasz Holda, and Stephen Smith (Dkt. No. 230) ("Hi-Tech Order"). Plaintiff's Ex. 1.

75. Section II of the Hi-Tech Order ("PROHIBITED UNSUBSTANTIATED CLAIMS FOR WEIGHT LOSS PRODUCTS") orders that "Defendants . . . in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any weight loss product, are hereby permanently restrained and enjoined from making any representation, in any manner, expressly or by implication, including through the use of endorsements, that:

a. Such product is an effective treatment for obesity;

b. Such product causes rapid or substantial loss of weight or fat;

c. Such product causes a specified loss of weight or fat;

d. Such product affects human metabolism, appetite, or body fat;

e. Such product is safe;

f. Such product has virtually no side effects; or

g. Such product is equivalent or superior to any drug that the Food and Drug Administration has approved for sale in the United States for the purpose of treating obesity or causing weight loss;

unless the representation, including any 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."

Plaintiff's Ex. 1 at 14-15.

76. Section VI of the Hi-Tech Order ("WARNING OF HEALTH RISKS OF YOHIMBINE") orders that "in any advertisement, promotional material, or product label for any covered product or program containing yohimbine that contains any representation about the efficacy, benefits, performance, safety, or side effects of such product, and during any discussion relating to the use of such product communicated via electronic mail or any telephone line, Defendants, their officers, agents, servants, representatives, and employees shall make clearly and prominently, the

following disclosure: **WARNING**: This product can raise blood pressure and interfere with other drugs you may be taking. Talk to your doctor about this product." Plaintiff's Ex. 1 at 17-18 (emphasis original).

77. Section VII of the Hi-Tech Order ("OTHER PROHIBITED CLAIMS") orders that "Defendants . . . in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of endorsements, about the health benefits, absolute or comparative benefits, safety, or efficacy of such product or service, unless, at the time the representation is made, Defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation." Plaintiff's Ex. 1 at 18-19.

78. Section XV of the Hi-Tech Order ("RETENTION OF JURISDICTION") orders that "this Court shall retain jurisdiction of this matter for purposes of construction, modification, and enforcement of this Order." Plaintiff's Ex. 1 at 33.

79. The Hi-Tech Order defines "Advertising" or "Advertisement" as "any written or verbal statement, illustration, or depiction that is designed to effect a sale or create interest in the purchasing of goods or services whether it appears in a brochure, newspaper, magazine, pamphlet, leaflet, circular, mailer, book insert, free standing insert, letter, catalogue, poster, chart, billboard, public transit card, point of purchase display, packaging, package insert, label, film, slide, radio, television or cable television, audio program transmitted over a telephone system, program-length commercial ('infomercial'), Internet website (including metatags), or in any other medium." Plaintiff's Ex. 1 at 6 (Definitions ¶ 2).

80. The Hi-Tech Order defines "Competent and reliable scientific evidence" as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." Plaintiff's Ex. 1 at 7 (Definitions ¶ 3).

81. In relevant part, the Hi-Tech Order defines "Clear(ly) and Prominent(ly)" to mean:

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

C. On a product label, the disclosure shall be in a type size and location sufficiently noticeable for an ordinary consumer to read and comprehend it and in print that contrasts with the background against which it appears. ***Provided, however***, if a disclosure on a bottle label or package label is made in a location other than the principal display panel, the bottle label or package label shall (i) include the statement, **"See important safety warning(s) on [insert disclosure location]**," in a type size and location on the principal display panel sufficiently noticeable for an ordinary consumer to read and comprehend it and in print that contrasts with the background against which it appears; and (ii) place the disclosure on the bottle label and, if applicable, the package label, within a border that is a color or shade that contrasts with the background against which it appears. ***Provided further***, that in a multi-page insert, the disclosure shall appear on the cover or first page.

D. In the case of advertisements disseminated by means of interactive electronic medium, such as software, the Internet, or online services, "in close proximity" means on the same Web page, online service page, or other electronic page, and proximate to the triggering representation, and does not include disclosures accessed or displayed through hyperlinks, pop-ups, interstitials, or other means.

E. The disclosure shall be in understandable language and syntax. Nothing contrary to, inconsistent with, or in mitigation of the disclosure shall be used in any advertisement or on any label. Plaintiff's Ex. 1 at 5-7 (Definitions ¶ 4).

82. The Hi-Tech Order identifies "Weight Loss Product" as "any product, program, or service designed, used, or marketed to prevent weight gain or produce weight loss, reduce or eliminate fat, slim, or increase caloric deficit in a user of the product, program, or service." Plaintiff's Ex. 1 at 10 (Definitions ¶ 6).

83. The Hi-Tech Order defines "Covered product or service" as "any health-related service or program, weight loss product, dietary supplement, food, drug, or device." Plaintiff's Ex. 1 at 11 (Definitions ¶ 11).

C. Hi-Tech, Wheat, And Smith Had Actual Notice Of The Hi-Tech Order.

84. Hi-Tech received a copy of the Hi-Tech Order on December 16, 2008. Plaintiff's Ex. 11 at 5.

85. Wheat received a copy of the Hi-Tech Order on December 16, 2008. Plaintiff's Ex. 13; Plaintiff's Ex. 18 at 9.

86. Smith received a copy of the Hi-Tech Order on December 16, 2008. Plaintiff's Ex. 15 at 4-5; Plaintiff's Ex. 18 at 9; Plaintiff's Ex. 24 (adopting Plaintiff's Ex. 18).

D. Wheat And Smith Understood The Hi-Tech Order's Substantiation Requirement.

87. Correspondence involving both Wheat and Smith demonstrate that they understood that in order for their advertising claims to be substantiated by "competent and reliable scientific evidence," the Hi-Tech Order required, at a minimum, double-blind, placebo-controlled studies of the products themselves. *See* FOF ¶¶ 88-121.

88. On March 16, 2010, in an email he wrote from prison to Hi-Tech employees Jeff Jones, Brandon Schopp, and Mike Smith, Wheat stated: "With the FTC's verdict in essence saying 'ingredient-specific advertising' is

excluded from 'valid and scientific substantiation,' which is the FTC standard – Vic will not want to assume the liability for any ads we may run. As you guys saw when you tried to get an ad approved for the ECRM show you could not get any of the attorneys to agree on what was acceptable except a bottle and even then they wanted to delete things from the Fastin box that would show up on the ad. 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." Plaintiff's Ex. 94 at 3.

89. On March 22, 2010, in an email he wrote from prison to Stephen 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." Plaintiff's Ex. 95 at 4.

90. On March 23, 2010, in an email he wrote from prison to Stephen Smith, Wheat stated: "[I]f Vic stays in place it will be a slow process to get ads approved . . . . I believe if we are going to advertise we will need to make a

change as Jody 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." Plaintiff's Ex. 95 at 3.

91. On March 28, 2010, in an email he wrote from prison to Stephen Smith, Wheat stated: "[Victor Kelley] also wants Jody [Schilleci] and Tim [Fulmer] to sign off on legal opinions as to any ads HT [Hi-Tech] may run while he is in command, which I can not [sic] blame him. There lies the problem as with the way the Courts have ruled there is nothing we can say about the product that a lawyer would feel comfortable signing off on. 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 advertising case that a company has not done a double-blind placebo study on the product itself." Plaintiff's Ex. 96 at 3.

92. 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." Plaintiff's Ex. 98 at 3 (emphasis original).

93. On July 7, 2010, in an email he wrote from prison to Arthur Leach and Joseph Schilleci, in connection with Hi-Tech's motion for a writ of certiorari to the Supreme Court relating to the Hi-Tech Order, Wheat stated: "[I]f our set of facts is not good enough then a double-blind placebo study would be required." Plaintiff's Ex. 100 at 3.

94. On July 20, 2010, during a telephone call made while he was incarcerated in federal prison, Wheat spoke with Stephen Smith. Plaintiff's Ex. 106 at 3-4.

95. During the July 20, 2010 telephone call, Wheat told Smith that he had reviewed the injunction for the first time in two years. Plaintiff's Ex. 106 at 5:2-4.

96. During the July 20, 2010 telephone call with Smith, Wheat stated that "rapid 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." Plaintiff's Ex. 106 at 7:6-14; 8:19-9:1.

97. During the same phone call, Wheat stated the following: "There were some things like fat loss . . . . and there's a couple of other things we're prohibited from saying. Increasing the metabolic rate was claim one. We can't say that." Plaintiff's Ex. 106 at 5:6-12; *see also id.* at 5:14-6:9.

98. Contempt Defendants'[4] attorneys repeatedly expressed concern that Contempt Defendants' advertising claims violated the Hi-Tech Order. *See* Plaintiff's Exs. 99, 103, 104, 117.

99. Schilleci, Leach, Kelley, and Fulmer wrote a memorandum, dated June 4, 2010, addressed to Jared Wheat, relating to Hi-Tech's proposed advertising for Fastin ("June 4, 2010 Memo"). Plaintiff's Ex. 117; *see also* 1/21/14 Trial Tr. at 110:2-9, 12-13.

100. Victor Kelley testified that he and Art Leach were concerned that "aggressive" advertising claims could subject Wheat to contempt proceedings. 1/21/14 Trial Tr. at 101:16-102:7; *see also id.* at 121:16-19 ("Our intention was to bring to Jared's attention the possibility of sanctions in the future.")

[4] "Contempt Defendants" refers to defendants, Hi-Tech Pharmaceuticals, Inc., ("Hi-Tech"), Jared Wheat, and Stephen Smith, collectively.

101. Wheat received the June 4, 2010 memo. Plaintiff's Ex. 114 at 6.

102. The June 4, 2010 Memo was based on Schilleci, Leach, Kelley, and Fulmer's review of the Hi-Tech Order and the Court's 2008 summary judgment opinion. Plaintiff's Ex. 117 at 2, 4.

103. The June 4, 2010 Memo states: "[B]ased upon our review, we have grave concerns that the publication of the proposed Fastin® advertisement would not be in compliance with the broad scope of the FTC Injunction." Plaintiff's Ex. 117 at 2.

104. The June 4, 2010 Memo states:

"A review of the Fastin® advertisement reveals the following statements:

- 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."

Plaintiff's Ex. 117 at 3 (emphasis original).

105. The June 4, 2010 Memo states: "As demonstrated by the highlighted sections above, it appears that the language in the Fastin® advertisement includes specifically prohibited language under the FTC Injunction regarding rapid fat and weight loss and increased metabolism, among other things." Plaintiff's Ex. 117 at 3; *see also* 1/21/14 Trial Tr. at 113:11-19.

106. The June 4, 2010 Memo states: "As shown above, it appears that the Fastin® advertisement actually does refer to the product rather than the ingredients by referencing 'Fastin® . . . causes dramatic weight loss.' Moreover, Judge Pannell clearly expressed his opinion that these types of advertisements were directed toward to [sic] the product, rather than the ingredients, because of the implied representations contained therein." Plaintiff's Ex. 117 at 4; *see also* Trial Tr. 113:20-23.

107. In connection with Sections I and II of the Hi-Tech Order, the June 4, 2010 Memo states that, with respect to any weight-loss product, "the FTC Injunction also makes it a requirement that any representation be

supported by competent and reliable scientific evidence." Plaintiff's Ex. 117 at 2, 4.

108. The June 4, 2010 Memo states that "we believe it is safe to say that Judge Pannell did not then and would not now find . . . ingredient specific substantiation to be consistent with the express language in the FTC Injunction requiring 'competent and reliable scientific evidence.'" Plaintiff's Ex. 117 at 4.

109. The June 4, 2010 Memo states that "even assuming that the Fastin® advertisement would satisfy FDA standards, it appears unlikely that it in its current form it would satisfy the prohibitions of the FTC Injunction." Plaintiff's Ex. 117 at 4.

110. In connection with Section VII of the Hi-Tech Order, the June 4, 2010 Memo states that "under the FTC Injunction, with respect to any dietary supplement an advertisement cannot make any representation regarding benefits or performance of the product without competent and reliable scientific evidence." Plaintiff's Ex. 117 at 4.

111. The June 4 Memo states:

"Additionally, although the following representations do not directly refer to the product, they appear to suggest benefits and/or performance:

- 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."

Plaintiff's Ex. 117 at 5 (emphasis original).

112. The June 4, 2010 Memo states that "[u]nder the FTC Injunction, these statements are required to be supported by 'competent and reliable scientific evidence.' Once again, based upon Judge Pannell's and the FTC's findings, it would seem unlikely that 'ingredient specific substantiation' would be considered compliant with this provision. Therefore, it 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." Plaintiff's Ex. 117 at 5.

113. The June 4, 2010 Memo states:

> "Accordingly it is our opinion that at this point your options are as follows:
>
> 1) Publish the Fastin® advertisement as written. We advise against this.
>
> 2) Amend the advertising, as well as future advertisements, in accordance with above. This would be acceptable.
>
> 3) Maintain the status quo and refrain from advertising until such time as you are back home and can make clearer decisions. This would be acceptable.
>
> 4) Shut down. This may be the safest approach, but seems unadvisable at this time."

Plaintiff's Ex. 117 at 6.

114. The June 4, 2010 Memo concludes:

> "Based upon the foregoing, it is our opinion that if the Fastin® advertisement were published in its present form the FTC would

take the matter back before Judge Pannell for a finding of contempt against Hi-Tech and you personally. In this regard, as described above, it is our view that Judge Pannell would likely agree with the FTC. As Art and Vic have explained previously, such a contempt finding could not only impose civil penalties, but more importantly, could impose criminal penalties, including potentially extending your confinement. It is our opinion that the very real potential for such serious consequences should dictate your decision to withhold the publication of the Fastin® advertisement as currently printed."

Plaintiff's Ex. 117 at 5; *see also* 1/21/14 Trial Tr. at 120:1-6.

115. Kelley testified that the "very real potential" for criminal contempt sanctions "predicated" the drafting of the June 4, 2010 Memo. 1/21/14 Trial Tr. at 119:7-25.

116. Kelley testified that he believed that if Wheat went forward with the claims identified in the memo, he risked criminal contempt penalties. 1/21/14 Trial Tr. at 120:1-4.

117. After receiving the memo, Contempt Defendants continued to make the following claims on their product packaging:

a. Rapid Fat Loss Catalyst. *See* Plaintiff's Exs. 46-50, 146, 274, 290; Defendants' Ex. 59.

b. Rapid Fat Loss Thermogenic Intensifier. *See* Plaintiff's Exs. 46, 48, 50, 146, 274, 290.

c. Increases the Metabolic Rate, Promoting Thermogenesis (The Burning of Stored Body Fat). *See* Plaintiff's Exs. 46, 48, 50, 146, 274, 290.

d. Rapid Fat Burner. *See* Plaintiff's Exs. 46, 48, 50, 146, 274, 290.

e. Do Not Consume Unless Rapid Fat and Weight Loss Are Your Desired Result. Plaintiff's Exs. 46, 50; *see also* Plaintiff's Exs. 56, 276.

118. On July 9, 2010, in an email he wrote from prison to Victor Kelley, Wheat stated: "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." Plaintiff's Ex. 101 at 3.

119. On July 20, 2010, after he reviewed Contempt Defendants' proposed Fastin ad, another of Hi-Tech's attorneys, Ed Novotny recommended that Contempt Defendants remove the claim: "Warning: Extremely Potent Diet

Aid! Do Not Consume Unless Rapid Fat And Weight Loss Are Your Desired Result." Defendants' Ex. 13 at 1, 4; 1/23/14 Trial Tr. at 92:11-24, 94:4-25.

120. During the July 20, 2010 telephone call, Wheat and Smith conversed about Hi-Tech attorney Ed Novotny's advice to do away with the claim "warning, extremely potent diet aid, do not consume . . . ." Plaintiff's Ex. 106 at 5:14-6:9.

121. Despite Novotny's recommendation, the "Warning: Extremely Potent Diet Aid! Do Not Consume Unless Rapid Fat And Weight Loss Are Your Desired Result," continued to appear on Fastin packaging through at least December 31, 2011. *See* Plaintiff's Exs. 46, 50; *see also* Defendants' Ex. 65 at 20 (Table 2-1) (showing sales of 20-count Fastin through December 31, 2011).

E. Final Judgment Against Wright.

122. On December 16, 2008, this Court issued a Final Judgment and Permanent Injunction Against Terrill Mark Wright, M.D. (Dkt. No. 229) ("Wright Order"). Plaintiff's Ex. 2.

123. Section II of the Wright Order ("PROHIBITED UNSUBSTANTIATED CLAIMS FOR WEIGHT LOSS PRODUCTS") orders that "Defendant . . . in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any weight loss product, is hereby permanently restrained and enjoined from making any representation, in any manner, expressly or by implication, including through the use of endorsements, that:

a. Such product is an effective treatment for obesity;

b. Such product causes rapid or substantial loss of weight or fat;

c. Such product causes a specified loss of weight or fat;

d. Such product affects human metabolism, appetite, or body fat;

e. Such product is safe;

f. Such product has virtually no side effects; or

g. Such product is equivalent or superior to any drug that the Food and Drug Administration has approved for sale in the United States for the purpose of treating obesity or causing weight loss;

unless the representation, including any representation made through the use of endorsements is true and non-misleading, and, at the time the representation is made, Defendant possesses and relies upon competent and reliable scientific evidence that substantiates the representation. *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." Plaintiff's Ex. 2 at 9-10 (emphasis original).

124. Section XI of the Wright Order ("RETENTION OF JURISDICTION") orders that "this Court shall retain jurisdiction of this matter for purposes of construction, modification, and enforcement of this Order." Plaintiff's Ex. 2 at 25.

125. The Wright Order defines "Competent and reliable scientific evidence" as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using

procedures generally accepted in the profession to yield accurate and reliable results." Plaintiff's Ex. 2 at 6 (Definitions ¶ 3).

126. The Wright Order defines "Weight Loss Product" as "any product, program, or service designed, used, or marketed to prevent weight gain or produce weight loss, reduce or eliminate fat, slim, or increase caloric deficit in a user of the product, program, or service." Plaintiff's Ex. 2 at 7 (Definitions ¶ 4).

127. Wright admits that he received the Wright Order. Plaintiff's Ex. 16 at 5.

III. The Advertising And Sale Of Fastin, Lipodrene, Benzedrine, And Stimerex-ES

A. The Advertising And Sale Of Fastin

128. From January 1, 2009 through at least November 10, 2014, Contempt Defendants advertised Fastin with unsubstantiated, unqualified, causal efficacy claims. *See* FOF ¶¶ 129-170.

129. From at least October 2010 through at least December 14, 2012, Hi-Tech, Wheat, Smith, and Wright advertised Fastin with unsubstantiated, unqualified, causal efficacy claims through print ads appearing in national publications 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 Fall, Whole Living, Women's Day, and *Women's World* magazines. Plaintiff's Ex. 7 ¶ 1; Plaintiff's Ex. 8 ¶ 1; Plaintiff's Ex. 43 at 3 (full page-Fastin print ad); Plaintiff's Ex. 44 (multi-product "Diet & Energy and Muscle & Strength" print ad); Plaintiff's Ex. 18 at 10-13; Plaintiff's Ex. 20 at 4; Plaintiff's Ex. 32 at 5-10.

130. Hi-Tech, Wheat, Smith, and Wright also disseminated the unsubstantiated Fastin print ads through the website www.hitechpharma.com through early January 2014. 1/22/14 Trial Tr. at 56:18-57:5; *see also* 1/21/14 Trial Tr. at 29:24-30:19, 31:16-32:5, 36:18-37:19, 42:8-43:10, 43:16-44:7; *see also* Plaintiff's Ex. 272 at 3, 29.

131. From at least September 17, 2010 through at least January 21, 2014, Hi-Tech, Wheat, and Smith have advertised and offered Fastin for sale using unsubstantiated, unqualified, causal efficacy claims on their website, www.hitechpharma.com. Plaintiff's Ex. 7 ¶ 2; Plaintiff's Ex. 8 ¶ 1; Plaintiff's Ex. 18 at 12, 14-15; Plaintiff's Exs. 45, 284, 286-288; 1/22/14 Trial

Tr. at 56:18-57:5; *see also* 1/21/14 Trial Tr. at 29:24-30:19, 31:16-32:5, 36:18-37:19, 42:8-43:10, 43:16-44:7.

132. From at least January 1, 2009 through at least November 10, 2014, Contempt Defendants advertised Fastin through product packaging and labels that contained unsubstantiated, unqualified, causal efficacy claims that are distributed both directly by Contempt Defendants and through retail outlets. Plaintiff's Ex. 7 ¶ 3; Plaintiff's Ex. 8 ¶ 3; Plaintiff's Ex. 41 at 8-9; Plaintiff's Exs. 46-51, 273-274, 284, 289-290; Wheat Dep. at 47:21-48:2; 1/21/14 Trial Tr. at 49:7-50:14, 50:25-51:6; 1/22/14 Trial Tr. 92:25-93:7; Dkt. Nos. 672, 796.

133. Hi-Tech's advertising budget tripled from 2010 to 2011, from $1.3 million to $3.9 million, enabling Hi-Tech to pick up more retail accounts, with Fastin picking up the most accounts as a result of the increased advertising. Wheat Dep. at 100:1-6, 100:11-101:4; Plaintiff's Ex. 207 at 3, 5.

1. Representations That Fastin Causes Rapid Or Substantial Loss of Weight

134. Contempt Defendants make numerous, unqualified claims that Fastin causes rapid or substantial weight loss on the product's packaging and labels. *See* FOF ¶¶ 135-137.

135. The Fastin box for the 60-count stock-keeping unit ("SKU"), Plaintiff's Ex. 46 at 3-4, contains the following express statements:

a. "EXTREME WEIGHT LOSS GUARANTEED!" (caps original);

b. "WARNING: EXTREMELY POTENT DIET AID! DO NOT CONSUME UNLESS RAPID FAT AND WEIGHT LOSS ARE YOUR DESIRED RESULT." (caps original);

c. "Increases the release of Norepinephrine and Dopamine for dramatic weight loss."

d. The Fastin box for the 30-count SKU, Plaintiff's Ex. 48 at 2, contains the following express statement: "Increases the release of Norepinephrine and Dopamine for dramatic weight loss."

136. The Fastin box for the 20-count SKU, Plaintiff's Ex. 50 at 3-4, contains the following express statements:

a. "WARNING: EXTREMELY POTENT DIET AID! DO NOT CONSUME UNLESS RAPID FAT AND WEIGHT LOSS ARE YOUR DESIRED RESULT." (caps original)

b. "Increases the Release of Norepinephrine and Dopamine for Dramatic Weight Loss"; and

c. "Fastin® is a pharmaceutical-grade dietary supplement indicated for weight loss in extremely overweight individuals."

137. The statements identified in Paragraphs 135-136 represent, expressly or by implication that Fastin causes rapid or substantial loss of weight.

2. Representations That Fastin Causes Rapid Or Substantial Loss Of Fat.

138. Contempt Defendants make numerous, unqualified claims that Fastin causes rapid or substantial fat loss in the product's print ads, packaging, and labels. *See* FOF ¶¶ 139-145.

139. The full-page Fastin print ad, Plaintiff's Ex. 43 at 3, contains the following express statements:

a. "Extreme Fat Burner"; and

b. "Rapid Fat Loss" (on photo of Fastin box).

c. The Fastin box for the 60-count SKU, Plaintiff's Ex. 46 at 3-4, contains the following express statements:

d. "Rapid Fat Loss";

e. "Rapid Fat Burner";

f. "WARNING: EXTREMELY POTENT DIET AID! DO NOT CONSUME UNLESS RAPID FAT AND WEIGHT LOSS ARE YOUR DESIRED RESULT." (caps original); and

g. "Rapid Fat Loss Catalyst."

140. The Fastin label for the 60-count SKU, Plaintiff's Ex. 47 at 3-4, contains the following express statement: "Rapid Fat Loss Catalyst."

141. The Fastin box for the 30-count SKU, Plaintiff's Ex. 48 at 2, contains the following express statements:

a. "RAPID FAT BURNER" (caps original);

b. "RAPID FAT LOSS CATALYST" (caps original);

c. "Increases the metabolic rate, promoting thermogenesis (The Burning of Stored Body Fat)"; and

d. "RAPID FAT LOSS" (caps original).

142. The Fastin label for the 30-count SKU, Plaintiff's Ex. 49 at 2, contains the following express statement: "Rapid Fat Loss Catalyst."

143. The Fastin box for the 20-count SKU, Plaintiff's Ex. 50 at 3-4, contains the following express statements:

a. "Rapid Fat Loss";

b. "Rapid Fat Burner";

c. "WARNING: EXTREMELY POTENT DIET AID! DO NOT CONSUME UNLESS RAPID FAT AND WEIGHT LOSS ARE YOUR DESIRED RESULT." (caps original); and

d. "RAPID FAT LOSS CATALYST" (caps original).

144. The Fastin blister-pack for the 3-count SKU, Plaintiff's Ex. 51 at 1, contains the following express statement: "Rapid Fat Loss."

145. The statements identified in Paragraphs 139-144 represent, expressly or by implication, that Fastin causes rapid or substantial loss of fat.

3. Representations That Fastin Affects Body Fat

146. Contempt Defendants make numerous representations that Fastin affects body fat, including by causing the burning or loss of fat, in the product's print ads, product packaging and labels. *See* FOF ¶¶ 147-154.

147. The full page Fastin print ad, Plaintiff's Ex. 43 at 3, contains the following express statements:

a. "Fat Mobilizer";

b. "Novel Fat Burner";

c. "EXTREME FAT BURNER" (caps original);

d. "Rapid Fat Loss" (on photo of Fastin box); and

e. "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)."

148. The Fastin box for the 60-count SKU, Plaintiff's Ex. 46 at 3-4, contains the following express statements:

a. "RAPID FAT LOSS" (caps original);

b. "RAPID FAT BURNER" (caps original);

c. "WARNING: EXTREMELY POTENT DIET AID! DO NOT CONSUME UNLESS RAPID FAT AND WEIGHT LOSS ARE YOUR DESIRED RESULT." (caps original);

d. "Increases the metabolic rate, promoting thermogenesis (The Burning of Stored Body Fat)"; and

e. "RAPID FAT LOSS CATALYST" (caps original)

149. The Fastin label for the 60-count SKU, Plaintiff's Ex. 47 at 3-4, contains the following express statement: "Rapid Fat Loss Catalyst."

150. The Fastin box for the 30-count SKU, Plaintiff's Ex. 48 at 2, contains the following express statements:

a. "RAPID FAT BURNER" (caps original);

b. "RAPID FAT LOSS CATALYST" (caps original);

c. "Increases the metabolic rate, promoting thermogenesis (The Burning of Stored Body Fat)";

d. "RAPID FAT LOSS" (caps original); and

e. "THERMOGENIC INTENSIFIER" (caps original).

151. The Fastin label for the 30-count SKU, Plaintiff's Ex. 49 at 2, contains the following express statement: "Rapid Fat Loss Catalyst."

152. The Fastin box for the 20-count SKU, Plaintiff's Ex. 50 at 3-4, contains the following express statements:

a. "RAPID FAT LOSS" (caps original);

b. "RAPID FAT BURNER" (caps original);

c. "WARNING: EXTREMELY POTENT DIET AID! DO NOT CONSUME UNLESS RAPID FAT AND WEIGHT LOSS ARE YOUR DESIRED RESULT." (caps original);

d. "Increases the Metabolic Rate, Promoting Thermogenesis (The Burning of Stored Body Fat)";

e. "RAPID FAT LOSS CATALYST" (caps original); and

f. "Fastin®'s pharmaceutical-grade fat loss catalysts achieve extraordinary results."

153. The Fastin blister-pack for the 3-count SKU, Plaintiff's Exhibit 51 at 2, contains the following express statement: "Rapid Fat Loss."

154. The statements identified in Paragraphs 147-153 represent, expressly or by implication that Fastin affects body fat.

4. Representations That Fastin Affects Human Metabolism

155. Contempt Defendants made numerous, unqualified representation that Fastin affects human metabolism, including by causing an increase in human metabolism, on the product's packaging and labels. *See* FOF ¶ 156-159.

156. The Fastin box for the 60-count SKU, Plaintiff's Ex. 46 at 3-4, contains the following express statement: "Increases the metabolic rate, promoting thermogenesis (The Burning of Stored Body Fat)."

157. The Fastin box for the 30-count Fastin SKU, Plaintiff's Ex. 48 at 2, contains the following express statement: "Increases the metabolic rate, promoting thermogenesis (The Burning of Stored Body Fat)."

158. The Fastin box for the 20-count SKU, Plaintiff's Ex. 50 at 3-4, contains the following express statement: "Increases the Metabolic Rate, Promoting Thermogenesis (The Burning of Stored Body Fat)."

159. The statements identified in Paragraphs 156-158 represent, expressly or by implication, that Fastin affects human metabolism.

5. Representations That Fastin Affects Appetite

160. Contempt Defendants made numerous, unqualified representations that Fastin affects appetite, including by causing a decrease in appetite, in the product's print ads and packaging. *See* FOF ¶¶ 161-163.

161. The full page Fastin print ad, Plaintiff's Ex. 43 at 3, contains the following express statement: ". . . Curbs the Appetite!"

162. The Fastin box for the 20-count SKU, Plaintiff's Ex. 50 at 4, contains the following express statement: "Fastin® has both immediate and delayed release profiles for appetite suppression, energy, and weight loss."

163. The statements identified in Paragraphs 161-162 represent, expressly or by implication, that Fastin affects appetite.

B. Wright's Expert Endorsement of Fastin

164. In his expert endorsement of Fastin, Wright makes unqualified representations that the product affects body fat, including by causing fat burning. *See* FOF ¶¶ 165-170.

165. The full-page Fastin print ad contains a photograph of Wright. *See* Plaintiff's Ex. 43 at 3 (identifying Wright).

166. Wright reviewed the Fastin print ad. Wheat Dep. at 68:10-69:10.

167. Wright knew that he appeared in the Fastin print ad. Wheat Dep. at 68:10-12.

168. Wright approved his endorsement in the Fastin print ad. Wheat Dep. at 68:13-69:10.

169. The full-page Fastin print ad, Plaintiff's Ex. 43 at 3, contains the following express statements:

a. "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."

b. "Extreme Fat Burner."

170. The statements identified in Paragraph 169 represent, expressly or by implication, including through the use of an endorsement, that Fastin affects body fat.

C. The Advertising and Sale of Lipodrene

171. From January 1, 2009 through at least November 10, 2014, Contempt Defendants advertised Lipodrene using unsubstantiated, unqualified, causal efficacy claims. *See* FOF ¶¶ 172-208.

172. From at least October 2010 through at least December 14 2012, Hi-Tech, Wheat, and Smith advertised Lipodrene through print ads containing unsubstantiated, unqualified, causal efficacy claims that appeared in national publications such as *Flex*, *Muscle & Fitness*, and *MuscleMag International* magazines. Plaintiff's Ex. 7 ¶ 5; Plaintiff's Ex. 8 ¶ 5; Plaintiff's Ex. 52 (2-page Lipodrene print ad); Plaintiff's Ex. 44 (multi-product "Diet & Energy and Muscle & Strength" print ad); Plaintiff's Ex. 18 at 16-19; Plaintiff's Ex. 20 at 4; Plaintiff's Ex. 32 at 8-10.

173. Contempt Defendants also disseminated the Lipodrene print ads containing unsubstantiated, unqualified, causal efficacy claims through the website www.hitechpharma.com through early January 2014. 1/22/14 Trial Tr. at 56:18-57:5; *see also* 1/21/14 Trial Tr. at 29:24-30:19, 31:16-32:5, 36:18-37:19, 42:8-43:10, 43:16-44:7; *see also* Plaintiff's Ex. 272 at 9-12, 29.

174. From at least September 17, 2010 through January 21, 2014, Hi-Tech, Wheat, and Smith also advertised and offered Lipodrene for sale using unsubstantiated, unqualified, causal efficacy claims on the www.hitechpharma.com website. Plaintiff's Ex. 7 ¶ 6; Plaintiff's Ex. 8 ¶ 6; Plaintiff's Ex. 18 at 16-17, 20-21; Plaintiff's Ex. 53; Plaintiff's Ex. 286; 1/22/14 Trial Tr. at 56:18-57:5; *see also* 1/21/14 Trial Tr. at 29:24-30:19, 31:16-32:5, 36:18-37:19, 42:8-43:10, 43:16-44:7.

175. From at least January 1, 2009 through at least November 10, 2014, Hi-Tech, Wheat, and Smith advertised Lipodrene through product packaging and labels that contain unsubstantiated, unqualified, causal efficacy claims and that are distributed both by Contempt Defendants directly and through retail outlets. Plaintiff's Ex. 7 ¶ 7; Plaintiff's Ex. 8 ¶ 7; Plaintiff's Ex. 41 at 4-7; Plaintiff's Ex. 54-56; Wheat Dep. at 47:21-48:2; 1/21/14 Trial Tr. at 48:12-49:6; 1/22/14 Trial Tr. at 92:25-93:7; Dkt. No. 796.

1. Representations That Lipodrene Causes Rapid Or Substantial Loss Of Weight

176. Contempt Defendants made numerous, unqualified representations that Lipodrene causes rapid or substantial weight loss, in the product's print ads, packaging and labels. *See* FOF ¶¶ 177-180.

177. The two-page Lipodrene print ad, Plaintiff's Ex. 52 at 3, contains the following express statements:

a. "Join the millions of American's [sic] who have consumed over 1 Billion dosages of Lipodrene® . . . And watch the pounds Melt Away!" (ellipses original); and

b. "Try Lipodrene® and watch the inches melt away."

178. The Lipodrene label for the 100-count SKU, Plaintiff's Ex. 54 at 3, contains the following express statement: "LIPODRENE WILL CAUSE RAPID FAT AND WEIGHT LOSS WITH USAGE" (caps original).

179. The Lipodrene label for the 20-count SKU, Plaintiff's Ex. 55 at 2, contains the following express statement: "LIPODRENE WILL CAUSE RAPID FAT AND WEIGHT LOSS WITH USAGE" (caps original).

180. The Lipodrene blister pack for the 2-count SKU, Plaintiff's Ex. 56 at 3, contains the following express statement: "LIPODRENE® WILL CAUSE RAPID FAT AND WEIGHT LOSS WITH USAGE" (caps original).

181. The statements identified in Paragraphs 177-180 represent, expressly or by implication, that Lipodrene causes rapid or substantial loss of weight.

2. Representations That Lipodrene Causes Rapid Or Substantial Loss Of Fat.

182. Contempt Defendants made numerous, unqualified representations that Lipodrene causes rapid or substantial fat loss, in the product's print ads, webpages, packaging, and labels. *See* FOF ¶¶ 183-188.

183. The two-page Lipodrene print ad, Plaintiff's Ex. 52 at 3, contains the following express statements;

a. "Is a Novel Fat Burner that Helps Melt Away Pounds!"

b. "REVOLUTIONARY FAT ASSASSIN™" (caps original); and

c. "Lipodrene® is truly a Fat Assassin™ unlike any other 'Fat Burner.'"

184. The multi-product "Diet & Energy and Muscle & Strength" print ad, Plaintiff's Ex. 44 at 3, contains the following express statement: "Hi-Tech's Flagship Fat Loss Product with 25 mg Ephedra Extract – Annihilate Fat!"

185. The Lipodrene hitechpharma.com webpage, Plaintiff's Ex. 53 at 3, contains the following express statement: "Whether you want to simply transform your body into a leaner, more attractive one, or you want to get jacked and ripped to shreds. Lipodrene® is the right move to strip away fat and feel great all day!"

186. The Lipodrene label for the 100-count SKU, Plaintiff's Ex. 54 at 3, contains the following express statement: "LIPODRENE WILL CAUSE RAPID FAT AND WEIGHT LOSS WITH USAGE" (caps original).

187. The Lipodrene label for the 20-count SKU, Plaintiff's Ex. 55 at 2, contains the following express statement: "LIPODRENE WILL CAUSE RAPID FAT AND WEIGHT LOSS WITH USAGE" (caps original).

188. The Lipodrene blister pack for the two-count SKU, Plaintiff's Ex. 56 at 3, contains the following express statement: "LIPODRENE® WILL CAUSE RAPID FAT LOSS AND WEIGHT LOSS WITH USAGE" (caps in original).

189. The statements identified in Paragraphs 183-188 represent, expressly or by implication, that Lipodrene causes rapid or substantial loss of fat.

3. Representations That Lipodrene Affects Body Fat.

190. Contempt Defendants made numerous, unqualified representations that Lipodrene affects body fat, including by causing the burning or loss of fat, in the product's print ads, webpages, packaging, and labels. *See* FOF ¶ 191-196.

191. The two-page Lipodrene print ad, Plaintiff's Ex. 52 at 3, contains the following express statements:

a. "Is a Novel Fat Burner that Helps Melt Away Pounds!";

b. "REVOLUTIONARY FAT ASSASSIN™ (caps original);

c. "Lipodrene® is truly a Fat Assassin™ unlike any other 'Fat Burner'."

192. The multi-product "Diet & Energy and Muscle & Strength" print ad, Plaintiff's Ex. 44 at 3, contains the following express statements:

a. ". . . [T]he 'Gold Standard' by which all fat loss products are judged.";

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

c. "Lipodrene utilizes a multi-pathway approach to help you get 'Ripped Up' while preserving hard earned muscle. By preserving muscle mass during periods of fat loss, the 'fat burning' effect is dramatically amplified."

193. The Lipodrene hitechpharma.com webpage, Plaintiff's Ex. 53 at 3, contains the following express statements:

a. "Extremely Potent Thermogenic Intensifier";

b. "Lipodrene® not only remains Hi-Tech's flagship fat-burner, but is the Gold Standard in the weight loss industry for one simple reason . . . It Works!"; and

c. "Whether you want to simply transform your body into a leaner, more attractive one, or you want to get jacked and ripped to shreds, Lipodrene® is the right move to strip away fat and feel great all day!"

194. The Lipodrene label for the 100-count SKU, Plaintiff's Ex. 54 at 3-4, contains the following express statements:

a. "LIPODRENE WILL CAUSE RAPID FAT AND WEIGHT LOSS WITH USAGE." (caps original);

b. "DO NOT CONSUME UNLESS FAT LOSS AND WEIGHT LOSS ARE YOUR INTENDED RESULT" (caps original);

c. "Increases the metabolic rate, promoting thermogenesis (the burning of stored body fat)"; and

d. "Inhibits the absorption of dietary fats by acting as a lipase inhibitor."

195. The Lipodrene label for the 20-count SKU, Plaintiff's Ex. 55 at 2, contains the following express statements:

a. "LIPODRENE WILL CAUSE RAPID FAT AND WEIGHT LOSS WITH USAGE." (caps original);

b. "DO NOT CONSUME UNLESS FAT LOSS AND WEIGHT LOSS ARE YOUR INTENDED RESULT" (caps original).

196. The Lipodrene blister pack for the two-count SKU, Plaintiff's Ex. 56 at 3, contains the following express statements:

a. "LIPODRENE® WILL CAUSE RAPID FAT AND WEIGHT LOSS WITH USAGE." (caps original);

b. "DO NOT CONSUME UNLESS FAT LOSS AND WEIGHT LOSS ARE YOUR INTENDED RESULT (caps original);

c. (Under heading "Key Benefits of of [sic] Lipodrene"): "Increases the metabolic rate, promoting thermogenesis (the burning of stored body fat)"; and

d. (Under heading "Key Benefits of of [sic] Lipodrene"): "Inhibits the absorption of dietary fats by acting as a lipase inhibitor."

197. The statements identified in Paragraphs 191-196 represent, expressly or by implication, that Lipodrene affects body fat.

4. Representations That Lipodrene Affects Human Metabolism

198. Contempt Defendants made numerous, unqualified representations that Lipodrene affects human metabolism, including by causing an increase in the metabolic rate, in the product's webpage, packaging and labels. *See* FOF ¶¶ 199-202.

199. The Lipodrene hitechpharma.com webpage, Plaintiff's Ex. 53 at 3, contains the following express statement: "Extremely Potent Thermogenic Intensifier."

200. The Lipodrene label for the 100-count SKU, Plaintiff's Ex. 54 at 3-4, contains the following express statements:

a. "FOR ADVANCED APPETITE CONTROL and METABOLIC STIMULATION" (caps original); and

b. "Increases the metabolic rate, promoting thermogenesis (the burning of stored body fat)."

201. The Lipodrene label for the 20-count SKU, Plaintiff's Ex. 55 at 2, contains the following express statement: "FOR ADVANCED APPETITE CONTROL AND METABOLIC STIMULATION" (caps original).

202. The Lipodrene blister pack for the two-count SKU, Plaintiff's Ex. 56 at 3, contains the following express statements:

a. "FOR ADVANCED APPETITE CONTROL and METABOLIC STIMULATION!" (caps original); and

b. "Increases the metabolic rate, promoting thermogenesis (the burning of stored body fat)."

203. The statements identified in Paragraphs 199-202 represent, expressly or by implication, that Lipodrene affects human metabolism.

5. Representations That Lipodrene Affects Appetite

204. Contempt Defendants made numerous, unqualified representations that Lipodrene affects appetite, including by causing a decrease in appetite, in the product's packaging and labels. *See* FOF ¶¶ 205-207.

205. The Lipodrene label for the 100-count SKU, Plaintiff's Ex. 54 at 3-4, contains the following express statements:

a. "FOR ADVANCED APPETITE CONTROL AND METABOLIC STIMULATION" (caps in original); and

b. "Slows the absorption of serotonin, which helps in weight management by controlling food cravings and supressing [sic] the appetite."

206. The Lipodrene label for the 20-count SKU, Plaintiff's Ex. 55 at 2, contains the following express statement: "FOR ADVANCED APPETITE CONTROL and METABOLIC STIMULATION" (caps original).

207. The Lipodrene blister pack for the two-count SKU, Plaintiff's Ex. 56 at 3, contains the following express statements:

a. "FOR ADVANCED APPETITE CONTROL and METABOLIC STIMULATION!" (caps original); and

b. "Slows the absorption of serotonin, which helps in weight management by controlling food cravings and suppressing the appetite."

208. The statements identified in Paragraphs 205-207 represent, expressly or by implication, that Lipodrene affects appetite.

D. The Advertising And Sale Of Benzedrine

209. From January 1, 2009 through at least November 10, 2014, Contempt Defendants advertised Benzedrine using unsubstantiated, unqualified, causal efficacy claims. *See* FOF ¶¶ 210-228.

210. From at least September 2010 through at least November 2011, Hi-Tech, Wheat, and Smith disseminated print ads for Benzedrine that contain unsubstantiated, unqualified, causal efficacy claims through national magazines such as *Flex*, *Muscle & Fitness, MuscleMag International,* and *Muscular Development*. Plaintiff's Ex. 7 ¶ 9; Plaintiff's Ex. 8 ¶ 9; Plaintiff's Ex. 18 at 22-24; Plaintiff's Ex. 57.

211. Contempt Defendants also disseminated the unsubstantiated Benzedrine print ad through the website www.hitechpharma.com through early January 2014. 1/22/14 Trial Tr. at 56:18-57:5; *see also* 1/21/14 Trial Tr. at 29:24-30:19, 31:16-32:5, 42:8-43:10, 43:16-44:7; Plaintiff's Ex. 272 at 16.

212. From at least September 17, 2010 through January 21, 2014, Contempt Defendants advertised and offered Benzedrine for sale using unsubstantiated, unqualified, causal efficacy claims on the www.hitechpharma.com website. Plaintiff's Ex. 7 ¶ 10; Plaintiff's Ex. 8

¶ 10; Plaintiff's Ex. 18 at 22-23, 25-26; Plaintiff's Ex. 58; Plaintiff's Ex. 287; 1/22/14 Trial Tr. at 56:18-57:5; *see also* 1/21/14 Trial Tr. at 29:24-30:19, 31:16-32:5, 36:18-37:19, 42:8-43:10, 43:16-44:7.

213. From at least January 1, 2009 through November 10, 2014, Hi-Tech, Wheat, and Smith advertised Benzedrine through product packaging and labels that contain unsubstantiated, unqualified causal efficacy claims that are distributed both by Contempt Defendants directly and through retail outlets. Plaintiff's Ex. 7 ¶ 11; Plaintiff's Ex. 8 ¶ 11; Plaintiff's Exs. 59-60; Wheat Dep. at 47:21-48:2; Dkt. Nos. 672, 796.

1. Representations That Benzedrine Causes Rapid Or Substantial Loss Of Fat

214. Contempt Defendants made numerous, unqualified representations that Benzedrine causes rapid or substantial loss of fat in the product's print ad, webpage, and packaging. *See* FOF ¶¶ 215-217.

215. The full-page Benzedrine print ad, Plaintiff's Ex. 57 at 3, contains the following express statement: "ANNIHILATE THE FAT WHILE FIRING UP YOUR ENERGY!" (caps original).

216. The Benzedrine hitechpharma.com webpage, Plaintiff's Ex. 58 at 3, contains the following express statements:

a. "Benzedrine™ is a Hi-Tech Weight Loss & Energy Enhancement Supplement that will help you annihilate fat and speed things up!"; and

b. "Benzedrine™ simply blows fat away!"

217. The Benzedrine box for the 60-count SKU, Plaintiff's Ex. 59 at 3, contains the following express statement: "ANNIHILATE THE FAT WHILE FIRING UP YOUR ENERGY" (caps original).

218. The statements identified in Paragraphs 215-217 represent, expressly or by implication, that Benzedrine causes rapid or substantial loss of fat.

2. Representations that Benzedrine Affects Body Fat.

219. Contempt Defendants made numerous, unqualified representations that Benzedrine affects body fat, including by causing loss or burning of fat, in the product's print ad, webpage, and product packaging. *See* FOF ¶¶ 220-222.

220. The full-page Benzedrine print ad, Plaintiff's Ex. 57 at 3, contains the following express statements:

a. "ANNIHILATE THE FAT WHILE FIRING UP YOUR ENERGY!" (caps original);

b. "THE STRONGEST FAT BURNER/ENERGIZER EVER PRODUCED!" (caps original); and

c. "When Hi-Tech developed Benzedrine™, we were determined to create the most potent Fat Burner/Energizer known to man."

221. The Benzedrine hitechpharma.com webpage, Plaintiff's Ex. 58 at 3, contains the following express statements:

a. "Benzedrine™ is a Hi-Tech Weight-Loss & Energy Enhancement Supplement that will help you annihilate fat and speed things up!"; and

b. "Benzedrine™ simply blows fat away!"

222. The Benzedrine box for the 60-count SKU, Plaintiff's Ex. 59 at 3, contains the following express statement: "ANNIHILATE THE FAT WHILE FIRING UP YOUR ENERGY" (caps original).

223. The statements identified in Paragraphs 220-222 represent, expressly or by implication, that Benzedrine affects body fat.

3. Representations That Benzedrine Affects Appetite

224. Contempt Defendants made numerous, unqualified representations that Benzedrine affects appetite, including by causing a decrease in appetite, in the product's webpage, packaging, and labels. *See* FOF ¶¶ 225-227.

225. The Benzedrine hitechpharma.com webpage, Plaintiff's Ex. 58 at 3, contains the following express statement: "Unmatched Anorectic Activity to Manage Caloric Intake."

226. The Benzedrine box for the 60-count SKU, Plaintiff's Ex. 59 at 4, contains the following express statement: "THE FIRST ANORECTIC SUPPLEMENT EVER PRODUCED" (caps original).

227. The Benzedrine label for the 60-count SKU, Plaintiff's Ex. 60 at 3, contains the following statement: "THE FIRST ANORECTIC SUPPLEMENT EVER PRODUCED!" (caps original).

228. The statements identified in Paragraphs 225-227 represent, expressly or by implication, that Benzedrine affects appetite.

E. The Advertising and Sale of Stimerex-ES

229. From January 1, 2009 through at least November 10, 2014, Contempt Defendants advertised Stimerex-ES using unsubstantiated, unqualified, causal efficacy claims. *See* FOF ¶¶ 230-254.

230. From at least October 2010 through at least December 14, 2012, Hi-Tech, Wheat and Smith disseminated print ads for Stimerex-ES that contains unsubstantiated, unqualified, causal efficacy claims through national magazines such as *Flex*, *Muscle & Fitness*, *MuscleMag International,* and *Muscular Development*. Plaintiff's Ex. 7 ¶ 13; Plaintiff's Ex. 8 ¶ 13, Plaintiff's Ex. 18 at 27-30; Plaintiff's Ex. 20 at 4; Plaintiff's Ex. 32 at 8-10; Plaintiff's Ex. 44; Plaintiff's Ex. 61.

231. Contempt Defendants also disseminated the unsubstantiated Stimerex-ES print ads through the website www.hitechpharma.com through at least December 30, 2013. Plaintiff's Ex. 272 at 23-25.

232. From at least September 17, 2010 through January 21, 2014, Hi-Tech, Wheat, and Smith advertised and offered Stimerex-ES for sale using unsubstantiated claims through the www.hitechpharma.com website. Plaintiff's Ex. 7 ¶ 14; Plaintiff's Ex. 8 ¶ 14; Plaintiff's Ex. 18 at 27-28, 31-32;

Plaintiff's Ex. 62; Plaintiff's Ex. 288; 1/22/14 Trial Tr. at 56:18-57:5; *see also* 1/21/14 Trial Tr. at 29:24-30:19, 31:16-32:5, 36:18-37:19, 42:8-43:10, 43:16-44:7.

233. From at least January 1, 2009 through November 10, 2014, Hi-Tech, Wheat, and Smith advertised Stimerex-ES through product packaging and labels that contain unsubstantiated claims and that are distributed both by Contempt Defendants directly and through retail outlets. Plaintiff's Ex. 7 ¶ 15; Plaintiff's Ex. 8 ¶ 15; Plaintiff's Ex. 18 at 28; Plaintiff's Ex. 41 at 12-14; Plaintiff's Ex. 63-65; Wheat Dep. at 47:21-48:2; 1/22/14 Trial Tr. at 92:25-93:7; Dkt. No. 796.

1. Representations That Stimerex-ES Causes Rapid Or Substantial Loss Of Weight

234. Contempt Defendants made numerous, unqualified representations that Stimerex-ES causes rapid or substantial weight loss in the product's print ad, and webpage. *See* FOF ¶¶ 235-236.

235. The two-page Stimerex-ES print ad, Plaintiff's Ex. 61 at 3, contains the following express statements:

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

b. "THE LEAN MACHINE AKA: STIMEREX-ES®" [with visual depiction of an overweight woman walking through a device that looks like a metal detector attached to a bottle of Stimerex-ES, and emerging shapely and toned].

236. The Stimerex-ES hitechpharma.com webpage, Plaintiff's Ex. 62 at 3, contains the following express statements:

a. "Get Shredded and Melt the Pounds Away!"; and

b. "If you are looking for a fat burner to light you up so you can watch the pounds melt away . . . then Stimerex-ES® is just what you are looking for." (ellipses original).

237. The statements identified in Paragraphs 235-236 represent, expressly or by implication, that Stimerex-ES causes rapid or substantial loss of weight.

2. Representations That Stimerex-ES Causes Rapid Or Substantial Loss Of Fat

238. Contempt Defendants made numerous, unqualified representations that Stimerex-ES causes rapid or substantial fat loss in the product's print ads, webpage, and product packaging. *See* FOF ¶¶ 239-242.

239. The two-page Stimerex-ES print ad, Plaintiff's Ex. 61 at 3, contains the following express statement: "Stimerex-ES® is hardcore stimulant action who want their fat burner to light them up all day as their pounds melt away!"

240. The multi-product "Diet & Energy and Muscle & Strength" print ad, Plaintiff's Ex. 44 at 3, contains the following express statement: "Stimerex-ES will help you assassinate fat and speed things up!"

241. The Stimerex-ES hitechpharma.com webpage, Plaintiff's Ex. 62 at 3, contains the following express statement: "If you are looking for a fat burner to light you up so you can watch the pounds melt away . . . then Stimerex-ES is just what you are looking for" (ellipses original).

242. The Stimerex-ES blister pack for the two-count SKU, Plaintiff's Ex. 65 at 2, contains the following express statement, under the heading "Key Benefits

of Stimerex-ES": "High Performance Thermogenic Intensifier for Maximum Fat Loss."

243. The statements identified in Paragraphs 239-242 represent, expressly or by implication, that Stimerex-ES cause rapid or substantial loss of fat.

3. Representations that Stimerex-ES Affects Body Fat

244. Contempt Defendants made numerous, unqualified representations that Stimerex-ES affects body fat, including by causing the burning or loss of body fat, in the product's print ads, webpage, packaging, and labels. *See* FOF ¶¶ 245-250.

245. The two-page Stimerex-ES print ad, Plaintiff's Ex. 61 at 3, contains the following express statements:

a. "Hi-Tech offers the Strongest Fat Burner/Energizer to ever hit the market!";

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

c. "Stimerex-ES® – the King of Fat Burners™ . . . adds 25mg of ephedra extract to this revolutionary Fat Burner/Energizer!" (ellipses original).

246. The multi-product "Diet & Energy and Muscle & Strength" print ad, Plaintiff's Ex. 44 at 3, contains the following express statements:

a. "Stimerex-ES® is undeniably the most powerful, [sic] fat loss and energy boost formula ever created." and

b. "If you are looking for a fat-burner to light you up so you can watch the pounds melt away . . . then Stimerex-ES® is just what you are looking for" (ellipses original).

247. The Stimerex-ES webpage, Plaintiff's Ex. 62, contains the following express statements:

a. "The Ultimate Fat Burner Ever Created";

b. "Fat Burner/Energizer";

c. "Stimerex-ES® is designed as the ultimate fat burner/energizer."; and

d. "If you are looking for a fat burner to light you up so you can watch the pounds melt away . . . then Stimerex-ES® is just what you are looking for" (ellipses original).

248. The Stimerex-ES label for the 90-count SKU, Plaintiff's Ex. 63 at 3, contains the following express statement: "Stimerex-ES® (Extra Strength) w/ 25 mg Ephedra Extract Fat Burner/Energizer."

249. The Stimerex-ES label for the 20-count SKU, Plaintiff's Ex. 64 at 2, contains the following express statement: "Stimerex-ES (Extra Strength) w/ 25 mg Ephedra Extract Fat Burner/Energizer."

250. The Stimerex-ES blister pack for the two-count SKU, Plaintiff's Ex. 65 at 2, contains the following express statements:

a. "Stimerex ES® Fat Burner/Energizer";

b. (Under heading "Key Benefits of Stimerex-ES"): "High Performance Thermogenic Intensifier for Maximum Fat Loss"; and

c. (Under heading "Key Benefits of Stimerex-ES"): "Targets Fat Loss and Weight Loss in The Love Handles, Glutes, and Thighs."

251. The statements identified in Paragraphs 245-250 represent, expressly or by implication, that Stimerex-ES affects body fat.

4. Representations That Stimerex-ES Has Comparable Efficacy To Ephedrine-Containing Dietary Supplements.

252. Contempt Defendants made unqualified representations that Stimerex-ES has efficacy comparable to ephedrine-containing dietary supplements in the product's print ad. *See* FOF ¶ 253.

253. The two-page Stimerex-ES print ad, Plaintiff's Ex. 61 at 3, contains the following express statements:

a. "The benefits of ephedra are now 'Back in Black!'" [beneath a picture of the black, diamond shaped Stimerex-ES tablets]; and

b. "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."

254. The statements identified in Paragraph 253 represent, expressly or by implication, that Stimerex-ES provides benefits, performance, or efficacy comparable to ephedrine-containing dietary supplements.

IV. Contempt Defendants' Unqualified, Causal, Product-Specific Efficacy Claims For Fastin, Lipodrene, Benzedrine, And Stimerex-ES Are Unsubstantiated.

A. Contempt Defendants Are Required To Have Well-Controlled, Product-Specific, Randomized, Clinical Testing to Substantiate Their Unqualified, Causal Efficacy Claims.

255. The FTC presented testimony from Dr. Louis J. Aronne regarding what constitutes "competent and reliable scientific evidence" sufficient to substantiate Contempt Defendants' unqualified, causal efficacy claims. *See generally* 3/27/17 Trial Tr. at 42-125; 3/28/17 Trial Tr. at 4-24, 123-135.

256. The FTC also presented rebuttal testimony from Dr. Richard van Breemen responding to Contempt Defendants' contention that those in the "dietary supplement field" do not require well-controlled, product-specific, randomized clinical tests to substantiate unqualified, causal efficacy claims. *See* 4/5/17 Trial Tr. at 128-150.

1. Both Dr. Aronne And Dr. van Breemen Are Well-Qualified To Offer Testimony Regarding What Constitutes Competent And Reliable Scientific Evidence To Substantiate Contempt Defendants' Unqualified, Causal Efficacy Claims.

257. Dr. Aronne is well-qualified as an expert in the fields of weight loss and obesity, including the causes, prevention, consequences, and treatments thereof; the design, conduct, and analysis of clinical trials, including trials

to evaluate potential treatments for obesity or weight loss; and the statistical analysis of the results of clinical trials. *See* FOF ¶¶ 258-277.

258. Dr. Aronne is the Sanford I. Weill Professor of Metabolic Research and a clinical professor at Weill-Cornell Medical College. 3/27/17 Trial Tr. at 33:23-25; *see also* Plaintiff's Ex. 695 at 1. The Sanford I. Weill Professor of Metabolic Research is an endowed position. 3/27/17 Trial Tr. at 33:25-34:1, 34:9-15.

259. Dr. Aronne has served on the faculty of Weill-Cornell Medical College since 1986. Plaintiff's Ex. 580 ¶ 2; Plaintiff's Ex. 695 at 1. He is also an adjunct professor of medicine at Columbia University College of Physicians and Surgeons in the division of endocrinology. 3/27/17 Trial Tr. at 34:6-8; *see also* Plaintiff's Ex. 695 at 2.

260. When teaching advanced learners, residents, fellows, and other faculty members, the use of dietary supplements comes up on a regular basis in Dr. Aronne's faculty work. *See* 3/27/17 Trial Tr. at 40:23-41:3. Dr. Aronne and his colleagues are constantly evaluating the potential efficacy of compounds – including dietary supplements – to determine if they are appropriate for use as treatments for obesity and weight loss. *Id.* at 41:3-8.

261. Dr. Aronne is also the Director of the Comprehensive Weight Control Center at Weill Cornell Medical College, a multi-disciplinary center and division of endocrinology, metabolism, and diabetes that treats hundreds of overweight and obese patients. 3/27/17 Trial Tr. at 34:1-5; Plaintiff's Ex. 695 at 1; Plaintiff's Ex. 581 ¶ 12.

262. Dr. Aronne is a Doctor of Medicine, having received his degree from Johns Hopkins University School of Medicine in 1981. 3/27/17 Trial Tr. at 16-20; Plaintiff's Ex. 580 ¶¶ 2-3; Plaintiff's Ex. 695 at 1. He is licensed in New York and is an attending physician at New York Presbyterian Hospital. Plaintiff's Ex. 580 ¶ 2; Plaintiff's Ex. 695 at 2.

263. Prior to receiving his medical degree, Dr. Aronne earned a Bachelor's of Science in Biochemistry from Trinity College. 3/27/17 Trial Tr. at 34:16:-23; Plaintiff's Ex. 580 ¶ 3; Plaintiff's Ex. 695 at 1.

264. Dr. Aronne is certified by the American Board of Internal Medicine. 3/27/17 Trial Tr. at 34:24-35:1; Plaintiff's Ex. 580 ¶ 3; Plaintiff's Ex. 695 at 2.

265. Dr. Aronne is also a Fellow for the American College of Physicians. Plaintiff's Ex. 580 ¶ 3; Plaintiff's Ex. 695 at 3.

266. Dr. Aronne is currently a Fellow of The Obesity Society (TOS), the obesity research society for the United States, Mexico, and Canada. 3/27/17 Trial Tr. at 35:8-10; Plaintiff's Ex. 695 at 3. He served as that organization's President from 2004-2005, and its Vice President from January 2003 until October 2003. *See* 3/27/17 Trial Tr. at 35:11-16; Plaintiff's Ex. 580 ¶ 4; Plaintiff's Ex. 695 at 3.

267. Dr. Aronne also was Chair of The Obesity Society's Education Committee from 1998-2002 and Chair of the NIH Practical Guide Development Committee from 1998-2000. 3/27/17 Trial Tr. at 35:11-22; Plaintiff's Ex. 580 ¶ 4; Plaintiff's Ex. 695 at 3.

268. As Chairman of the Practical Guide Development Committee, Dr. Aronne edited the National Institute of Health's first guide to obesity treatment (titled *Practical Guide to the Identification, Evaluation and Treatment of Overweight and Obesity in Adults*), released in the year 2000. 3/27/17 Trial Tr. at 35:17-22; Plaintiff's Ex. 580 ¶ 4. That guide formed the basis for subsequent guidance, the most recent of which was released in 2013. 3/27/17 Trial Tr. at 35:23-25.

269. Dr. Aronne is currently the Chairman of the American Board of Obesity Medicine, having served in that capacity since January 2016. 3/27/17 Trial Tr. at 36:1-10; Plaintiff's Ex. 580 ¶ 5; Plaintiff's Ex. 695 at 3. He previously served as its Vice-Chairman from November 2013 through January 2016 and as a Director from January 2011 through November 2013. Plaintiff's Ex. 580 ¶ 5; Plaintiff's Ex. 695 at 3.

270. The American Board of Obesity Medicine is a certification body that has certified over 2,000 physicians (480 in the last year) in the field of obesity medicine – the most rapidly growing area of medicine. 3/27/17 Trial Tr. at 36:1-11.

271. Dr. Aronne has served as a principal or co-investigator on at least 40 clinical trials. 3/27/17 Trial Tr. at 36:14-21; *see also* Plaintiff's 695 at 4-6.

272. As a principal investigator, Dr. Aronne is involved in the design of the trials, supervision of the staff conducting the trials, and analysis of the trial's data. 3/27/17 Trial Tr. at 36:22-37:1.

273. Dr. Aronne's research focuses on the treatment of obesity, obesity-related health risks and the science of body weight regulation. Plaintiff's Ex. 580 ¶ 6.

274. He has made more than 100 invited presentations on obesity and related topics. Plaintiff's Ex. 580 ¶ 7; *see* 3/27/17 Trial Tr. at 37:23-38:2. He has authored, co-authored, or published numerous books, book chapters, abstracts, and more than 60 peer-reviewed journal articles. Plaintiff's Ex. 580 ¶ 7; *see also* 3/27/17 Trial Tr. at 37:7-10 (Dr. Aronne has more than 70 publications in total); Plaintiff's Ex. 695 at 7-13. Most of Dr. Aronne's publications are on subjects related to weight loss and obesity, including its causes, prevention, consequences, and treatment. Plaintiff's Ex. 580 ¶ 7.

275. Dr. Aronne served as an associate editor for the Journal of Obesity, which is the main obesity research journal for the United States, Canada, and Mexico. 3/27/17 Trial Tr. at 37:11-20. He served in that capacity for five years, during which he reviewed four papers per month. *Id.* In addition, he has served as both a peer reviewer and editor for a variety of journals, reviewing studies performed by others. *Id.*

276. Dr. Aronne also has specific experience with dietary supplements. As Director of the Comprehensive Weight Control Center at Weill Cornell Medical College, Dr. Aronne is involved in the study of a supplement currently seeking FDA approval. 3/27/17 Trial Tr. at 36:14-21; *see also*

Plaintiff's Ex. 581 ¶ 12. Dr. Aronne is also on the Board of Directors of two dietary supplement companies, MYOS RENS Technology, Inc. and Jamieson Labs. Plaintiff's Ex. 581 ¶ 17; *see also* 3/27/17 Trial Tr. at 38:8-19.

277. As Dr. Aronne explained, dietary supplements have a role to play in the weight loss process. *See* 3/28/17 Trial Tr. at 27:8-11, 135:1-20. Specifically, dietary supplements "could provide a greater amount of weight loss, enough weight loss to provide health benefit[s] and have other potential benefits to the population." 3/28/17 Trial Tr. at 27:8-11; *see also id.* at 135:1-20.

278. Dr. van Breemen is well-qualified as an expert in dietary supplements research and development, pharmacology, and pharmacognosy. *See* FOF ¶¶ 279-282.

279. Dr. van Breemen obtained a Ph.D. in pharmacology in 1985 and is currently the Matthias C. Lu Professor of Pharmacy, and a professor of medicinal chemistry and pharmacognosy, at the University of Illinois at Chicago ("UIC"). 4/5/17 Trial Tr. at 128:12-15; Defendants' Ex. 140 ¶¶ 2-3; Defendants' Ex. 140 at 26.

280. Classes taught by Dr. van Breemen include Survey of Research in Pharmaceutical Sciences, Research Techniques in Pharmacognosy, Structure Elucidation of Natural Products, and Advanced Pharmacognosy II. Defendants' Ex. 140 at 54-55.

281. Dr. van Breemen has served as the Director or co-Director of the UIC/NIH Center for Botanical Dietary Supplement Research since the Center's 1999 founding. 4/5/17 Trial Tr. at 129:1-4, 130:18-131:4; Defendants' Ex. 140 ¶ 2. The UIC Center is one of only three botanical centers supported by the National Institute of Health's Office of Dietary Supplements. 4/5/17 Trial Tr. at 131:5-11; Defendants' Ex. 140 ¶ 2.

282. Dr. van Breemen has authored over 300 peer-reviewed publications and books, over 200 of which relate to the research and development of dietary supplements or to methods of developing safe and effective supplements. 4/5/17 Trial Tr. at 133:17-24; Defendants' Ex. 140 at 27-52. His work has been cited twice by the NIH in its Annual Bibliography of Significant Advances in Dietary Supplement Research. 4/5/17 Trial Tr. at 133:25-134:8; Defendants' Ex. 140 at 34, 39.

2. Dr. Aronne Applied A Reliable Methodology To Determine That Well-Controlled, Product-Specific, Randomized Clinical Testing Is Required To Substantiate Contempt Defendants' Unqualified, Product-Specific, Causal Efficacy Claims.

283. In determining what constitutes "competent and reliable scientific evidence" sufficient to substantiate Contempt Defendants' unqualified, product-specific, causal efficacy claims, Dr. Aronne applied a reliable methodology that is based on well-accepted scientific principles in the fields of obesity, weight loss, and body weight regulation. *See* FOF ¶¶ 284-466.

284. Dr. Aronne looked specifically at what constitutes "competent and reliable scientific evidence" for weight-loss dietary supplements to substantiate the following types of claims: (1) claims that the products cause rapid or substantial weight loss; (2) claims that the products cause rapid or substantial fat loss; (3) claims that the products suppress appetite; (4) claims that the products increase metabolism; and (5) claims that the products affect body fat. 3/27/17 Trial Tr. at 43:5-10; Plaintiff's Ex. 580 ¶ 10.

285. In determining what constitutes "competent and reliable scientific evidence" for the products at issue, Dr. Aronne used the following definition: "tests , analyses, research, studies, or other evidence based on expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." 3/27/17 Trial Tr. at 45:8-17; Plaintiff's Ex. 580 ¶ 20.

286. Dr. Aronne applied this standard in evaluating Contempt Defendants' advertising claims for Fastin, Lipodrene, Benzedrine, and Stimerex-ES. 3/27/17 Trial Tr. at 45:8-17; Plaintiff's Ex. 580 ¶ 21.

287. Dr. Aronne testified that experts in the relevant areas – weight loss, obesity treatment, and body weight regulation – would include medical professionals (both practitioners and researchers), academics, and members of the relevant professional organizations. 3/27/17 Trial Tr. at 46:17-47:7; Plaintiff's Ex. 580 ¶ 21. Contempt Defendants' expert La Puma agreed that the relevant area included both obesity and weight loss. 3/30/17 Trial Tr. at 18:7-14; *see also id.* at 50:15-16, 50:24-51:1.

288. Dr. Aronne then testified that in the fields of weight loss, obesity treatment, and body weight regulation, experts would 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 to substantiate claims that a dietary supplement causes rapid or substantial weight or fat loss or affects human metabolism, appetite, or body fat." 3/27/17 Trial Tr. at 47:8-48:16; Plaintiff's Ex. 580 ¶ 21.

289. Dr. van Breemen explained that "experts in the fields of pharmacology and dietary supplements" require the same level of evidence required by experts in the field of weight loss to substantiate claims of dietary supplement efficacy: "appropriately-sized, product-specific, randomized, double-blind, and placebo-controlled clinical trials." Defendants' Ex. 140 ¶ 36; *see also* 4/5/17 Trial Tr. at 140:11-22.

a. The Necessity Of Human Clinical Trials

290. Dr. Aronne's testimony establishes that it is well-accepted in the fields of obesity, weight loss, and body weight regulation that in order to establish the efficacy of a product in humans, human clinical trials are necessary and that animal and in vitro studies are not sufficient, either alone or in combination. *See* FOF ¶¶ 291, 294, 298-303. That testimony is corroborated by the FTC's rebuttal expert Dr. Richard van Breemen and by Contempt Defendants' expert witnesses. *See* FOF ¶¶ 292-293, 295-297, 304-316.

291. Dr. Aronne testified that in order to substantiate claims about the efficacy of a product on humans, studies of the product's efficacy must be conducted on human subjects. 3/27/17 Trial Tr. at 48:20-24; Plaintiff's Ex. 580 ¶ 22. *In vitro* and animal studies are insufficient to substantiate efficacy claims. *See* 3/27/17 Trial Tr. at 48:20-50:23.

292. Dr. van Breemen further explained that "[o]nly human clinical trials can prove how the relative contributions from all known and unknown constituents of complex botanical dietary supplements affect the efficacy and safety of the finished product." Defendants' Ex. 140 ¶ 22.

293. As Dr. van Breemen testified, "Animal studies like other preclinical development assays have their place and can provide some useful information about safety, but they do not directly translate to efficacy in humans. . . . [E]xtrapolating the efficacy from an animal, laboratory animal model to humans is just – it's not enough." 4/5/17 Trial Tr. at 146:22-147:9.

294. Although *in vitro* studies may be of some value generally, in understanding certain biochemical reactions, such reactions of cells outside the body are not indicative of what will occur inside the human body, and cannot be extrapolated to humans. Plaintiff's Ex. 580 ¶ 22; *see also* 3/27/17 Trial Tr. at 48:25-49:3 ("An in vitro study . . . gives you insight into molecular mechanisms, but it doesn't tell you if something would actually cause weight loss."); *id.* at 49:20-50:25.

295. Contempt Defendants' expert, Timothy Gaginella, agreed that "the primary purpose of in vitro studies is to serve as a screening tool" for

"whether there's any reason to continue evaluating whatever substance you're looking at." Gaginella Tr. at 171:5-8.[5]

296. Gaginella agreed that there are situations in which a scientist might predict that "a particular substance is going to have a certain effect on humans, but it ultimately does not have that predicted effect." Gaginella Tr. at 172:12-21. Gaginella agreed that "you don't always know why the product doesn't have the effect that you predicted." *Id.* at 172:22-173:3.

297. Contempt Defendants' expert Matthew Lee also agreed that "not every substance for which there's a plausible mechanism of action demonstrates efficacy once it's administered to humans." 3/29/17 Trial Tr. at 76:4-7.

298. Dr. Aronne testified that it is well accepted by experts in the field that the results of *in vitro* studies cannot be generalized to human populations. 3/27/17 Trial Tr. at 49:17-25.

299. Dr. Aronne explained that animal studies are insufficient to substantiate efficacy claims because "there are many findings that come from animal

[5] "Gaginella Tr." refers to the transcript of the February 28, 2017 *de bene esse* deposition of Timothy Gaginella. The transcript was entered into evidence as Defendants' Ex. 405a.

studies that are not substantiated in human trials." 3/27/17 Trial Tr. at 48:20-24. That is because "animals are very different from humans." *Id.* As a result, they respond to treatments differently from humans with regard to efficacy. *Id.* at 50:1-6.

300. Dr. Aronne testified that, for example, mice have a lot of brown fat tissue and, as a result, lose weight easily in response to stimulants. *Id.* at 50:6-7; 3/28/17 Trial Tr. at 54:13-55:1 (explaining physiological differences between mice and humans "that make mice studies unreliable"). However, he explained, "[t]hat doesn't work in humans in nearly the same way." 3/27/17 Trial Tr. at 50:7-8; *see also* 3/28/17 Trial Tr. at 50:18-23 ("[I]f you have fat mice around, maybe you could make a claim that fat mice will have an increase in metabolic rate or fat mice will lose weight. But that does not translate into what happens in humans.").

301. Dr. Aronne further explained that there are hundreds of examples of interventions that looked great in animal studies but failed as a treatment due to a lack of effectiveness in humans or due to side effects that did not appear in the animal studies. *See* 3/28/17 Trial Tr. at 55:2-9.

302. Dr. Aronne testified that it is well accepted by experts in the fields of obesity treatment and body weight regulation that the results of animal trials cannot be generalized to humans. 3/27/17 Trial Tr. at 50:11-12, 16-23; *see also* Plaintiff's Ex. 580 ¶ 22.

303. Dr. Aronne's opinions regarding the necessity of human trials is well-supported in the academic and scientific literature, as demonstrated in his expert report. Plaintiff's Ex. 580 ¶ 22.

304. Dr. van Breemen agreed with Dr. Aronne that "animal models are imprecise indicators of human safety and efficacy." Defendants' Ex. 140 ¶ 26. "[T]he only way to provide efficacy on humans is to test the product on humans." *Id.*; *see also* 4/5/17 Trial Tr. at 146:22-147:9.

305. Contempt Defendants' expert Gaginella also agreed that "the primary purpose of animal studies is to serve as a screening tool" for "whether there's any reason to continue to evaluate whatever substance you're looking at." Gaginella Tr. at 170:15-24.

306. In fact, Gaginella admitted that "it's much more difficult to [extend] experimental results in animals with botanicals to humans than it is with

conventional drugs" because "in a botanical there are multiple components in addition to the active principles." Gaginella Tr. at 173:4-17.

307. Gaginella co-authored a book titled, "Phytotherapy: A Quick Reference Guide." Gaginella Tr. at 154:6-13; Plaintiff's Ex. 536 (excerpts); Defendants' Ex. 324 (whole book). Gaginella either wrote or reviewed all of the chapters in the book. Gaginella Tr. at 154:19-155:5. Gaginella did not disagree with anything in the book at the time that it was published. *Id.* at 155:6-20.

308. Chapter 6 of "Phytotherapy: A Quick Reference Guide" states: "Herbal medicines, before appearing in the pharmacy as a medicine, should be required to undergo pharmacological and toxicological testing on animals and clinical trials in humans." Plaintiff's Ex. 536 at 21.

309. Gaginella agreed that "only human studies can confirm that a specific substance actually has an effect in humans" and that "there are limitations on extrapolating data obtained in animal studies [and in in vitro studies] to humans." Gaginella Tr. at 170:25-171:4, 171:22-25, 177:20-23.

310. Contempt Defendants' expert Hoffman agreed that animal studies and in vitro studies are insufficient to support product efficacy claims. 3/30/17 Trial Tr. at 199:1-8.

311. Hoffman also agreed "that many dietary supplements have little to no scientific support in human subjects." 3/30/17 Trial Tr. at 217:6-21.

312. Contempt Defendants' expert La Puma agreed that "you can ***project*** what will ***likely*** happen physiologically in a person if you look at laboratory [i.e., in vitro] studies and animal studies, but you can only ***know*** what happens in a person by studying people." 3/30/17 Trial Tr. at 51:20-52:2 (emphasis added).

313. Lee agreed that there "are limitations . . . extrapolating from animal studies to how substances will act in humans" and that there "are limitations to extrapolating from in vitro studies to how substances will act in humans." 3/29/17 Trial Tr. at 72:13-19. In fact, Lee admitted, "you can't use animal studies to predict how a human is going to absorb a substance" because "in animal studies you bypass certain limitations that might exist in the human body." *Id.* at 73:13-19.

314. Lee agreed that to be sure that a substance actually has efficacy in humans, "you would need to test that substance in humans." *Id.* at 77:2-6. Lee also admitted that "[w]hen you're studying dietary supplements, human trials are the most reliable form of evidence." *Id.* at 78:2-4.

315. Similarly, Gaginella agreed "to know how a human would metabolize any of the products at issue in this case, you would need to test those products on humans." Gaginella Tr. at 174:10-14.

316. Chapter 6 of "Phytotherapy: A Quick Reference Guide," co-authored by Gaginella also states: "The chemical complexity of herbal medicines causes multiple effects in humans which must be tested only throughout [sic] human clinical trials." Plaintiff's Ex. 536 at 22.

b. The Necessity Of Placebo Controls And Double Blinding

317. Dr. Aronne's testimony establishes that in the fields of obesity, weight loss, and body weight regulation, it is well-accepted that studies must both be placebo-controlled and double-blinded in order to yield accurate and reliable results. *See* FOF ¶¶ 318-327. Dr. Aronne's testimony is corroborated by the testimony of Contempt Defendants' own experts. *See* FOF ¶¶ 328-334.

318. For a study to provide reliable evidence that a treatment actually has an effect, the study must include a control group. 3/27/17 Trial Tr. at 50:24-51:11; Plaintiff's Ex. 580 ¶ 23.

319. The need for a placebo-control group is well-accepted by experts in the field because it is well-established in medical research that, when human subjects know that a treatment is being tested to determine its effect on a condition, that knowledge can influence the results of a study in a way that is unrelated to the content of the treatment. This is also known as the "placebo effect." Plaintiff's Ex. 580 ¶ 23; *see also* 3/27/17 Trial Tr. at 50:24-51:11, 51:22-52:2, 52:21-53:2.

320. The placebo effect occurs due to psychological effects or subconscious changes in behavior resulting from the subject's belief that he or she is receiving a potentially potent treatment and from the investigator's bias in knowing that the subject has received the active treatment. 3/27/17 Trial Tr. at 50:24-51:11, 52:21-53:2; Plaintiff's Ex. 580 ¶ 23.

321. The use of a control group treated with a placebo – an inert pill that has no therapeutic effect and should cause no change in the condition being studied – mitigates the placebo effect. Plaintiff's Ex. 580 ¶ 23.

322. The placebo-control group should consist of people having the same characteristics as the people receiving the studied treatment. 3/27/17 Trial Tr. at 51:16-21, 52:3-8; Plaintiff's Ex. 580 ¶ 23.

323. The placebo-control group should receive treatment that appears, in all ways possible, identical to the active treatment being studied, including the instructions provided, number of visits, and treatment personnel. This is to ensure that neither the active treatment group nor the control group know which treatment they are receiving. This is known as "blinding." Plaintiff's Ex. 580 ¶ 24.

324. Similarly, where the investigator knows what treatment a subject is getting, that knowledge will bias the results of the study. 3/27/17 Trial Tr. at 52:21-53:2.; Plaintiff's Ex. 580 ¶ 25. As a result, the researchers also must be blinded with regard to which subjects are receiving the active treatment under study. 3/27/17 Trial Tr. at 52:21-53:2; Plaintiff's Ex. 580 ¶ 25. This is known as "double blinding" and is important to prevent the researchers and subjects from being influenced by a belief that the treatment will or will not be effective. 3/27/17 Trial Tr. at 52:21-53:2; Plaintiff's Ex. 580 ¶ 25. If during the course of the study, the treatment allocation is unmasked to

either the researcher or the subject, the double blinding is corrupted and bias may be introduced into the study. Plaintiff's Ex. 580 ¶ 25.

325. The necessity of double-blinding is well-accepted by experts in the field. 3/27/17 Tr. at 53:3-6.

326. Dr. Aronne's opinions regarding the necessity of placebo control groups and double blinding are well-supported in the academic and scientific literature, as demonstrated in his expert report. 3/27/17 Trial Tr. at 53:7-17; Plaintiff's Ex. 580 ¶¶ 23-26.

327. In fact, according to the textbook chapter "Understanding Research: A Clinician's Perspective of Basic, Applied, and Clinical Investigations," upon which Contempt Defendants' Expert Hoffman relies, "[c]ontrolled clinical trials, if properly conducted, are the ***only*** type of experiment that can extrapolate cause and effect." Defendants' Ex. 281 at 10 (Denegar and Jensen p. 99) (emphasis added); Defendants' Ex. 134 ¶ 15.

328. Contempt Defendants' expert Hoffman agreed that "to establish efficacy of a product for weight loss in humans, you would need a placebo-controlled study." 3/30/17 Trial Tr. at 223:6-12; *see also id.* at 200:22-201:6 (admitting

that "you need a placebo-controlled study in humans to substantiate an efficacy claim about a product in humans").

329. Chapter 6 of "Phytotherapy: A Quick Reference Guide", co-authored by Contempt Defendants' expert Gaginella, states: "When evaluating human studies, additional considerations come into play. It is essential to rule out a placebo effect." Plaintiff's Ex. 536 at 22.

330. Gaginella agreed that "it's essential to rule out a placebo effect when evaluating human studies" and that "a placebo group is necessary to rule out a placebo effect." Gaginella Tr. at 164:20-165:19.

331. Contempt Defendants' expert Lee agreed that use of a placebo control is a procedure "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." 3/29/17 Trial Tr. at 69:2-21; FOF ¶ 80 (definition of "competent and reliable scientific evidence").

332. Lee also agreed that double-blinding is a procedure "generally accepted in the profession to yield accurate and reliable results." 3/29/17 Trial Tr. at 69:22-25; FOF ¶ 80. In Lee's view, a study that is double-blinded is, all else being equal, more reliable than one that is not. *Id.* at 70:1-4. Lee admitted

that a double-blind placebo-controlled trial reduced the potential for bias on the part of both researchers and subjects. *Id.* at 70:25-71:12.

333. Lee also agreed that "a study that is carefully controlled, with blinding of subjects and researchers, is likely to yield more reliable results." Defendants' Ex. 132 ¶ 20.

334. Contempt Defendants' expert Gaginella agreed that "a study that is carefully controlled, with blinding of subjects and researchers, is likely to yield more reliable results." Gaginella Tr. at 166:14-19.

c. The Necessity Of Randomization

335. Dr. Aronne's testimony establishes that in the fields of obesity, weight loss, and body weight regulation, it is well-accepted that studies must be randomized in order to yield accurate and reliable results. FOF ¶¶ 336-338. Dr. Aronne's testimony is corroborated by Contempt Defendants' own expert witnesses. *See* FOF ¶¶ 339-341.

336. In order to have accurate and reliable results, subjects should be assigned to either the treatment group or the control group randomly – a process called "randomization." 3/27/17 Trial Tr. at 52:3-12; Plaintiff's Ex. 580 ¶ 26.

337. Randomization serves two purposes. First, it eliminates the possibility that researchers may consciously or subconsciously employ a "selection bias" regarding the assignment of individual subjects to particular groups. Plaintiff's Ex. 580 ¶ 26. Second, it allows the researchers to rely upon the statistical likelihood that the makeup of both treatment and placebo group will be statistically similar on all relevant characteristics (such as starting weight or caloric intake in a weight-loss study). *Id.*

338. Dr. Aronne's opinions regarding the necessity of randomization are well-accepted by experts in the field and well-supported in the academic and scientific literature, as demonstrated in his expert report. 3/27/17 Trial Tr. at 52:13-15, 53:7-17; Plaintiff's Ex. 580 ¶ 26.

339. Contempt Defendants' expert Lee agreed that randomization is a procedure "generally accepted in the profession to yield accurate and reliable results." 3/29/17 Trial Tr. at 69:14-17; FOF ¶ 80 (definition of "competent and reliable scientific evidence").

340. Contempt Defendants' expert Hoffman agreed that "most studies should be conducted using randomization [into] placebo and experimental groups." 3/30/17 Trial Tr. at 222:12-16.

341. Contempt Defendants' expert La Puma agreed that it is "typical and not uncommon" for studies to describe in their design how the study was randomized. 3/30/17 Trial Tr. at 91:18-25. He also admitted that a study is entitled to greater weight if the report described the manner in which the study is randomized because "if the author can talk about the kind of randomization technique that was used, then that often helps the reader understand whether [the study] was done seriously." 3/30/17 Trial Tr. at 92:1-6.

d. The NecessityOof Sufficiently-Sized Studies

342. Dr. Aronne's testimony establishes that it is well-accepted in the fields of obesity, weight loss, and body weight regulation that studies must be sufficiently sized in order to yield accurate and reliable results. FOF ¶¶ 343-348, 350-355. Dr. Aronne's testimony is corroborated both by FTC rebuttal expert Richard van Breemen and by Contempt Defendants' own expert witnesses. FOF ¶¶ 349, 356-361.

343. In order to yield accurate and reliable results, studies should test enough subjects to permit the conclusion that any measured effect is reliable and generalizable. *See* Plaintiff's Ex. 580 ¶ 27.

344. The size of a study will differ depending on the purpose of the study. 3/27/17 Trial Tr. at 53:18-24. For example, a study looking solely at the efficacy of a substance may be smaller than one seeking to prove the safety of a substance. *Id.*

345. Appropriate study size is determined by what is known as a "power" calculation. Plaintiff's Ex. 580 ¶¶ 27-28. Power is the likelihood that a study will detect an effect when there is an effect to be detected. *Id.*

346. Power is affected chiefly by the size of the effect and the size of the sample being used to detect it. Plaintiff's Ex. 580 ¶¶ 27-28. Bigger effects are easier to detect than smaller effects, while larger samples are more sensitive than smaller samples. *Id.*; *see also* 3/28/17 Trial Tr. at 95:8-9 (explaining that power calculation depends on what variable is being measured). The more participants in a study the greater the probability of detecting a real treatment effect. Plaintiff's Ex. 580 ¶¶ 27-28.

347. Small studies with low power and few participants are frequently discredited as the findings are deemed unreliable. Plaintiff's Ex. 580 ¶ 27. In such studies, the finding could be occurring at random even though the

results appear to be statistically significant. 3/27/17 Trial Tr. at 53:25-54:9. Such studies are considered "underpowered." *Id.*

348. Dr. Aronne explained that small studies have a low probability of finding true effects, and they demonstrate an exaggerated estimate of the magnitude of the effect when a true effect is discovered. Plaintiff's Ex. 580 ¶ 27; *see also* 3/27/17 Trial Tr. at 53:25-54:9. 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. Plaintiff's Ex. 580 ¶ 27; *see also* 3/27/17 Trial Tr. at 54:10-19; 3/28/17 Trial Tr. at 119:5-13 (noting that in a study of 10-12 people, "the effect of one or two people can bias the result").

349. Contempt Defendants' expert Heuer agreed that "[o]n a study with very small numbers" the results from one subject can alter the outcome of the entire study. 4/4/17 Trial Tr. at 142:16-18.

350. A study may also be underpowered if it starts with the number of participants called for by the power calculation, but during the course of the study subjects drop out. 3/27/17 Trial Tr. at 54:20-25. Dr. Aronne

explained that weight-loss studies have a fairly high dropout rate. 3/28/17 Trial Tr. at 67:18-21.

351. The necessity of appropriately-sized trials is one that is shared by experts in the field. 3/27/17 Trial Tr. at 55:1-3.

352. Dr. Aronne's opinion that appropriately-sized trials are necessary is well-supported in the scientific and academic literature. *See* 3/27/17 Trial Tr. at 55:4-5; Plaintiff's Ex. 580 ¶¶ 27-28.

353. In order to demonstrate efficacy for weight loss for a dietary supplement, Dr. Aronne testified that 30 subjects per arm would be the minimum number of subjects required. *See* 3/27/17 Trial Tr. at 55:6-17. Dr. Aronne further explained that the number of subjects necessary to have a sufficiently-sized study depends on the number that will allow a researcher to maintain statistical power while allowing for the fact that some subjects will drop out of the study. 3/28/17 Trial Tr. at 37:14-38:1.

354. Because some side effects only show up infrequently, in order to determine the safety of a dietary supplement, more participants are often required. *See* 3/27/17 Trial Tr. at 55:6-17; Plaintiff's Ex. 580 ¶ 29. However, that does not impact the number of subjects necessary to

demonstrate the efficacy of the supplement. 3/27/17 Trial Tr. at 56:3-11; Plaintiff's Ex. 580 ¶ 29.

355. Dr. Aronne's expert reports in this case have consistently contrasted the larger studies necessary to identify side effects (which could require hundreds or thousands per arm) with those looking to determine efficacy alone (which generally require 20 to 40). Defendants' Ex. 137 at 8; Plaintiff's Ex. 580 ¶ 29; Plaintiff's Ex. 581 ¶ 50.

356. Dr. van Breemen also explained that "appropriately sized" clinical trials are necessary to substantiate dietary supplement efficacy claims. Defendants' Ex. 140 ¶ 14.

357. Dr. van Breemen further explained that the number of subjects necessary will "depend upon the outcomes to be measured, how they're going to be measured, what the expected uncertainty might be about those measurements, how well defined they are, whether they're subjective or objectively observable." 4/5/17 Trial Tr. at 168:9-169:5.

358. Dr. van Breemen, like Dr. Aronne, testified that a power calculation was the proper means by which to determine how many subjects are necessary in a study: "[T]he power calculation is the calculation that takes into

account all the variables and enables you to determine how many subjects would be required to achieve an outcome which is reliable." 4/5/17 Trial Tr. at 169:9-19.

359. Contempt Defendants' expert Hoffman agreed that small trials present a greater risk of false positives than do larger trials. 3/30/17 Trial Tr. at 205:18-24. Hoffman admitted that because of the risk of false positives, "it's important to conduct several studies in order to prove efficacy." *Id.* at 205:25-206:8.

360. Contempt Defendants' expert Lee agreed that, all else being equal, a study with a larger sample size should be given more weight than one with a small sample size. 3/29/17 Trial Tr. at 70:5-10.

361. Although Contempt Defendants' expert Gaginella attempted to change his testimony at his *de bene esse* deposition, he agreed, at his discovery deposition, that the "the only way to be certain that the products at issue in this litigation have effects on body weight regulation" would be "large randomized double-blind placebo controlled trial[s]." Gaginella Tr. at 175:5-176:12.

e. The Necessity Of Appropriate Duration

362. Dr. Aronne's testimony establishes that it is well-accepted in the fields of obesity, weight loss, and body weight regulation that studies must be of an appropriate duration in order to yield accurate and reliable results sufficient to substantiate unqualified claims of efficacy for weight loss, fat loss, metabolism enhancement, and appetite suppression. FOF ¶¶ 363-375. Dr. Aronne's testimony is corroborated by Contempt Defendants' own expert witnesses. FOF ¶¶ 376-382.

363. To provide reliable scientific evidence that any observed effect has lasting character, the studies must be of sufficient duration. 3/27/17 Trial Tr. at 58:21-59:7; Plaintiff's Ex. 580 ¶ 30.

364. Dr. Aronne testified that based on his review of innumerable weight-loss studies, 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. 3/27/17 Trial Tr. at 58:21-59:11; Plaintiff's Ex. 580 ¶ 30.

365. Dr. Aronne further explained that experts in the field require at least six-month studies because "studies of shorter duration may demonstrate

weight results that are transient and may not be sustained beyond a few weeks." 3/28/17 Trial Tr. at 62:7-10.

366. Dr. Aronne testified that weight loss is a complicated process that is more difficult than it first appears. 3/27/17 Trial Tr. at 45:18-21. Specifically, he testified that there is a growing body of evidence that weight gain of any type and being overweight are associated with changes in nerves in the brain that conduct signals between fat cells, the stomach, the intestines, and the rest of the brain. *Id.* at 45:21-25. Because of these changes, when people try to lose weight, a resistance mechanism kicks in, making it difficult to lose weight. *Id.* at 45:25-46:2; *see also id.* at 61:19-62:6 (testifying that when metabolism increases acutely the body compensates by increasing appetite, preventing weight loss).

367. Dr. Aronne illustrated this testimony with the example of the hormone Leptin. *See* 3/27/17 Trial Tr. at 46:9-16. When a person loses weight, their fat cells produce Leptin in smaller quantities. *Id.* at 46:11-13. As a result, the person loses a sense of fullness and his or her metabolism is dramatically reduced, stopping their weight loss. 3/27/17 Trial Tr. at 46:13-16.

368. Dr. Aronne further testified that although a caloric deficit is necessary for weight loss, these compensating mechanisms slow down the rate of weight loss, ultimately causing a plateau. 3/27/17 Trial Tr. at 46:3-8.

369. An appropriately-sized six-month product-specific study to determine the efficacy of a substance can be accomplished in approximately one year from patient enrollment to the completion of testing, and no longer than two years from study design through the completion of the data analysis. Plaintiff's Ex. 581 ¶ 51; *see also* 3/27/17 Trial Tr. at 74:15-23.

370. Studies that are shorter than six months may demonstrate weight-loss results that are solely transient and are not sustained beyond a few weeks. Plaintiff's Ex. 580 ¶ 31; Plaintiff's Ex. 581 ¶ 47; *see also* 3/27/17 Trial Tr. at 59:12-15 (testifying that "[i]t's very difficult" to draw any conclusions regarding weight loss based on shorter studies.").

371. Dr. Aronne testified that experts in the field would not consider an eight-week study of weight loss to be a "long term" study. 3/27/17 Trial Tr. at 59:19-24.

372. Dr. Aronne testified that examples of Prozac and Zoloft illustrate this principle. 3/27/17 Trial Tr. at 60:9-18; Plaintiff's Ex. 581 ¶ 23. Both

substances were hypothesized to have efficacy for weight loss, and short-term studies supported that hypothesis. 3/27/17 Trial Tr. at 60:9-18; Plaintiff's Ex. 581 ¶ 23. However, longer duration, randomized, placebo-controlled studies demonstrated that people who initially lost weight on these substances regained it with longer-term use. 3/27/17 Trial Tr. at 60:9-18; Plaintiff's Ex. 581 ¶ 23. Thus, both products were rejected as efficacious weight-loss aids. 3/27/17 Trial Tr. at 60:9-18; Plaintiff's Ex. 581 ¶ 23.

373. Dr. Aronne testified that acute metabolic studies – studies where measurements are made over a few hours – cannot be extrapolated to longer periods of time. 3/27/17 Trial Tr. at 59:25-60:6; *see also* Plaintiff's Ex. 581 ¶ 47 (explaining that the results of acute metabolic studies cannot be extrapolated beyond the duration of the test). In other words, if a metabolic study lasts for three hours in duration, it cannot substantiate a claim of metabolic effect over a greater-than-three-hour period. Plaintiff's Ex. 581 ¶ 47.

374. Dr. Aronne's opinion that acute studies cannot be extrapolated to longer periods of time is well-accepted by experts in the field. 3/27/17 Trial Tr. at 60:4-8.

375. Dr. Aronne's opinion that acute studies cannot be extrapolated to longer periods of time is well-supported in the academic and scientific literature, as demonstrated in his expert report. Plaintiff's Ex. 580 ¶¶ 30-31.

376. Contempt Defendants' expert Jacobs admitted "if you take the acute study by itself, we don't know what the prolonged effect would be." 4/3/17 Trial Tr. at 76:2-3.

377. Contempt Defendants' expert Heuer admitted that you cannot determine whether actual weight loss occurs based on an acute study. 4/4/17 Trial Tr. at 65:4-7.

378. Contempt Defendants' expert Gaginella agreed that without further testing, "you can only ***hypothesize***" that an effect seen in an acute test will continue over time. Gaginella Tr. at 170:7-11 (emphasis added). Gaginella also admitted that "to evaluate the effect of a product beyond the acute time frame, you would need to test beyond the acute time period." *Id.* at 170:2-6.

379. Contempt Defendants' expert Hoffman agreed that "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***." 3/30/17 Trial Tr. at 207:2-6 (emphasis added). Hoffman also agreed that it was "very correct" that "one reason you can't extrapolate is because things might happen physiologically that could reduce the effect of a substance over time." *Id.* at 207:7-10.

380. Hoffman also explained that if a product increases metabolism acutely, "I wouldn't extrapolate to weight loss." 3/30/17 Trial Tr. at 206:19-24.

381. Hoffman admitted, in reference to one of the Meltdown studies upon which Contempt Defendants rely (Defendants' Ex. 107), that it would be "***incorrect***" to extrapolate the results of a six-hour study to six days, six weeks, or six months. 3/30/17 Trial Tr. at 213:3-19 (emphasis added).

382. Contempt Defendants' expert Lee explained in his expert report that "a study of longer duration can provide better evidence that the claimed effect will persist." Defendants' Ex. 132 at 71:20-24.

f. The Necessity Of Product-Specific Testing

383. Dr. Aronne's testimony establishes that it is well-accepted in the fields of obesity, weight loss, and body weight regulation that in order to yield accurate and reliable results concerning the efficacy of a product, product-specific testimony is necessary. FOF ¶¶ 384-394, 397-398. Dr. Aronne's testimony is corroborated by both FTC rebuttal expert Dr. van Breemen and by Contempt Defendants' own expert witnesses. FOF ¶¶ 395-396, 399-407.

384. In order to substantiate a claim or claims for what effect a product has, it is important that the study tests the product itself – not just the constituent ingredients – on the population upon which it is intended to be used, at the dosage that the product is claimed to cause the effect. Plaintiff's Ex. 580 ¶¶ 21, 32.

385. Dr. Aronne 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. 3/27/17 Trial Tr. at 68:19-25 (testifying that "there are interactions between compounds that

could be contained within a product that would produce uncertain results"); Plaintiff's Ex. 580 ¶ 33.

386. The necessity of product-specific testing to demonstrate the efficacy of a dietary supplement is a view that is widely-accepted among experts in the fields of obesity, weight loss, and body weight regulation. 3/28/17 Trial Tr. at 124:4-18, 124:25-125:4.

387. The necessity of product-specific testing to demonstrate the efficacy of a dietary supplement is a view that is well-supported in the academic and scientific literature, as demonstrated in Dr. Aronne's expert report. Plaintiff's Ex. 580 ¶¶ 32-36.

388. Product-specific testing is essential to assess any confounding factors or antagonistic effects. 3/27/17 Trial Tr. at 69:1-15 ; Plaintiff's Ex. 580 ¶ 35.

389. Confounding occurs when a causal relationship between two items is biased due to a common cause that is unaccounted for. Plaintiff's Ex. 580 ¶ 35; *see also* 3/27/17 Trial Tr. at 69:1-15.

390. Dr. Aronne explained that confounding occurs, for example, when a combination (ingredient A + ingredient B) was reported to promote weight loss in a study, while ingredient C was also part of the combination and

contributing to the weight loss observed. The weight loss would be misattributed, and this would confound the results of the study. Plaintiff's Ex. 580 ¶ 35. Accordingly, a product made up of multiple compounds must be studied as a whole. *See* 3/27/17 Trial Tr. at 69:1-15

391. 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 "[y]ou really don't know what the effectiveness is going to be, again, because you have an extra component." 3/27/17 Trial Tr. at 69:22-70:2.

392. The concept of confounding is one that is well-accepted by experts in the fields of obesity and weight management. *See* 3/27/17 Trial Tr. at 69:16-21.

393. Antagonistic effects occur when two or more agents in combination have an overall effect that is less than the sum of their individual effects. Plaintiff's Ex. 580 ¶ 36.

394. For example, Dr. Aronne testified that in the weight control context, a combination of two drugs were tested and the subjects did not experience the additional weight loss that researchers expected. *See* 3/27/17 Trial Tr.

at 70:11-23 ("The prediction was that one plus one would equal two, but it was not the case.")

395. Similarly, Dr. van Breemen explained that Citrus aurantium, an ingredient in the Hi-Tech products, inhibits an enzyme responsible for metabolizing over half of all drugs and natural products. Defendants' Ex. 140 ¶ 22.

396. Contempt Defendants' expert Gaginella agreed that "to know whether there are antagonistic effects in a combination of ingredients, you need to test that combination of ingredients." Gaginella Tr. at 178:5-9. He also agreed that "ingredients in a product might interfere with each other even though that hadn't been predicted." *Id.* at 177:24-178:3.

397. Dr. Aronne also explained that you cannot assume based on a mechanism of action that a combination of ingredients will have a synergistic effect with one another. 3/27/17 Trial Tr. at 70:24-71:1. A synergistic effect is where a combination of ingredients works better than the sum of the effects of the ingredients administered individually. *Id.* at 71:8-12 ("It would be one plus one equals three").

398. In order to determine whether a synergistic effect occurs, Dr. Aronne explained that you would have to test the product knowing the weight loss

caused by each of the ingredients, and then determine whether the combination product actually demonstrated synergy. 3/27/17 Trial Tr. at 71:3-7.

399. Dr. van Breemen agreed with Dr. Aronne that studies of ingredients in a dietary supplement are insufficient to support claims about the efficacy of the supplement as a whole. 4/5/17 Trial Tr. at 142:12-143:16; Defendants' Ex. 140 ¶ 20.

400. In particular, Dr. van Breemen explained that "[s]cientists actively working in the dietary supplement field, myself included, believe that identifying active ingredients in a complex mixture that interact with a particular pharmacological target is an important part, but only part, of the total evidence that spans preclinical studies through clinical evaluation of efficacy and safety." Defendants' Ex. 140 ¶ 21.

401. Dr. van Breemen concluded that "[c]learly, mixtures of ingredients can have very different effects than those of individual ingredients." Defendants' Ex. 140 ¶ 24. He explained that this is especially true of dietary supplements because of the "chemical diversity and complexity of botanical dietary supplements" caused by "the presence of plant

secondary metabolites." *Id.* ¶ 17; *see also* 4/5/17 Trial Tr. at 149:3-150:11 ("[W]e don't understand yet or know all of the secondary metabolites of all the plants that are being used in botanical dietary supplements today, and therefore there's no way to extrapolate from interaction studies with a few of those compounds [to] what might happen if you put all of them together.").

402. Contempt Defendants' expert Lee agreed that predictions made by pharmacologists regarding the effect that a substance will have on humans sometimes turn out to be wrong when the substance is tested in humans. 3/29/17 Trial Tr. at 75:10-23.

403. Contempt Defendants' expert Hoffman considers the Hi-Tech products "combination products" because they have multiple ingredients. 3/30/17 Trial Tr. at 188:13-20, 223:13-17.

404. Although Hoffman attempted to walk back his previous testimony at trial, he previously admitted, at both his deposition in this case and a deposition in an unrelated case, that "when you have a combination product, you can't draw conclusions unless you're testing the combination product itself." 3/30/17 Trial Tr. at 224:18-23, 224:24-225:17.

405. Similarly, although Contempt Defendants' expert La Puma attempted to change his testimony at trial, at his deposition he previously admitted that it is "difficult to identify the single ingredient effect in any dietary supplement that's a combination." 3/30/17 Trial Tr. at 52:3-53:5.

406. La Puma further admitted that "of course" the combination of ingredients in a substance matters. 3/30/17 Trial Tr. at 53:7-9.

407. Contempt Defendants' expert Jacobs wrote in a non-litigation context, prior to being engaged as an expert, that "[I]t is acknowledged that ***the effects*** of any multi-ingredient nutritional supplement product ***will be specific to [that] particular combination of ingredients***." Plaintiff's Ex. 596 at SUP003589 (emphasis added); *see also* Plaintiff's Ex. 598 at 9 (emphasis added); 4/3/17 Trial Tr. at 165:25-167:21.

408. Dr. Aronne's testimony regarding the inability to extrapolate from one combination of ingredients to another is supported by Contempt Defendants' own reliance materials. *See* FOF ¶¶ 409-412.

409. For example, Contempt Defendants rely on a study, by Zenk, of a product called Lean System 7 as part of their substantiation for the claims for their products. *See* Defendants' Ex. 225; *see also* Defendants' Ex. 103 at 4

(identifying Lean System 7 study as one of the "Studies Relied On By Hi-Tech Pharmaceuticals"). The Lean System 7 study was an 8-week study in which 47 subjects enrolled and 35 completed the study. 3/30/17 Trial Tr. at 93:20-94:8; *see also* Defendants' Ex. 225 at 1. The endpoints of the study included body weight, body mass index, and body fat. 3/30/17 Trial Tr. at 94:9-15; *see also* Defendants' Ex. 225 at 1.

410. Lean System 7 contains seven ingredients, including an ingredient not present in the Hi-Tech products, called 7-Keto. 3/30/17 Trial Tr. at 94:19-23. Prior to the Zenk study, two studies had been conducted on 7-Keto alone and showed significant results for weight and fat loss when that single ingredient was compared to placebo. *See* 3/30/17 Trial Tr. at 96:19-97:16; *see* Defendants' Ex. 225 at 2. After the 7-Keto studies were performed, the makers of Lean System 7 added additional ingredients, including caffeine (in the form of guarana) and citrus aurantium, specifically to "take advantage of the thermogenic attributes of these ingredients to create a synergistic combination for increasing [resting metabolic rate], enhancing weight and fat loss, and improving body composition during a program of diet and exercise." Defendants' Ex. 225

at 2; *see also* 3/30/17 Trial Tr. 95:6-10, 95:15-18, 96:17-97:17-98:7. In other words, Lean System 7 was formulated because the manufacturers thought there would be synergy between the ingredients that enhanced weight and fat loss. 3/30 Trial Tr. at 98:8-14; *see also* Defendants' Ex. 225 at 2.

411. However, despite this, the study found that Lean System 7 did not cause greater weight loss than placebo. Defendants' Ex. 225 at 4. In fact, the p value for weight loss was .93, which means that there is a 93 percent chance that any body weight lost in the test group, as compared to the placebo group, was due to random chance. *See* 3/30/17 Trial Tr. at 99:21-100:3; *see also* Defendants' Ex. 225 at 4. Similarly, the study found Lean System 7 did not cause greater fat loss than placebo. *See* Defendants' Ex. 225 at 4. Specifically, the p value for fat loss was .47, meaning that there is a 47 percent chance that any loss of body fat in the test group, as compared to the placebo group, was due to random chance. 3/30/17 Trial Tr. at 101:7-10. The study also found that Lean System 7 did not cause a greater reduction in body mass index (BMI) than placebo. *See* Defendants' Ex. 225 at 4. Specifically, the p value for BMI was .93, meaning there was a 93

percent chance that any change in BMI in the test group, as compared to the control group, was due to random chance. 3/30/17 at 101:24-102:2.

412. Contempt Defendants' expert La Puma admitted that he could not rule out that the caffeine or the citrus aurantium in the Lean System 7 antagonized the Keto-7, stating "[e]verything is possible," and further admitted that this is because the product was comprised of "seven different ingredients." 3/30/17 Trial Tr. at 104:10-17.

g. The Necessity Of Dosage-Specific Testing

413. Dr. Aronne's testimony establishes that in the fields of obesity, weight loss, and body weight regulation, in order to yield accurate and reliable results, the products must be tested at the same dosage at which they will be ingested. FOF ¶¶ 414-419. Dr. Aronne's testimony is corroborated by Contempt Defendants' own expert witnesses and by the very studies on which they rely as substantiation. FOF ¶¶ 420-424.

414. The studies of the product must involve the same dosage of the product for which the product claims are made because all dietary supplements have a dose-response relationship. Plaintiff's Ex. 580 ¶ 37.

415. Dr. Aronne explained that dosage-specific testing is "crucial" because higher or lower dosages of a product will not result in the same efficacy as a particular tested dosage. 3/27/17 Trial Tr. at 71:13-19.

416. A dose-response relationship measures the relationship between the quantity of a substance and its overall effect on an organism. Plaintiff's Ex. 580 ¶ 37.

417. Dr. Aronne explained that you cannot extrapolate the results of a test of a substance at a high dosage to lower dosages because "it could be that there's a threshold effect so the efficacy only occurs beyond a certain dose." 3/27/17 Trial Tr. at 71:20-25. For example, 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. Plaintiff's Ex. 580 ¶ 37. To the contrary, 5 grams might be the threshold amount needed to cause *any* effect. *Id.* 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. *Id.*

418. The necessity of dosage-specific testing is well-accepted in the field. 3/27/17 Trial Tr. at 72:1-3.

419. The necessity of dosage-specific testing is supported by academic and scientific literature in the fields of obesity and weight management. 3/27/17 Trial Tr. at 72:6-8; Plaintiff's Ex. 580 ¶ 37.

420. Contempt Defendants' expert Hoffman agreed that "when making a claim based on scientific testing, . . . the testing should be done on a similar dosage of the product that you're talking about." 3/30/17 Trial Tr. at 198:3-7.

421. At his deposition, Hoffman also agreed that "a problem with many companies" is that they "rely exclusively on research which is conducted using key ingredients within the product of sale[,] rather than the actual finished product[,] often at dosages that are much higher than what is used in the actual product of sale." 3/30/17 Trial Tr. at 221:10-22. Hoffman also agreed that the use of ingredient studies is a "shortcoming." *Id.* at 221:23-222:11. At trial, Hoffman tried to change his testimony, declaring that he "would ***assume***" that the effects observed in the

Meltdown studies would be the "the same or enhanced in the Hi-Tech product." *Id.* at 220:6-13 (emphasis added).

422. Hoffman has written that "[c]omparisons between weight loss supplements need to be performed carefully considering the large variability seen in ingredients or different concentrations of ingredients." Plaintiff's Ex. 528 at 3; 3/30/17 Trial Tr. at 211:6-13.

423. Chapter 9 of "Phytotherapy: A Quick Reference Guide", co-authored by Contempt Defendants' expert Gaginella, states: "[I]t is well known that herbal medicines must be used in a specific type of formulation (dosage form) in order to achieve the desired results." Plaintiff's Ex. 536 at 45.

424. In one of the Meltdown studies relied upon by Contempt Defendants as substantiation for their efficacy claims, Bloomer writes that many dietary supplements used for weight or fat loss "have little to no scientific support in human subjects . . . . Specifically, many products rely exclusively on research which is conducted using the 'key ingredient' within the product of sale, rather than the actual finished product, often at dosages that are much higher than what is used in the actual product of sale." Bloomer described this as a "shortcoming." Defendants' Ex. 107 at 2.

h. The Necessity Of Appropriate Endpoints

425. Dr. Aronne's testimony establishes that it is well-accepted in the fields of obesity, weight loss, and body weight regulation, that in order to yield accurate and reliable results, the studies must examine the appropriate endpoints for the parameter being tested. FOF ¶¶ 426-429, 433-439 . Dr. Aronne's testimony is corroborated by the testimony of Contempt Defendants' own expert witnesses. FOF ¶¶ 430-432, 440-443 .

i. Endpoints for Weight Loss

426. In order to determine whether a product is efficacious for causing weight loss, change in weight is the appropriate endpoint that should be measured in the study. 3/27/17 Trial Tr. at 60:19-61:3.

427. Dr. Aronne testified that one cannot determine whether weight loss is occurring or will occur based on a study of purported metabolic endpoints because the body compensates for increases in metabolism in ways that are designed to prevent weight loss. 3/27/17 Trial Tr. at 61:19-62:6; *see also* FOF ¶ 366 (describing counter-regulatory mechanisms).

ii. Endpoints for Fat Loss

428. In order to determine whether a product is efficacious for causing fat loss, change in body fat is the appropriate measured endpoint of the study. 3/27/17 Trial Tr. at 62:7-20.

429. Dr. Aronne testified that you cannot extrapolate from metabolic measures to determine whether fat loss occurs or will occur in the future because the body compensates for increases in metabolism in ways that are designed to prevent fat loss. 3/27/17 Trial Tr. at 62:24-63:4; 3/28/17 Trial Tr. at 28:11-22 ("[I]f you look at the effort to get someone to lose weight by increasing energy expenditure, it's stymied by an increase in appetite. So unless you can reduce appetite, reduce food intake, it's extremely difficult to get someone to lose weight."); *id.* at 31:4-7 ("[I]ncreasing energy expenditure alone is an area that has been fraught with hazard for almost a hundred years."); *id.* at 57:19-58:9 (explaining that acute effects cannot be assumed to continue chronically "because the body finds ways around it").

430. Contempt Defendants' expert Jacobs conceded that metabolic studies do not substantiate fat loss claims. 4/3/17 Trial Tr. at 75:18-76:5.

431. Contempt Defendants' expert Gaginella admitted that a substance that increases an individual's metabolic rate doesn't necessarily cause weight or fat loss. Gaginella Tr. at 136:11-137:2.

432. Contempt Defendants' expert Hoffman agreed that a study measuring energy expenditure does not support a claim of fat loss or weight loss. 3/30/17 Trial Tr. at 208:9-12, 209:18-210:7.

iii. Endpoints for Appetite Suppression

433. Dr. Aronne testified that in order to determine whether a substance causes a decrease in appetite, appropriate endpoints are whether the appetite is suppressed and whether the subjects actually lose weight. 3/27/17 Trial Tr. at 63:5-9.

434. Dr. Aronne further testified that you cannot extrapolate from metabolism studies to determine whether appetite is affected. 3/27/17 Trial Tr. at 63:10-12.

iv. Endpoints For Metabolism

435. Dr. Aronne testified that a study that shows that thermogenesis (i.e., an increase in heat making) has occurred does not necessarily indicate that an increase in metabolism has occurred. 3/27/17 Trial Tr. at 63:13-17.

436. Dr. Aronne further testified that there is no relationship between thermogenesis and "fat burning." 3/27/17 Trial Tr. at 63:18-20.

437. He explained that this is because thermogenesis does not tell you the source of the fuel that the body is using to create the heat. 3/27/17 Trial Tr. at 63:18-64:4 ("So when you look at measures of thermogenesis, they can't tell you if it's consumed body fat or if it's food that's been consumed, whether it's protein, carbohydrate. It's not possible to tell.")

438. He further explained that the body uses fuel sources in a particular order, testifying that if there is food in a person's system, the body will use the food first before resorting to stored energy forms. 3/27/17 Trial Tr. at 64:23-65:7. It is only when people are in a fasting state that their bodies will resort to using other forms of fuel. *Id.* But, as he noted, "we are rarely in a fasting state." *Id.*

439. Even when in a fasting state, Dr. Aronne explained that fat is typically not the first form of energy that the body uses to create heat through thermogenesis, noting that the body typically uses "carbohydrates first, body stores of carbohydrate called glycogen, protein, and ***finally fat***." 3/27/17 Trial Tr. at 64:5-11 (emphasis added); *see also id.* at 65:3-5.

440. Contempt Defendants' expert Lee agreed that an increase in thermogenesis "doesn't necessarily mean that fat has been burned." 3/29/17 Trial Tr. at 89:8-19.

441. Specifically, Lee admitted that when energy expenditure increases, the body first looks to recently ingested food and then to stored glycogen as sources of energy. Only after those sources are exhausted does the body begin to break down fat. 3/29/17 Trial Tr. at 88:9-89:3.

442. Gaginella also explained that when thermogenesis occurs, "first you burn carbohydrate, then fat." Gaginella Tr. at 70:19-24.

443. Therefore, as Lee admitted, "when an individual is not in a fasted state, stored body fat is not the primary source of stored energy." 3/29/17 Trial Tr. at 89:20-23.

444. Contempt Defendants do not qualify any of their advertising claims by stating that fat burning will only occur if the consumer is in a fasted state. *See* FOF ¶¶ 128-254, *supra.*

445. Moreover, none of the directions for any of the products at issue instruct consumers to consume the products in a fasted state. *See* FOF ¶¶ 446-448.

446. Instead, all of the packaging for Fastin, Lipodrene, and Benzedrine simply states, "Take 1-2 tablets in the morning and 1 tablet ***after lunch***." Plaintiff's Ex. 46 at 4 (emphasis added); Plaintiff's Ex. 47 at 3; Plaintiff's Ex. 48 at 2; Plaintiff's Ex. 49 at 2; Plaintiff's Ex. 50 at 4; Plaintiff's Ex. 51 at 2; Plaintiff's Ex. 54 at 3; Plaintiff's Ex. 55 at 2; Plaintiff's Ex. 56 at 3; Plaintiff's Ex. 59 at 4; Plaintiff' Ex. 60 at 3.

447. The Stimerex-ES packaging also includes no fasting instruction, instead directing consumers to "[t]ake 1 tablet three times daily." Plaintiff's Ex. 63 at 3; Plaintiff's Ex. 64 at 2; Plaintiff's Ex. 65 at 2.

448. Contempt Defendants' print advertisements and web pages contain no dosing instructions at all. *See, e.g.*, Plaintiff's Exs. 43-45, 52-53, 57-58, 61-62.

i. The Necessity Of Statistical Significance

449. Dr. Aronne's testimony establishes that it is well-accepted in the fields of obesity, weight loss, and body weight regulation that in order to yield accurate and reliable results studies must arrive at a statistically significant result. FOF ¶¶ 450-455. Dr. Aronne's testimony is corroborated by the testimony of Contempt Defendants' own expert witnesses. FOF ¶¶ 456-458.

450. Dr. Aronne opined that after a study is completed, the results need to be "appropriately analyzed." *See* Plaintiff's Ex. 580 ¶ 21.

451. After a clinical trial has been completed, it is necessary to perform a statistical analysis of the collected data to compare the results for the active treatment group and the results for the control group. 3/27/17 Trial Tr. at 65:8-66:1; Plaintiff's Ex. 580 ¶ 39. The outcome of this analysis is referred to as the "p" value. Plaintiff's Ex. 580 ¶ 39.

452. A given treatment may be determined efficacious only if the difference between the results for the active treatment group and the results for the control group is statistically significant. 3/27/17 Trial Tr. at 65:16-66:4; Plaintiff's Ex. 580 ¶ 39. If the p-value is equal to or less than .05, the results are statistically significant. 3/27/17 Trial Tr. at 66:5-15. This means that there is a 5 percent chance or less that the difference noted between the groups is due to random chance. *Id.*

453. If a study does not have a statistically significant result between groups, "there's no difference between the treatment and the control group," making it difficult to draw any conclusions about a substance's efficacy. 3/27/17 Trial Tr. at 66:16-23.

454. Dr. Aronne also explained that even where there is statistical significance, the study might show that the result is not clinically significant. 3/27/17 Trial Tr. at 66:24-67:5. For example, Dr. Aronne explained that with a large enough study population, a loss of two pounds over six months might be statistically significant but "the public would not consider that to be clinically significant." *Id.* at 67:6-18.

455. The need for statistical significance is one that is well-accepted by experts in the field and well-supported in the academic and scientific literature, as demonstrated in Dr. Aronne's expert report. 3/27/17 Trial Tr. at 66:24-67:5; Plaintiff's Ex. 580¶ 39.

456. Contempt Defendants' expert Lee admitted that "a study that fails to show a statistically significant difference between a test and control group may indicate that the measured effects are merely the result of placebo effect or chance." Defendants' Ex. 132 ¶ 20.

457. In his expert report, Contempt Defendants' expert La Puma admitted that statistical significance was a "well accepted" scientific technique. Defendants' Ex. 130 ¶ 22.

458. Contempt Defendants' expert Gaginella agreed that "some study results that are statistically significant are so small that they would mean only a trivial effect on consumer health." Gaginella Tr. at 166:24-167:5. Lee also agreed with this statement. Defendants' Ex. 132 ¶ 20.

j. Peer Review Is Necessary But Not Sufficient

459. For a study to be considered competent and reliable scientific evidence, it should be published in a peer-reviewed journal. 3/27/17 Trial Tr. at 56:25-57:6; Plaintiff's Ex. 580 ¶ 41.

460. Peer review enables persons not involved in the conduct of the study to look at the technique and the quality of the evidence and provide assurance to others that the study has been conducted properly. 3/27/17 Trial Tr. at 56:25-57:6.

461. Peer review, however, is not sufficient to determine whether a study is competent or reliable, because such studies can have major flaws and it is not always possible for the reviewers to understand the nature of the trial or to review everything that has been done in the study. 3/27/17 Trial Tr. at 57: 21-58:7; Plaintiff's Ex. 580 ¶ 41.

462. For example, a 22-week study relating to the efficacy of green coffee extract in weight loss was published in 2012 but later retracted in 2014 when investigation revealed that the data's validity was questionable. 3/27/17 Trial Tr. at 58:7-20; Plaintiff's Ex. 580 ¶ 42. This illustrates one of the limitations of peer review, as a reviewer cannot evaluate for falsification of data. 3/27/17 Trial Tr. at 58:4-6; Plaintiff's Ex. 580 ¶ 42.

463. Dr. Aronne's opinion that peer review is necessary but not sufficient is well-accepted in the field and well-supported in the academic and scientific literature, as demonstrated in his expert report. Plaintiff's Ex. 580 ¶¶ 41-42.

464. Contempt Defendants' expert Heuer agreed that the fact that a study is published in a peer-reviewed journal is not a sufficient basis to determine that the studied substance has an effect. 4/4/17 Trial Tr. at 121:17-24.

465. Anecdotal evidence of a product's effect, such as reports of results for individual patients or a small group of patients, is not sufficient to demonstrate the efficacy of a product. 3/27/17 Trial Tr. at 56:17-24; Plaintiff's Ex. 580 ¶ 38. This is true even if there are many anecdotes. 3/27/17 Trial Tr. at 56:21-24.

466. Contempt Defendants' expert Hoffman agreed that anecdotal evidence is not evidence of causation, but rather "is the initial steps of developing hypotheses, ***speculation***." 3/30/17 Trial Tr. at 215:17-21 (emphasis added).

B. Contempt Defendants Hi-Tech, Wheat, And Smith Did Not Possess And Rely Upon Competent And Reliable Scientific Evidence.

1. Contempt Defendants Had No Product-Specific RCTs To Substantiate Their Unqualified Causal Efficacy Claims.

467. There is no dispute that there are no studies of the four Hi-Tech products at issue. FOF ¶¶ 468-471.

468. Wheat admitted that no double-blind, placebo-controlled study of Fastin was performed. Wheat Dep. at 97:18-21, 102:14-103:21, 111:4-7.

469. Wheat admitted that no double-blind, placebo-controlled study of Lipodrene was performed. Wheat Dep. at 97:22-24, 102:14-103:21, 111:4-7.

470. Wheat admitted that no double-blind, placebo-controlled study of Benzedrine was performed. Wheat Dep. at 97:25-98:3, 102:14-103:21, 111:4-7.

471. Wheat admitted that no double-blind, placebo-controlled study of Stimerex-ES was performed. Wheat Dep. at 98:4-7, 102:14-103:21, 111:4-7.

2. Studies of Products With Different Formulations Do Not Substantiate Contempt Defendants' Claims For Fastin, Lipodrene, Benzedrine, And Stimerex-ES.

472. Several of Contempt Defendants' experts claim that studies of certain products with different formulations, Fastin-XR, Fastin-RR, and Meltdown, are sufficient to substantiate Contempt Defendants' claims. *See* Plaintiff's Ex. 581 ¶¶ 54, 75.

473. Dr. Aronne testified that none of the studies of these products constitute competent and reliable scientific evidence to substantiate Contempt Defendants' claims. *See* FOF ¶¶ 479-80, 482, 484-93, 499-522, 526, 533, 541-47, 568, 575-76, 579-83; Plaintiff's Ex. 580 ¶¶ 47, 101; Plaintiff's Ex. 581 ¶¶ 54, 57-82.

a. The Fastin-XR Metabolism Study Does Not Substantiate Contempt Defendants' Unqualified, Product-Specific, Causal Efficacy Claims.

474. The Fastin-XR acute metabolism study does not substantiate claims for the products at issue for several reasons. First, Fastin-XR has a different formulation from the products at issue. FOF ¶¶ 475-478. Second, as an acute study of metabolism, the Fastin-XR study cannot substantiate claims of weight loss, fat loss, or appetite suppression. FOF ¶ 479. Third, severe

flaws in the study design and execution preclude the study from being considered competent and reliable scientific evidence to substantiate unqualified metabolism claims. FOF ¶¶ 480-493.

i. Fastin-XR Has A Different Formulation Than The Products At Issue.

475. Fastin and Fastin-XR have different formulations. *Compare* Plaintiff's Ex. 580 ¶¶ 51, 53-55 *with* Plaintiff's Ex. 514 at 2 (Fastin-XR formulation). Not only does Fastin-XR have ingredients that are not common to the other products, but certain common ingredients are also not present in identical amounts. *Id.*

476. Specifically, Fastin-XR contains 150 mg of caffeine, 20 mg of theobromine, 15 mg of 10% yohimbe, 200 mg of acacia rigidula extract, 50 mg of 98% green tea, 25 mg of naringin, 20 mg synephrine Hcl, 7.5 mg 5-methoxytryptamine, and 45 mg 1,3 dimethylamylamine (DMAA). *See* Plaintiff's Ex. 514 at 2. In contrast, Fastin contains 65 mg methylsynephrine HCL, 100 mg B-phenylethylamine, 5 mg N-methyl-b-phenylethylamine HCL, 100 mg caffeine, 50 mg theobromine, 1.5 mg yohimbe HCL, 10 mg synephrine, and 45 mg 1,3 dimethylamine HCL. *See id.* at 2.

477. Contempt Defendants treat the differences in the formulation between Fastin and Fastin-XR as significant. *See* Plaintiff's Ex. 67 at 3. Specifically, they tout the fact that Fastin-XR "is even more potent than Fastin" and explain that the increased potency is due to "an additional 180 mg of Thermo-Rx® phenylethylamine alkaloids and another 50 mg of caffeine." *Id.* Moreover, they admit that "another ingredient in Fastin®-XR (not found in the original Fastin®) . . . 5-Methoxytryptamine . . .supports the activity of the neurotransmitter serotonin that also favorably influences the hunger centers in your brain so that you feel full." *Id.*

478. Jacobs admits that the Fastin-XR metabolism study was not designed to isolate the effects of the ingredients that are not present in Fastin. 4/3/17 Trial Tr. at 98:17-23.

ii. The Fastin-XR Study Does Not Examine Appropriate Endpoints To Substantiate Weight Loss, Fat Loss, Or Appetite Claims.

479. The Fastin-XR study, which examined 10 persons over a three-hour period, did not measure weight loss, fat loss, or appetite at all, and is insufficient to substantiate any claim regarding those parameters. 3/27/17 Trial Tr. at 117:5-13, 117:21-118:14; Plaintiff's Ex. 580 ¶ 47.

iii. The Fastin-XR Study Is Too Flawed In Design And Execution To Constitute Competent And Reliable Scientific Evidence.

480. Nor is the Fastin-XR metabolism study sufficient to substantiate metabolism claims due to a variety of methodological flaws, including its small size and short duration. Plaintiff's Ex. 581 ¶ 59.

481. Indeed, in his direct examination, Jacobs admitted that it would be "impossible to predict," based on his three-hour acute study, "what would happen over an extended period." 3/31/17 Trial Tr. at 164:3-9.

482. The Fastin-XR metabolism study is underpowered. 3/27/17 Trial Tr. at 120:3-7, 124:12-18; Plaintiff's Ex. 581 ¶ 59. Jacobs' own power calculation required 12 participants for the study to yield valid results, yet Jacobs reported results for only 10 participants. Plaintiff's Ex. 581 ¶ 59; *see also* Plaintiff's Ex. 596 at SUP003592.

483. Jacobs attempted to hide the fact that his study was underpowered by claiming in his report of the study results that the power calculation actually called for 10, rather than 12, participants. Defendants' Ex. 110 at 9. This was false. In the protocol that Jacobs submitted to an Institutional Review Board before starting the study, Jacobs explained that "based on

the assumption of a very strong effect size (0.9) with moderate power level (0.7), . . . 12 subjects [are] needed for this study." Plaintiff's Ex. 596 at SUP003592; 4/3/17 Trial Tr. at 102:13-21, 104:2-6, 105:8-15. At trial, Jacobs first stated that there was a "possibility" that he had conducted a new power analysis that resulted in the lower result of 10 subjects. This too was false. In fact, when asked at deposition whether he had ever redone his power analysis to determine whether 10 subjects would provide sufficient power, Jacobs answered, "oh, heavens no." *Id.* at 105:19-106:7, 109:9-110:12.

484. Jacobs, the sole investigator responsible for the Fastin-XR metabolism study, including the administration of all study dosages and all data calculations, also enrolled himself in the study. 3/27/17 Trial Tr. at 119:12-20; Plaintiff's Ex. 581 ¶ 68; Plaintiff's Ex. 620.

485. Dr. Aronne explained that it is inappropriate for investigators in a study to enroll themselves as subjects. 3/27/17 Trial Tr. at 119:12-15. Contempt Defendants' expert Heuer testified that the International Guidelines for Clinical Trials state that investigators should not be enrolled in clinical trials. 4/4/17 Trial Tr. at 137:10-14.

486. Dr. Aronne further explained that in a clinical trial, a subject is enrolled in a study once they have signed the informed consent form, which indicates their agreement to participate in the study. 3/28/17 Trial Tr. at 4:23-5:10. Jacobs completed a consent form, indicating his enrollment in the study. *Id.* at 5:11-6:11; Plaintiff's Ex. 620. The consent form identified Jacobs as the "research participant." Plaintiff's Ex. 620 at 8; *see also* 3/28/17 Trial Tr. at 6:4-8.

487. Jacobs enrolled himself in the study as "Subject 12". 3/28/17 Trial Tr. at 6:12-7:3, 7:8-8:23, 9:25-11:6; Plaintiff's Ex. 581 ¶ 68; Plaintiff's Ex. 621; 4/3/17 Trial Tr. at 111:15-25. He then ran the study on himself, which included ingesting pills from each arm of the study. 3/28/17 Trial Tr. at 6:12-7:3, 7:8-8:23, 9:25-11:6; Plaintiff's Ex. 581 ¶ 68; Plaintiff's Ex. 621; Plaintiff's Ex. 622 at 1; 4/3/17 Trial Tr. at 42:1-43:21. Jacobs participated in the study concurrently with the other study participants. 3/28/17 Trial Tr. at 11:17-12:24; *compare* Plaintiff's Ex. 621 (dated test sheets for Subject 12 (Jacobs)) *with* Plaintiff's Exs. 623-24 (dated test sheets for Subjects 4 and 6).

488. Jacobs' enrollment in the study violated the study protocol because he did not meet the study inclusion criteria based on his age and a preexisting medical condition. Plaintiff's Ex. 581 ¶ 69; 4/3/17 Trial Tr. at 42:5-12.

489. Jacobs administered himself unblinded doses of certain treatments (acacia and Fastin-XR) when his initial results did not meet his expectation. 3/28/17 Trial Tr. at 8:14-23, 10:14-11:2; 4/3/17 Trial Tr. at 47:1-48:25; *see also* Plaintiff's Ex. 581 ¶ 70. His unblinding the study where it did not meet his preconceived expectations introduces a bias that irrevocably compromised the Fastin-XR metabolism study's validity. Plaintiff's Ex. 581 ¶ 70; 4/3/17 Trial Tr. at 113:24-114:1, 119:14-17; *see also* 3/28/17 Trial Tr. at 11:7-16.

490. Jacobs also did not disclose in his expert report that he had tested Fastin-XR on himself. Defendants' Ex. 129; 4/3/17 Trial Tr. at 119:18-121:6. Nor did he disclose that the Fastin-XR demonstrated a poor result in his expert report. Defendants' Ex. 129.

491. Jacobs did not include his results in the study data or the publication of its results, despite the fact that he had complete data for all treatment arms. 3/27/17 Trial Tr. at 120:3-7; 3/28/17 Trial Tr. at 13:19-22; Plaintiff's Ex. 581

¶ 72. Dr. Aronne explained that, where you have complete data for a subject, to omit it from the study results is inappropriate. 3/27/17 Trial Tr. at 123:21-25.

492. Jacobs' exclusion of this data is significant because it demonstrated a poor result for Fastin-XR. 3/27/17 Trial Tr. at 120:8-13; Plaintiff's Ex. 581 ¶ 72; Plaintiff's Ex. 622 at 2 ("In general, the metabolic . . . responses to the supplement conditions (Fastin®-XR, caffeine, acacia) were significantly lower in [Jacobs] than those established in the present study with normotensive individuals.") Given the small size of the study, inclusion of unfavorable data would have negatively impacted the study's results. 3/27/17 Trial Tr. at 121:21-122:1, 124:5-10; Plaintiff's Ex. 581 ¶ 72.

493. Dr. Aronne testified that based on Jacobs' repeated protocol breaches, use of flawed methodology and inappropriate statistical methods to analyze study data, and failure to accurately report the study data, it is Dr. Aronne's opinion that Jacobs is not "a person in the field qualified" to conduct these types of tests and studies. 3/28/17 Trial Tr. at 24:7-17; Plaintiff's Ex. 581 ¶ 73; *see also* FOF ¶ 80 (definition of "competent and reliable scientific evidence").

b. The Fastin-RR Metabolism Study Does Not Substantiate Contempt Defendants' Unqualified, Product-Specific, Causal Efficacy Claims.

494. The Fastin-RR acute metabolism study does not substantiate claims for the products at issue for three reasons. First, Fastin-RR has a different formulation from the products at issue. FOF ¶¶ 495-498. Second, as an acute study of metabolism, the Fastin-RR study cannot substantiate claims of weight loss, fat loss, or appetite suppression. FOF ¶¶ 499-501. Third, severe flaws in the study design and execution preclude the study from being considered competent and reliable scientific evidence to substantiate even metabolism claims. FOF ¶¶ 502-522.

i. Fastin-RR Has A Different Formulation Than The Products At Issue.

495. Fastin and Fastin-RR have different formulations. *Compare* Plaintiff's Ex. 580 ¶ 51 *with* Plaintiff's Ex. 598 (Fastin-RR formulation). Not only does Fastin-RR have ingredients that are not common to the other products, but certain common ingredients are also not present in identical amounts. *Id.*

496. Specifically, Fastin-RR consists of 150 mg caffeine, 200 mg of phenylethylamine alkaloids (including B-phenylethylamine, N-Methyl-B-phenylethylamine, methylsynephrine, and R-Beta-

methylphenylethylamine) derived from Acacia Rigidula extract, 50 mg of theobromine, 45 mg of epigallocatechin gallate, 25 mg of naringen, 7.5 mg of 5-methoxytryptamine Hcl, 1.5 mg of Yohimbine Hcl, 20 mg synephrine HCL, 25 mg of Citrus Nasudaidai Hayata Extract, 12.5 mg Citrus Junos Sieb Ex Tanaka Extract, 12.5 mg Citrus Limonium Extract, and 50 mg Citrus Aurantium extract (yielding synephrine alkaloids). Plaintiff's Ex. 598 at 6-7.

497. In contrast, Fastin contains 65 mg methylsynephrine HCL, 100 mg B-phenylethylamine, 5 mg N-methyl-b-phenylethylamine HCL, 100 mg caffeine, 50 mg theobromine, 1.5 mg yohimbe HCL, 10 mg synephrine, and 45 mg 1,3 dimethylamine HCL. *See* Plaintiff's Ex. 514 at 2.

498. Jacobs admits that his Fastin-RR studies were "not designed to isolate how much of what you were seeing [was] due to [the] different ingredients." 4/3/17 Trial Tr. at 99:10-16.

ii. The Fastin-RR Study Does Not Measure Appropriate Endpoints To Substantiate Weight Loss, Fat Loss, Or Appetite Claims.

499. The Fastin-RR study, which reported results for 11 persons over a six-hour period, did not measure weight loss, fat loss, or appetite at all, and is

insufficient to substantiate any claim regarding those parameters. 3/28/17 Trial Tr. at 14:5-20; Plaintiff's Ex. 581 ¶ 58.

500. Jacobs designed the study to attempt to substantiate claims that Fastin-RR had an effect on appetite. *See* 3/28/17 Trial Tr. at 15:3-9. During the study, Jacobs had participants complete a "hunger scale," but declined to report the results because "it didn't work out too well" and "nothing dramatic came out of it." *Id.*; 4/3/17 Trial Tr. at 121:17-123:23. Dr. Aronne explained that it is inappropriate to abandon a line of inquiry in a study because it's not working out too well. 3/28/17 Trial Tr. at 15:10-14.

501. The published report of the Fastin-RR metabolism study does not mention the hunger scale, let alone that it failed to demonstrate that Fastin-RR decreases the subjects' appetite. 3/28/17 Trial Tr. at 15:3-9; Plaintiff's Ex. 581 ¶ 67; 4/3/17 Trial Tr. at 123:24-124:5. Jacobs also did not disclose the failed hunger scale in his expert reports. 4/3/17 Trial Tr. at 124:6-19.

iii. The Fastin-RR Metabolism Study Is Too Flawed In Design And Execution To Constitute Competent And Reliable Scientific Evidence To Support Unqualified Metabolism Claims.

502. Dr. Aronne also explained that the Fastin-RR metabolism study is not sufficient to substantiate metabolism claims due to a variety of

methodological flaws. 3/28/17 Trial Tr. at 15:15-22; Plaintiff's Ex. 581 ¶ 59.

503. First, Dr. Aronne explained that the Fastin-RR study is too small and too short to draw any conclusions about Fastin-RR's impact on metabolism. 3/28/17 Trial Tr. at 15:15-19; Plaintiff's Ex. 581 ¶ 58.

504. Jacobs agreed that his six-hour Fastin-RR study did not permit him to conclude that any Hi-Tech product would have any effect on metabolism beyond the six-hour timeframe. 4/3/17 Trial Tr. at 73:23-75:1.

505. Second, after completing his study, Jacobs once again misreported the results of his power analysis so that it would match with the number of participants who actually completed the study. *Compare* Plaintiff's Ex. 598 at 12 *with* Defendants' Ex. 120 at SUP000722. In the protocol submitted to an Institutional Review Board prior to the start of the study, Jacobs stated that "12 subjects are needed for this study." Plaintiff's Ex. 598 at 12; 4/3/17 Trial Tr. at 124:23-126:11. In the report he wrote after completing study, however, Jacobs stated that the power calculation actually had called for 10 subjects. Defendants' Ex. 120 at SUP000722; 4/3/17 Trial Tr. at 126:12-127:20.

506. Third, Dr. Aronne explained that the study was not properly randomized. 3/28/17 Trial Tr. at 16:4-6. He based this opinion on the fact that Jacobs "doesn't recall how he randomized the patients. He doesn't report how he randomized the patients, and he lost the randomization key." *Id.* at 16:7-11. Dr. Aronne explained that in a properly conducted randomized trial, the manner of randomization is reported and to fail to do so "is a breach of good clinical practice." *Id.* at 16:12-19; *see also* 3/30/17 Trial Tr. at 91:18-92:6 (Contempt Defendants' expert La Puma admitting that reporting randomization methodology is "typical and not uncommon").

507. Fourth, Jacobs broke the blind and re-administered study dosages in the Fastin-RR metabolism study when the study results and observations did not track what he expected. 3/28/17 Trial Tr. at 16:20-19:8; Plaintiff's Ex. 581 ¶ 61; Plaintiff's Ex. 612.

508. Dr. Aronne's opinion was based on deposition testimony by Jacobs that Jacobs would break the blind to identify the ingredient the subject ingested and then re-administer the dose in single-blinded fashion, with Jacobs fully aware of which ingredient the subject was then receiving. *See* 3/28/17 Trial Tr. at 18:11-14, 19:2-5; Plaintiff's Ex. 581 ¶ 61. At trial, Jacobs

changed his testimony to claim that he did not break the blind but rather readministered double-blinded dosages to rectify a clerical error. 4/3/17 Trial Tr. at 53:22-54:18**.** In neither his preliminary report of the study's results, the published report of the study, nor in his expert report did Jacobs report that dosages were readministered. *See* Defendants' Exs. 66, 120, and 129. Moreover, he continued to report the study as a "double-blind" study despite having administered single-blinded dosages. *See* Defendants' Ex. 66; 3/28/17 Trial Tr. at 74:3-10.

509. The breaking of the blind and inclusion of the "redo" data are protocol violations that invalidate the results of the Fastin-RR metabolism study. Plaintiff's Ex. 581 ¶ 61. That Jacobs expected certain results from certain tests calls into question whether the study was ever blinded to the administration of the treatment. Plaintiff's Ex. 581 ¶ 62. But even if the study were properly blinded at the start, the re-administration of doses where the tests did not show the expected result demonstrates that the study was biased towards showing a positive result for Fastin-RR. *Id.*

510. Fifth, Jacobs included subjects in the Fastin-RR study that violated his own protocol exclusion criteria – including subjects with medically managed hypertension. Plaintiff's Ex. 581 ¶ 64.

511. Sixth, Jacobs did not appropriately report the side effects of participants in the Fastin-RR study. 3/28/17 Trial Tr. at 19:18-24; Plaintiff's Ex. 581 ¶ 65. For example, Subject 9 experienced nausea, chest pain, and "coughed up fluids" during the test. 3/28/17 Trial Tr. at 21:13-22:6; Plaintiff's Ex. 581 ¶ 65; Plaintiff's Ex. 617. In his written report to the Independent Review Board ("IRB") overseeing the study, Jacobs reported only that the subject experienced "tingling fingers and perception of chest tightness." 3/28/17 Trial Tr. at 20:23-21:12; Plaintiff's Ex. 581 ¶ 65; Plaintiff's Ex. 615.

512. Jacobs similarly misrepresents Subject 9's symptoms in his expert report, stating only that "[t]wo of the three 'dropouts' included one male and one female participant who experienced symptoms with Fastin-RR which they found uncomfortable but were expected, including headache, tingling fingers and toes, and perception of increased heart rate and force." Defendants' Ex. 129 ¶ 63. Jacobs fails to disclose to the Court that Subject 9 coughed up fluids and experienced nausea, chest pressure, and a

headache. 4/3/17 Trial Tr. at 168:12-169:11. He identically misrepresented Subject 9's symptoms in his preliminary report of the study's results. Defendants' Ex. 120 at SUP000723.

513. Moreover, the published summary of the Fastin-RR metabolism study also fails to disclose the adverse side effects experienced by Subject 9. *See* Defendants' Ex. 66.

514. In fact, the published summary fails to disclose that there were any dropouts in the study, claiming that "[e]leven men (n=6) and women (n=5) . . . voluntarily participated in this research study. All research participants completed three-6 hour resting metabolic testing sessions . . . ." Defendants' Ex. 66. At trial, however, Jacobs claimed that he "believed [he] reported that we enrolled 14 persons with three dropouts, completing 11 persons." 4/3/17 Trial Tr. at 126:12-15. This was not true. *See* Defendants' Ex. 66.

515. Contempt Defendants' expert La Puma admitted both that it is typical to state how many people initially enrolled in a study and that it is "desirable" to describe how many people drop out of a study. 3/30/17 Trial Tr. at 92:7-13.

516. Jacobs also reported in his study write-up that the adverse events suffered by Subject 9 were not "unexpected." Defendants' Ex. 120 at SUP000723. In fact, however, when he was seeking IRB approval to conduct his study, Jacobs stated that "***any*** adverse event that occurs will be 'unanticipated.'" Plaintiff's Ex. 598 at 11 (emphasis added); 4/3/17 Trial Tr. at 133:1-134:7.

517. Dr. Aronne explained that the failure to accurately report the information concerning Subject 9 also impacted his evaluation of Jacobs' conduct of the study because reporting was not done "in an appropriate manner consistent with good clinical practice." 3/28/17 Trial Tr. at 23:9-14.

518. Contempt Defendants' expert La Puma agreed that where the reasons for a dropout are described, they "should be accurate." 3/30/17 Trial Tr. at 92:14-17

519. At trial, Jacobs attempted to explain his omission of the "coughing up fluids" adverse event by claiming when he wrote that Subject 9 was "coughing up fluids," he just meant that the subject had actually been drinking water and had swallowed it "down the wrong pipe." 4/3/17 Trial Tr. at 58:13-59:1, 130:20-131:2. When asked why he hadn't given this explanation at his deposition, Jacobs replied that "our major issue [at the

deposition] was that I was told to only answer the questions, and I answered those questions. I was told that I was talking too much." *Id.* at 131:22-132:3.

520. Dr. Aronne explained that if a patient in one of his clinical studies presented with these symptoms, it would cause "a concern that the patient is having a cardiac event, myocardial infarction, which is a heart attack, and arrhythmia, heart failure, [or] something like that." 3/28/17 Trial Tr. at 22:7-14. Under such circumstances, Dr. Aronne stated that, depending on the severity of the symptoms, he might send the subject to the emergency room, check their blood pressure and vital signs, perform an electrocardiogram (EKG), and examine them carefully – steps that Jacobs did not take with regard to Subject 9. 3/28/17 Trial Tr. at 22:15-22.

521. Based on his review of the Fastin-RR metabolism study, Dr. Aronne concluded that Jacobs is not a "person qualified" to conduct and evaluate tests, analyses, research, studies or other evidence "in an objective manner" because, among other things, "[h]e has demonstrated an inability to conduct a study in a proper manner. He has ignored clear-cut adverse events . . . broke the blind and readministered the doses in both [Fastin-XR

and Fastin-RR metabolism] studies on several occasions and did not report it in his study." 3/28/17 Trial Tr. at 24:7-17; *see also* FOF ¶ 80 (definition of "competent and reliable scientific evidence").

522. Dr. Aronne further explained that "the conduct of these studies in my opinion falls under the description of professional misconduct, [through a] consistent pattern of unprofessional practices that are biased towards a positive result. [Jacobs] doesn't like the result, he does it again until he gets the results he's looking for and doesn't report it. So even if you – if he were to make an error, to not report the error properly, to describe these studies as double-blinded, randomized when he can't find the randomization key and [doesn't] remember how [he] randomized the patient, it just is beyond the pale." 3/28/17 Trial Tr. at 24:18-25:5.

c. The Fastin-RR Weight Loss Study Does Not Substantiate Contempt Defendants' Unqualified Causal Efficacy Claims.

523. The Fastin-RR Weight Loss study does not substantiate claims for the products at issue for several reasons. First, Fastin-RR has a different formulation from the products at issue. FOF ¶ 524 . Second, an eight-week study is not sufficient to substantiate an unqualified weight loss or fat loss

claim. FOF ¶¶ 525-530. Third, there is no evidence that the Fastin-RR study was conducted properly. FOF ¶¶ 531-539.

i. Fastin-RR Has A Different Formulation Than The Products At Issue.

524. As discussed above, Fastin and Fastin-XR have different formulations, and Jacobs admits that his Fastin-RR studies were "not designed to isolate how much of what you were seeing [was] due to [the] different ingredients." FOF ¶¶ 495-498.

ii. The Fastin-RR Weight Loss Study's Duration Is Insufficient To Substantiate Contempt Defendants' Unqualified Causal Efficacy Claims.

525. Jacobs' eight-week study is not sufficient to substantiate weight and fat loss claims that are not in any way time-limited.

526. Dr. Aronne testified that based on his review of innumerable weight-loss studies, 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. 3/27/17 Trial Tr. at 58:21-59:11; Plaintiff's Ex. 580 ¶ 30. Dr. Aronne further explained that experts in the field require six-month studies because "six months is the point where we see maximal weight loss and studies of shorter

duration may demonstrate weight results that are transient and may not be sustained beyond a few weeks." 3/28/17 Trial Tr. at 62:7-10.

527. Jacobs' study falls well short of six months, and Jacobs did not offer any explanation for choosing the eight-week duration. Instead, during closing arguments, Wheat's counsel offered Contempt Defendants' only explanation, claiming that Hi-Tech's product labels instruct consumers not to take the products for longer than eight weeks. 4/6/17 Trial Tr. at 144:18-21, 146:12-14.

528. Counsel's explanation ignores that none of Contempt Defendants' advertising claims—whether on their product packaging, print advertisements, or websites—contain any time limitation. They are unqualified in their promises of rapid and substantial weight and fat loss. FOF ¶¶ 128-254.

529. Contempt Defendants also ignore that some product packaging and labels completely lack any statement about not taking the product for longer than eight weeks, *see* Plaintiff's Exs. 50, 56, 63, and that no such statement is included on Contempt Defendants' website or print advertisements. *See* Plaintiff's Exs. 44, 45, 52, 53, 57, 58, 61, 62.

530. Although some of Contempt Defendants' product packaging contains the statement, "Do not use for more than 8 weeks," that statement is buried in their lengthy, all-capital-letters safety warning that is far from the more prominent advertising claims. The warning is generally located on the inside of Contempt Defendants' product labels, such that the label must be peeled back (prior to purchase) for consumers to even see it. *See, e.g.*, Plaintiff's Exs. 47, 49, 54, 55. In fact, Contempt Defendants actually claim that consumer generally don't even read the label warnings that include the eight-week statement. *See* 4/6/17 Trial Tr. at 128:15-22.

iii. There Is No Evidence That The Fastin-RR Weight Loss Study Was Conducted Properly.

531. There is no evidence that the Jacobs' Fastin-RR Weight Loss study was conducted properly.

532. Jacobs' report of the Fastin-RR Weight Loss study identifies him as the sole "investigator responsible for the trial." Defendants' Ex. 64 at 2.

533. The serious methodological flaws in Jacobs' Fastin-RR and Fastin-XR metabolism studies are sufficient to conclude, as Dr. Aronne did, that Jacobs is not "a person in the field qualified" to conduct these types of

studies. FOF ¶ 493; *see also* FOF ¶ 80 (definition of "competent and reliable scientific evidence").

534. Jacobs submitted the Fastin-RR Weight Loss study protocol to an Institutional Review Board in March 2013, over one year after the FTC initiated contempt proceedings and Jacobs submitted his first expert report in this case. Plaintiff's Ex. 602 at 2.

535. In this protocol, unlike in his two previous Fastin-XR and Fastin-RR protocols, Jacobs did not report the results of any power analysis at all. *See* Plaintiff's Ex. 602.

536. Jacobs also omitted any mention of a power analysis from the report he wrote after completing the study. Defendants' Ex. 64. In the reports of his two prior studies, Jacobs instead misrepresented the results of his power calculation, *see* FOF ¶¶ 483,505.

537. Jacobs also omitted from his Fastin-RR Weight Loss study protocol and report any discussion of how the study was randomized, instead simply declaring that all subjects were randomized "in a double blind fashion." Plaintiff's Ex. 602 at 6; Defendants' Ex. 64 at 6. The omission of any

description of the actual randomization process in a departure from good clinical trial practices. FOF ¶¶ 335-341.

538. None of Contempt Defendants' other experts address any of the deficiencies in the Fastin-RR Weight Loss study in their expert report or testimony. In fact, based on those experts' disclosures, none of them even reviewed Jacobs' Fastin RR weight-loss study, notwithstanding that they were provided substantiation materials by Contempt Defendants and that they purportedly searched for additional relevant materials.

539. Additionally, the Fastin-RR Weight Loss study was only published in abbreviated "poster presentation" form. Defendants' Ex. 122. Jacobs described the poster presentation as an abstract. 3/31/17 Trial Tr. at 189:6-13. Contempt Defendants have not claimed that the Weight Loss study was peer-reviewed.

d. The Meltdown Studies Do Not Substantiate Contempt Defendants' Unqualified, Product-Specific, Causal Efficacy Claims.

540. The Meltdown studies do not substantiate claims for the Hi-Tech products at issue for several reasons. First, Meltdown has a significantly different formulation than any of the Hi-Tech products, including several

ingredients that may be responsible for any observed apparent effects of Meltdown that are not contained in the Hi-Tech products. FOF ¶¶ 542-567. Second, the acute metabolic studies of Meltdown cannot substantiate claims of weight loss, fat loss, or appetite suppression. FOF ¶¶ 568-574. Third, the acute metabolic studies of Meltdown cannot be extrapolated to a chronic metabolism claim. FOF ¶¶ 575-583.

541. Dr. Aronne reviewed the studies of Meltdown that Contempt Defendants claim substantiate their unqualified, product-specific, causal efficacy claims. 3/27/17 Trial Tr. at 102:14-16. Based on his review, he concluded that "there is no competent and reliable scientific evidence that Meltdown produces rapid and substantial weight loss, fat loss, effect on appetite, effect on body fat, [or] effect on metabolism." *Id.* at 102:17-24.

i. Meltdown Has A Significantly Different Formulation Than The Hi-Tech Products.

542. Meltdown's formulation significantly differs from each of the four Hi-Tech Products at issue. Compare Defendants' Ex. 106 at 3 with Plaintiff's Exs. 513-514.

543. First, Meltdown contains two ingredients not found in any of the Hi-Tech products that may contribute to any of Meltdown's potential efficacy:

tetradecylthioacetic acid and yerba mate. Plaintiff's Ex. 581 ¶¶ 80-81; *see also* Gaginella Tr. at 139:17-140:9, 140:14-22 (acknowledging presence of tetradecylthioacetic acid and yerba mate); 4/4/17 Trial Tr. at 149:8-14, 18-20.

544. Tetradecylthioacetic acid (TTA) is a free fatty acid. Plaintiff's Ex. 581 ¶ 80. When a free fatty acid is ingested, free fatty acid levels in the blood will rise, making it appear that fat is being mobilized. *Id.* Thus, any increase in free fatty acid levels in subjects ingesting Meltdown may be due to the presence of TTA in the product. *Id.*

545. In a recent study, yerba mate was evaluated in a randomized, double-blind, placebo-controlled trial over 12 weeks. Plaintiff's Ex. 581 ¶ 81. The study yielded statistically significant results for reduction of body fat mass and percent body mass when compared to placebo. *Id.*

546. Based on this study, Dr. Aronne explained that the yerba mate may be responsible, in part, or in whole, for any results observed in the studies of Meltdown. Plaintiff's Ex. 581 ¶ 81.

547. In any event, the presence of the yerba mate makes it impossible to attribute any efficacy Meltdown may have to any of the ingredients present in the Hi-Tech products. Plaintiff's Ex. 581 ¶ 81.

548. Fastin, Lipodrene, Benzedrine, and Stimerex-ES do not contain yerba mate or tetradecylthioacetic acid. Plaintiff's Exs. 513, 514.

549. In fact, when he conducted his own study of Meltdown, Contempt Defendants' expert Hoffman attributed the study's apparent transient effects to the combination of "yohimbine, yerba mate, and tetradecylthioacetic acid" in Meltdown. Defendants' Ex. 108 at 5.

550. Second, Meltdown contains three different forms of Yohimbine: 11-Hydroxy Yohimbine, Yohimbine HCL, and alpha-Yohimbine. Defendants' Ex. 106 at 3. None of the Hi-Tech Products contain 11-Hydroxy Yohimbine or alpha-Yohimbine, and only Fastin lists "Yohimbe HCL." Plaintiff's Ex. 514.

551. FDA regulations require that within each ingredient category on the product label, individual ingredients must be listed in the order in which they appear. 4/4/17 Trial Tr. at 125:1-7; 4/5/17 Trial Tr. at 18:11-18; 21 C.F.R. § 101.4(a) (ingredients "shall be listed by common or usual name in

descending order of predominance by weight"). As a result, because 11-Hydroxy Yohimbine is listed before Yohimbine HCl on the product label, the label indicates that there is more 11-Hydroxy Yohimbine in Meltdown than Yohimbine HCL. *See* Defendants' Ex. 106 at 3.

552. Third, there are 20 mg of hordenine in Meltdown. Hordenine is not present in any of the Hi-Tech Products. *Compare* Defendants' Ex. 106 at 3 *with* Plaintiff's Exs. 513, 514. Dr. Aronne explains that hordenine may also contribute to any acute efficacy demonstrated in the studies. *See* Plaintiff's Ex. 581 ¶ 82. He bases this conclusion on the fact that hordenine is known to release norepinephrine from the body's stores and the fact that increased norepinephrine levels were observed in certain of the Meltdown studies. *Id.*

553. Fourth, there are 138 mg, combined, of R-beta-Methylphenylethylamine and N-Methyl-beta-Phenylethylamine in Meltdown. Defendants' Ex. 106 at 3. There is no evidence that R-beta-Methylphenylethylamine is in any of the Hi-Tech Products, and Contempt Defendants have indicated that N-Methyl-beta-Phenylethylamine is only present in Fastin and only in a relatively small amount, 5 mg. Plaintiff's Ex. 513 at 1. Most of the Hi-Tech

Products do not specify which particular phenylethylamines are present. Phenylethylamines, however, are a large class of compounds, and most have not even been studied. 3/29/17 Trial Tr. at 66:3-67:6.

554. Fifth, Meltdown also contains 3'-5'-Cyclic Adenosine Monophosphate ("cAMP"), which the makers of Meltdown characterize as a "lipolytic trigger." *See* Defendants' Ex. 106 at 3.

555. Contempt Defendants' expert Heuer admitted that based on the design of the Meltdown studies, one cannot isolate the effects of the ingredients in Meltdown that are not present in the Hi-Tech products. 4/4/17 Trial Tr. at 150:11-16.

556. During trial, Contempt Defendants, for the first time, attempted to present a document that they claimed was the formulation for Meltdown that differed from the Meltdown product label in material ways. *See* Defendants' Ex. 124 at 1; 4/4/17 Trial Tr. at 183:2-184:3, 185:14-17.

557. According to Wheat (and nobody else), that document purports to be the actual Meltdown formulation. 4/4/17 Trial Tr. at 185:9-17. According to their expert disclosures, none of Contempt Defendants' expert witnesses considered or relied upon this document. Defendants' Ex. 125 ¶ 7;

Defendants' Ex. 126 at 3-4, 44-55; Defendants' Ex. 127 ¶¶ 4-5; Defendants' Ex. 128 at 3-4, 47-56; Defendants' Ex. 129 at 4-5, 80-90; Defendants' Ex. 130 at 4, 41-52; Defendants' Ex. 132 at 7-8, 62-77; Defendants' Ex. 133 at 13-15, 73-98; Defendants' Ex. 134 at 4-5, 120-123.

558. In fact, none of Contempt Defendants' expert witnesses address the formulation differences between Meltdown and the Hi-Tech products in their expert reports. *See* FOF ¶¶ 559-563.

559. Gaginella and Lee only rely upon the Meltdown studies as purported proof of the efficacy of phenylethylamines. Defendants' Ex. 126 at 22-24; Defendants' Ex. 132 ¶¶ 64-65. Neither Gaginella nor Lee gives any opinion regarding the non-common, additional ingredients in Meltdown but not the Hi-Tech products. *Id.*

560. La Puma's report lacks any mention of Meltdown at all. Defendants' Ex. 130.

561. Hoffman summarizes the results of two Meltdown studies, but fails to give any opinion regarding the non-common, additional ingredients in Meltdown. Defendants' Ex. 134 ¶¶ 35-37.

562. Jacobs discusses Meltdown study results, but describes Meltdown as a supplement "containing caffeine, yohimbe, synephrine, and acacia alkaloids," while failing to mention the non-common, additional ingredients. Defendants' Ex. 129 ¶¶ 53-59.

563. Heuer describes tetradecylthioacetic acid, yerba mate extract, and hordenine as "key ingredients" in Meltdown, but never discusses the effects of those non-common, additional ingredients and, in fact, wrongly claims that they are present in the Hi-Tech products. Defendants' Ex. 133 ¶ 93.

564. The document produced by Wheat materially differs from the actual Meltdown product label. *Compare* Defendants' Ex. 124 at 1 (Wheat document), *with* Defendants' Exs. 124 at 2 (Meltdown label), 106 at 3 (Meltdown label), 107 at 3 (Meltdown label).

565. First, "yerba mate" extract is listed on the product label but not on Wheat's document. Although Wheat claimed that the "CCK" listed on his document is another name for yerba mate, 4/4/17 Trial Tr. at 188:14, there is no support for that claim other than Wheat's self-serving statement.

566. Second, the actual Meltdown label indicates that there are 317 mg, combined, of caffeine, tetradecylthioacetic acid, yerba mate, and cAMP in a serving of Meltdown. Defendants' Ex. 124 at 2; 4/5/17 Trial Tr. at 21:7-19. One of the Meltdown studies similarly notes that there are 317 mg of this "proprietary blend." Defendants' Ex. 105 at 3. Even assuming that the "CCK" in Wheat's document (Defendants' Ex. 124 at 1) is actually yerba mate, the quantities of the four ingredients in Wheat's document total 275.2002002 mg, falling 42 mg short of the 317 mg that the label says are present.

567. Wheat's testimony is at odds with the Meltdown label, the studies of Meltdown, and FDA regulations.

ii. The Acute Metabolic Meltdown Studies Are Insufficient To Substantiate Any Weight Loss, Fat Loss, Or Appetite Suppression Claims.

568. None of the Meltdown studies measure weight loss, fat loss, or appetite suppression and thus cannot be used to substantiate such claims. *See* Defendants' Exs. 105-109; Plaintiff's Ex. 581 ¶ 78; 3/27/17 Trial Tr. at 104:9-18, 106:19-107:5, 3/28/17 Trial Tr. at 50:10-14; 3/29/17 Trial Tr. at 81:23-

82:8 (Contempt Defendants' expert Lee agreeing that Meltdown studies do not measure changes in weight or body composition).

569. Contempt Defendants' expert Hofmann also admitted that because the six-hour Bloomer Meltdown study did not measure weight loss or fat loss, it did not substantiate weight loss or fat loss claims even for Meltdown, much less the Hi-Tech Products. 3/30/17 Trial Tr. at 215:25-216:20.

570. Hoffman concedes that results of his own Meltdown study cannot be extrapolated to weight or fat loss, stating: "Additional research is warranted concerning the long-term effects of consumption of this supplement, and whether such supplementation can translate into weight loss or improved body composition." Defendants' Ex. 108 at 8.

571. Contempt Defendants' expert Heuer opined that the studies of Meltdown show that Meltdown "promote[s] fat burning and oxidation," not that it causes fat burning and oxidation. 4/4/17 Trial Tr. at 88:2-4.

572. Even the authors of the studies caution: "Additional research is warranted concerning the long-term effects of consumption of this supplement, and whether such supplementation can translate into weight loss or improved body composition." Defendants' Ex. 108 at 8; *see also* Defendants' Ex. 106

at 8 ("[I]ntervention studies are warranted to determine the impact of this dietary supplement on weight/fat loss."); Defendants' Ex. 109 at 5 ("Future research should examine the potential role that chronic intake of this supplement has on fat loss and body composition.").

573. Indeed, Contempt Defendants' expert Hoffman agreed with one Meltdown study's conclusion that "[W]hile anecdotal evidence indicates that Meltdown continues to exhibit potent effects on weight loss despite intake over periods of several weeks of use, ***well-controlled clinical trials are indeed needed to confirm this***." 3/30/17 Trial Tr. at 213:20-214:10, 215:5-7 (emphasis added); Defendants' Ex. 107 at 8.

574. Several of the Meltdown studies were conducted on subjects who were in a fasted state. Gaginella Tr. at 138:17-24, 144:12-17, 147:3-9. Fasted-state studies cannot be used to support fat burning or fat loss claims. *See* FOF ¶¶ 435-443.

iii. The Meltdown Studies Are Not Sufficient To Substantiate Unqualified Metabolism Claims Even For Meltdown.

575. Nor do the Meltdown studies constitute competent and reliable scientific evidence to substantiate increased metabolism claims. *See* Plaintiff's Ex. 580 ¶¶ 69, 71; Plaintiff's Ex. 581 ¶¶ 77-82.

576. Two Meltdown studies by Bloomer do not constitute competent and reliable scientific evidence because they are small (10 and 20 subjects respectively) and short in duration (90 minutes and 6 hours respectively). 3/27/17 Trial Tr. at 107:22-108:3, 111:6-13; Plaintiff's Ex. 580 ¶ 71; Defendants' Exs. 106-107.

577. The author of the studies reached the same conclusion, stating: "Whether or not the lipolytic effects are maintained ***with chronic intake*** remains to be determined, as ***most individuals experience some desensitization with chronic treatment***, which often requires a higher dosage in order to maintain effectiveness. Moreover due to the potent metabolic effects of dietary agents, it's possible that individuals who cease use after chronic intake may experience a lower resting metabolic rate as a result." Defendants' Ex. 107 at 8 (emphasis added). A lowered resting metabolic

rate is part of the resistance mechanism that prevents weight loss. *See* 3/28/17 at 46:16-47:

578. Contempt Defendants' expert Hoffman agreed with Bloomer that it would be "incorrect" to extrapolate the results of Bloomer's six-hour study beyond the six-hour time period. *See* FOF ¶ 381.

579. The Hoffman Meltdown study assessed the effects of Meltdown in ten subjects over three hours. 3/27/17 Trial Tr. at 113:1-6; Defendants' Ex. 108. The study's small size and short duration preclude it from being considered competent and reliable scientific evidence to substantiate increased metabolism claims, even for Meltdown. 3/27/17 Trial Tr. at 112:18-113:6.

580. The Jitomir study assessed the effects of Meltdown in 12 subjects over two hours post-ingestion. Defendants' Ex. 105. The study is both too small and too short in duration to constitute competent and reliable scientific evidence to support an increased metabolism claim, even for Meltdown. Plaintiff's Ex. 580 ¶ 71; 3/27/17 Trial Tr. at 107:6-9.

581. The study by Rashti assessed the effects of Meltdown RTD energy drink versus placebo in ten women over the course of three hours. *See* 3/27/17

Trial Tr. at 19:23; Defendants' Ex. 109. Both the small size and short duration of the study preclude it from being considered competent and reliable scientific evidence that Meltdown – let alone the Hi-Tech products – chronically increase metabolism. Plaintiff's Ex. 581 ¶ 77; *see also* 3/27/17 Trial Tr. at 104:25-105:12 ("It's a three hour study, so you can tell what happened over three hours. You can't tell what happened six hours later, ten hours later, the following day. And you definitely can't tell what happens to body weight, body composition, appetite, [or] metabolism over a prolonged period of time from a three hour study.")

582. In addition, because the Meltdown RTD was delivered as a liquid drink as opposed to in pill form, it cannot be appropriately compared to the Hi-Tech products. Plaintiff's Ex. 581 ¶ 77.

583. The study by Wilson is an unpublished, unblinded study that attempted to assess the effect of Meltdown in five subjects over three hours. 3/27/17 Trial Tr. at 103:6-14; Plaintiff's Ex. 581 ¶ 78. In addition to being unblinded, the Wilson study lacked a placebo control and did not include a calculation of statistical significance. 3/27/17 Trial Tr. at 103:15-19; Plaintiff's Ex. 581 ¶ 78. Thus, the Wilson study does not meet any of the

criteria necessary to constitute competent and reliable scientific evidence to substantiate claims about Meltdown, let alone Hi-Tech's weight loss products. 3/27/17 Trial Tr. at 103:20-23; Plaintiff's Ex. 581 ¶ 78.

3. Ingredient Studies Alone Do Not Substantiate Contempt Defendants' Unqualified, Causal Efficacy Claims.

584. Studies of the individual ingredients that comprise the Hi-Tech Pharmaceuticals' products at issue do not constitute competent and reliable scientific evidence to substantiate Contempt Defendants' unqualified, causal, product-specific efficacy claims. *See* FOF ¶¶ 585-627.

585. In forming his expert opinion, Dr. Aronne specifically reviewed ingredient-specific studies. *See* 3/27/17 Trial Tr. at 93:2-3.

586. Dr. Aronne explained that the ingredient-specific studies did not support Contempt Defendants' advertising claims because they were generally acute metabolic studies that did not measure weight loss, fat loss, or appetite, and thus, could not support claims that the products cause rapid or substantial weight loss, fat loss, or that the products affect body fat or appetite. 3/27/17 Trial Tr. at 93:14-94:1.

587. Dr. Aronne further explained that these acute, ingredient-specific studies cannot support claims of increased metabolism that are not time-limited. 3/27/17 Trial Tr. at 94:2-7.

588. In addition, many of these studies are confounded by the presence of ingredients that are not present in the Hi-Tech products, and thus, their results cannot be extrapolated to Fastin, Lipodrene, Benzedrine, and Stimerex-ES. *See, e.g.*, Plaintiff's Ex. 580 ¶¶ 69, 71, 114; Plaintiff's Ex. 581 ¶¶ 81, 83-84, 93, 99.

a. Studies Of Citrus Aurantium Do Not Substantiate Contempt Defendants' Unqualified, Product-Specific, Causal Efficacy Claims.

589. Studies of citrus aurantium do not substantiate Contempt Defendants' unqualified, product-specific causal efficacy claims. *See* FOF ¶¶ 590-596.

590. Dr. Aronne reviewed studies of citrus aurantium and concluded that citrus aurantium does not have efficacy for weight loss. *See* 3/27/17 Trial Tr. at 94:8-13; Plaintiff's Ex. 580 ¶¶ 65-79.

591. For example, Dr. Aronne relied on a systematic review of the literature concerning citrus aurantium authored by Bent that showed that citrus aurantium is not effective for weight loss. 3/27/17 Trial Tr. at 94:11-95:20.

592. Similarly, Dr. Aronne relied on a study by Seifert that showed that a combination of caffeine, citrus aurantium, and green tea had no effect on metabolism. *See* Plaintiff's Ex. 580 ¶ 77.

593. Dr. Aronne also explains that three acute studies cited by Contempt Defendants as support for citrus aurantium's supposed efficacy contain express limitations on their generalizability. *See* Plaintiff's Ex. 581 ¶¶ 95-97.

594. For example, in a 1997 unpublished metabolic study by Hedrei of seven subjects over a short period of time, the author expressly acknowledges that the study is underpowered and, thus, cannot yield generalizable results, stating: "A minimum of 14 lean, 14 obese subjects with diabetes, and 14 obese nondiabetic subjects are required in order to provide an 80% probability of detecting a difference of 8 Calories in metabolic rate with an intra-individual standard deviation of 6.4 calories. More studies have to be performed in order to bring the sample size to an acceptable number." Plaintiff's Ex. 581 ¶ 95.

595. Similarly, in a 1999 unpublished study by Pathak that studied 5 obese women over a short duration, the authors acknowledged "[m]ore obese

non-diabetic subjects need to be studied if they are to be compared to the lean population, as well as to affirm whether the [metabolic] values actually increase or decrease." Plaintiff's Ex. 581 ¶ 96. Dr. Aronne explains that the authors of the study recognize that the small number of subjects preclude accurate predictions about the study's reliability and whether the direction of the findings can be assured. *Id.*

596. Similarly, a 2005 study by Gougeon that tested the metabolic effects of a substance called "ZhiThin" consisting of synephrine derived from citrus aurantium, and 4 other ingredients not present in the Hi-Tech products, over 300 minutes in 30 subjects, acknowledged that "this acute response may not translate in a chronic effect or a clinically significant weight loss over time." Plaintiff's Ex. 581 ¶ 97. Thus, as Dr. Aronne explains, the authors of the study acknowledge that the apparent transient effect cannot be extrapolated to draw conclusions about the long-term effects of the substance. *Id.*

b. Studies Of Yohimbine Do Not Substantiate Contempt Defendants' Unqualified, Product-Specific, Causal Efficacy Claims.

597. Dr. Aronne also reviewed studies of yohimbine and concluded that based on those studies there is no competent and reliable scientific evidence that yohimbine has efficacy that would substantiate claims of rapid or substantial weight or fat loss, or claims of effect on body fat, metabolism, and appetite. 3/27/17 Trial Tr. at 95:21-96:15; *see also* Plaintiff's Ex. 580 ¶¶ 84-88.

598. For example, Dr. Aronne relied on a study by Leonard Sax titled "Yohimbine Does Not Affect Fat Distribution in Men." 3/27/17 Trial Tr. at 96:16-24. That study, which followed 33 subjects over a six-month period, concluded that treatment with yohimbine had no effect on "weight, [waist] circumference . . . [or] waist to hip ratio in comparison to the control group." *Id.* at 96:25-97:5.

599. Similarly, Dr. Aronne explains that an 8 week double-blind study of yohimbine in obese subjects showed no difference between the test and control groups with respect to body weight or lipid parameters. Plaintiff's Ex. 580 ¶ 84.

600. Dr. Aronne also explains that the studies Contempt Defendants cite as substantiation acknowledge limitations that preclude those studies from constituting competent and reliable scientific evidence that would substantiate their unqualified, causal efficacy claims. *See* Plaintiff's Ex. 581 ¶¶ 100-103.

601. For example, in a 1988 acute study by Galitzky, the authors recognize that the effect of yohimbine on lipolysis only appears when the subjects are in the fasting state and is "entirely negated and completely suppressed after ingestion of a meal." Plaintiff's Ex. 581 ¶ 100.

602. As discussed above, *see* FOF ¶ 444, Contempt Defendants' advertising claims are not limited to the fasting state, and consumers are not directed to take the products in a fasting state, *see* FOF ¶¶ 445-448.

603. Similarly in a 2006 Ostojic study, the authors acknowledge that yohimbine has a "minimal benefit" for fat loss and that the published data on the "effects of yohimbine administration on weight loss or fat reduction/distribution are both ***unconvincing*** and controversial." Plaintiff's Ex. 581 ¶ 103 (emphasis added). The authors of the Ostojic

study also note that yohimbine does not appear to increase metabolic parameters as some researchers had hypothesized. *Id.*

604. Dr. Aronne also explains that other studies of yohimbine on which Contempt Defendants rely involve yohimbine at significantly higher dosages than are present in the Hi-Tech Pharmaceuticals products. *See* Plaintiff's Ex. 581 ¶¶ 101-103. Accordingly, their results cannot be extrapolated to the Hi-Tech products. *See* FOF ¶¶ 413-424.

c. Studies Of Caffeine Do Not Substantiate Contempt Defendants' Unqualified, Product-Specific, Causal Efficacy Claims.

605. Dr. Aronne reviewed studies of caffeine and concluded, based on those studies, that "there is not competent and reliable scientific evidence that caffeine causes rapid and substantial weight loss, [or] that it has any effect on body fat, fat loss, and appetite." 3/27/17 Trial Tr. at 97:22-98:6.

606. Dr. Aronne also testified that there is no evidence that caffeine increases metabolism beyond acute time periods. 3/27/17 Trial Tr. at 98:22-99:1.

607. He explained that studies of caffeine do not constitute competent and reliable scientific evidence sufficient to support these claims because "[t]he body becomes habituated to caffeine rapidly" requiring a user to ingest

more and more to obtain the same effect. 3/27/17 Trial Tr. at 98:10-18. Accordingly, "using caffeine as a weight loss agent over a period of time has not proven to be effective . . . [a]nd it hasn't proven to be effective producing rapid and substantial weight loss." *Id.* at 98:10-22; *see also* Plaintiff's Ex. 580 ¶ 90.

608. For example, a 2006 10-person study of a "nutritionally enriched coffee drink" consisting of 450 mg of caffeine, 1200 mg of garcinia cambogia (which is not contained in any of the Hi-Tech products), and 360 mg of citrus aurantium (6% synephrine alkaloid) conducted by Contempt Defendants' expert Hoffman did not show a statistically significant increase in metabolism when the test group was compared to the placebo group. Plaintiff's Ex. 581 ¶ 83.

609. Similarly, Dr. Aronne explained that a 1989 study by Dulloo found that obese women did not lose more weight when consuming caffeine in comparison to placebo. Plaintiff's Ex. 580 ¶ 91.

610. Dr. Aronne explains that the remaining studies on caffeine are small, acute metabolic studies that cannot be extrapolated to substantiate Contempt Defendants' unqualified claims. *See* Plaintiff's Ex. 580 ¶¶ 94-102.

d. Studies Of Green Tea Do Not Substantiate Contempt Defendants' Unqualified Product Specific Causal Efficacy Claims.

611. Dr. Aronne also reviewed studies relating to green tea and concluded that "[t]here is no competent and reliable scientific evidence that green tea causes rapid and substantial weight loss, fat loss, changes in body fat, appetite, or metabolism." 3/27/17 Trial Tr. at 99:2-11.

612. In forming his opinion, Dr. Aronne relied on a meta-analysis prepared by the Cochrane Collaboration entitled "Green Tea for Weight Loss and Weight Maintenance in Overweight or Obese Adults." 3/27/17 Trial Tr. at 100:3-24. Dr. Aronne explained that the Cochrane Collaboration is very reputable and uses statistical methods to analyze different trials to determine whether conclusions can be drawn from small data sets. *Id.*

613. Dr. Aronne explained that the authors of the Cochrane Collaboration article concluded that "[g]reen tea preparations appear to induce small, statistically non-significant weight loss in overweight or obese adults. Because the weight loss is small, it is not likely to be clinically important. Green tea had no significant effect on the maintenance of weight loss." 3/27/17 Trial Tr. at 101:16-102:1.

e. Studies Of The Other Ingredients In The Hi-Tech Products Do Not Substantiate Contempt Defendants' Unqualified Product Specific Causal Efficacy Claims.

614. Dr. Aronne reviewed studies of the remainder of the individual ingredients that comprise the Hi-Tech Pharmaceuticals' products at issue and concluded that, for each ingredient, there is no competent and reliable scientific evidence to substantiate Contempt Defendants' unqualified, causal, product-specific efficacy claims. *See* FOF ¶¶ 615-627.

615. Dr. Aronne reviewed studies of phenylethylamines—sometimes identified by Contempt Defendants as "acacia extract" or "acacia rigidula extract"—and concluded that "[t]here is no competent and reliable scientific evidence that phenylethylamines cause substantial or rapid weight or fat loss, appetite suppression, or increased metabolism in humans." Plaintiff's Ex. 580 ¶ 58-63; Plaintiff's Ex. 581 ¶ 105.

616. Dr. Aronne reviewed studies of theobromine and concluded that "[t]here is no competent and reliable scientific evidence that theobromine anhydrous, theobromine, or Theobroma cocoa extract cause substantial or rapid weight or fat loss, appetite suppression, or increased metabolism in humans." Plaintiff's Ex. 580 ¶ 80-82.

617. Dr. Aronne reviewed studies of ephedra extract—which lacks the ephedra alkaloids banned by FDA—and concluded that "[t]here is no competent and reliable scientific evidence that ephedra extract without ephedra alkaloids causes substantial or rapid weight or fat loss, appetite suppression, or increased metabolism in humans." Plaintiff's Ex. 580 ¶ 103-104.

618. Dr. Aronne reviewed studies of hoodia and concluded that "[t]here is no competent and reliable scientific evidence that hoodia causes substantial or rapid weight or fat loss, appetite suppression, or increased metabolism in humans." Plaintiff's Ex. 580 ¶¶ 115-117; Plaintiff's Ex. 581 ¶¶ 87-90.

619. Dr. Aronne reviewed studies of cassia nomame and concluded that "[t]here is no competent and reliable scientific evidence that cassia nomame extract causes substantial or rapid weight or fat loss, appetite suppression, or increased metabolism in humans." Plaintiff's Ex. 580 ¶¶ 118-119.

620. Dr. Aronne reviewed studies of naringin—sometimes misspelled as "naringen" on Contempt Defendants' labels—and concluded that "[t]here is no competent and reliable scientific evidence that naringin causes

substantial or rapid weight or fat loss, appetite suppression, or increased metabolism in humans." Plaintiff's Ex. 580 ¶ 120.

621. Dr. Aronne reviewed studies of 6, 7 Dihydroxybergamottin ("DHB" or "bergamottin") and concluded that "[t]here is no competent and reliable scientific evidence that DHB causes substantial or rapid weight or fat loss, appetite suppression, or increased metabolism in humans." Plaintiff's Ex. 580 ¶ 121.

622. Dr. Aronne reviewed studies of 5-Methoxytryptamine HCL ("5-MT") and concluded that "[t]here is no competent and reliable scientific evidence that 5-MT causes substantial or rapid weight or fat loss, appetite suppression, or increased metabolism in humans." Plaintiff's Ex. 580 ¶ 122.

623. Dr. Aronne reviewed studies of L-5-hydroxytryptophan and concluded that "[t]here is no competent and reliable scientific evidence that L-5-hydroxytryptophan causes substantial or rapid weight or fat loss, appetite suppression, or increased metabolism in humans." Plaintiff's Ex. 580 ¶¶ 123-126.

624. Dr. Aronne reviewed studies of mucuna pruriens extract and concluded that "[t]here is no competent and reliable scientific evidence that mucuna pruriens extract causes substantial or rapid weight or fat loss, appetite suppression, or increased metabolism in humans." Plaintiff's Ex. 580 ¶ 127.

625. Dr. Aronne reviewed studies of dimethyl-aminoethanol (DMAE) bitartrate and concluded that "[t]here is no competent and reliable scientific evidence that DMAE bitartrate causes substantial or rapid weight or fat loss, appetite suppression, or increased metabolism in humans." Plaintiff's Ex. 580 ¶¶ 128-129.

626. Dr. Aronne reviewed studies of L-tyrosine ethylester and concluded that that "[t]here is no competent and reliable scientific evidence that L-tyrosine ethylester causes substantial or rapid weight or fat loss, appetite suppression, or increased metabolism in humans." Plaintiff's Ex. 580 ¶¶ 130-131.

627. Dr. Aronne reviewed studies of L-phenylalanine ethylester and concluded that "[t]here is no competent and reliable scientific evidence that L-phenylalanine ethylester causes substantial or rapid weight or fat loss,

appetite suppression, or increased metabolism in humans." Plaintiff's Ex. 580 ¶¶ 132-133.

4. Contempt Defendants' Comparative Claim For Stimerex-ES Is Unsubstantiated.

628. Dr. Aronne testified that "[t]here are no data regarding the effect of non-alkaloid ephedra extract on weight loss, fat loss, appetite, or food intake, or metabolism." Plaintiff's Ex. 580 ¶ 104. As a result, Dr. Aronne concluded that "[t]here is no competent and reliable scientific evidence that ephedra extract without ephedrine alkaloids causes substantial or rapid weight or fat loss, appetite suppression, or increased metabolism in humans." *Id.*

629. Contempt Defendants' expert Jacobs is not offering an opinion that the ephedra extract in Stimerex-ES has the same effect on increasing metabolic rate as ephedrine. 4/3/17 Trial Tr. at 76:15-21.

630. Jacobs is not offering the opinion that the acacia extract in Stimerex-ES has the same effects as ephedrine. 4/3/17 Trial Tr. at 76:22-77:3. Jacobs's opinions regarding acacia extract as compared to ephedrine are limited to the acacia's acute effects on metabolism, rather than its chronic effects on metabolism or any effects on fat loss. *Id.* at 77:9-19.

631. Jacobs admitted that the fact that a product includes acacia extract does not tell someone what particular phenylethylamines are in the product. 4/3/17 Trial Tr. at 79:14-17. Dr. Jacobs also admitted that, in his view, before he conducted his Fastin-XR metabolism study, "the body of knowledge surrounding acacia and phenylethylamines was sparse." *Id.* at 80:3-6. In fact, prior to being engaged to study Fastin XR, Jacobs was not even familiar with acacia. *Id.* at 80:7-10.

632. Jacobs' limited opinions regarding acacia extract, moreover, are based solely on his Fastin-XR acute metabolism study. 4/3/17 Trial Tr. at 77:20-24.

633. Contempt Defendants' expert Lee is not offering an opinion that either the ephedra extract or the acacia rigidula in Stimerex-ES has the same effect on increasing metabolic rate as ephedrine. 3/29/17 Trial Tr. at 64:15-65:3.

634. Dr. Aronne explained that the Fastin-XR metabolism study does not constitute competent and reliable scientific evidence regarding the efficacy of acacia because it is "too short, [and] too small. It's not studying fat, fat loss, weight loss[,] or other aspects that would be important." 3/28/17 Trial Tr. at 12:22-13:12. He further explained that the flaws in the study

design and execution also preclude the Fastin-XR study from constituting competent and reliable scientific evidence. *See* FOF ¶¶ 480-493, *supra*.

5. Contempt Defendants' Experts Do Not Address Contempt Defendants' Unqualified, Causal Efficacy Claims.

635. Contempt Defendants' experts do not testify that Contempt Defendants' unqualified, product-specific, causal weight loss, fat loss, and appetite suppression claims are substantiated. FOF ¶¶ 636-664. Rather, they confine their opinions to claims that are not at issue in this case, such as claims that the products "aid in weight loss" or "aid in substantial fat loss as part of a program of diet and exercise." *See* FOF 636, 641, 649-655, 657, 660, 662, 664.

636. Contempt Defendants' expert Gaginella does not opine that Contempt Defendants' unqualified, causal efficacy claims are substantiated. Instead, he states that, in his view, there is "competent and reliable scientific evidence" that 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." Defendants' Ex. 126 at 6 ¶ 1.

637. While on direct examination, Gaginella backed away from even the limited opinions contained in his report. When asked whether Fastin would aid

weight loss as part of a program of diet and exercise, Gaginella responded: "My opinion on that would be it's ***quite possible, but I – I can't say absolutely yes it would or it wouldn't***, but it is possible based on all the other information that I've reviewed and we've talked about." Gaginella Tr. at 131:8-16 (emphasis added).

638. Gaginella admitted that use of the Hi-Tech Products would not guarantee fat loss, adding that "I don't think anybody can guarantee that . . . any herbal product will do anything." Gaginella Tr. at 134:16-135:11.

639. On re-direct examination, counsel for Contempt Defendants asked Gaginella, "***[A]ssuming hypothetically*** that someone continued to take products that showed a certain effect acutely, is there any reason to ***assume*** that the product wouldn't have the same effect long term if you continued to take it?" Gaginella replied, "Not on the face it, no. You would ***assume*** that it would continue the same sort of an effect that it would be, yes." Gaginella Tr. at 185:4-12.

640. Contempt Defendants' expert witness, Jay Hoffman, admitted that he was "not offering any opinions on the [Hi-Tech] products" at all.

641. Instead, Hoffman's opinions are limited to certain statements concerning the ingredients in the products. 3/30/17 Trial Tr. at 175:10-14. Hoffman's ingredients opinions, moreover, are very narrow. Hoffman claimed that "the ingredients of the products have the ***potential*** to cause weight loss." *Id.* at 175:15-19 (emphasis added).

642. At trial, Contempt Defendants also conceded that Hoffman was not offering any opinion on Hi-Tech's claims, explaining that he "didn't review the claims in his expert report." *Id.* at 184:1-4.

643. At his deposition, moreover, Hoffman expressly admitted that he is offering no opinion "as to whether [Fastin, Lipodrene, Benzedrine, or Stimerex-ES] cause weight loss," much less rapid or substantial weight loss. 3/30/17 Trial Tr. at 175:24-176:6.

644. Hoffman also admitted at his deposition that he was not offering an opinion "as to whether [Fastin, Lipodrene, Benzedrine, or Stimerex-ES] cause fat loss," much less rapid or substantial fat loss. 3/30/17 Trial Tr. at 177:19-177:25. Similarly, Dr. Hoffman admitted at his deposition that he was offering no opinion as to whether the Hi-Tech products "affect body fat." 3/30/17 Trial Tr. at 179:21-180:2.

645. At his deposition, when asked about Contempt Defendants' "EXTREME WEIGHT LOSS GUARANTEED!" claim for Fastin, *see* FOF ¶ 135, *supra*, Hoffman said, "If I was a scientist that was employed by Hi-Tech prior to me being used as an expert witness, I would advise them differently." 3/30/17 Trial Tr. at 181:9-19. Hoffman also declared himself a "scientist not a marketing person," but nevertheless attempted to defend Contempt Defendants' "EXTREME WEIGHT LOSS GUARANTEED!" claim by calling it "puffery" and declaring it "no different than every other ad that's out there." *Id.* at 180:12-23.

646. At his deposition, Hoffman agreed that the Fastin claim "Increases the release of norepinephrine and dopamine for dramatic weight loss," FOF ¶¶ 135-136, was not substantiated. 3/30/17 Trial Tr. at 183:2-12. At trial, Hoffman changed his testimony and declared that he actually "wasn't aware of the ingredients" at the time he gave his deposition answer. *Id.* at 181:22-183:12.

647. When asked at his deposition whether Contempt Defendants possess substantiation for the Fastin claim, "EXTREMELY POTENT DIET AID! DO NOT CONSUME UNLESS RAPID FAT AND WEIGHT LOSS ARE

YOUR DESIRED RESULTS!," *see, e.g.*, FOF ¶ 134, *supra*, Hoffman said that he "would not feel comfortable" offering that opinion. 3/30/17 Trial Tr. at 184:24-185:9. At trial, Hoffman attempted to change his story, declaring this claim "part of the puffery." *Id.* at 184:11-23.

648. When asked whether Contempt Defendants possessed substantiation for the claim Benzedrine "simply blows fat away!," *see, e.g.*, FOF ¶ 216, *supra*, Hoffman again explained he "may not feel comfortable" giving an opinion because "my perspective is as a scientist" and "as a scientist I'm not sure how you can support something that shows simply blows fat away." 3/30/17 Trial Tr. 185:17-186:14. Hoffman proceeded to opine that the claim was "puffery," adding, "[w]e see this all the time, [a]nd when you turn on the TV, you'll see puffery all the time. That is common to what we see in this country." *Id.* at 186:15-21.

649. Another of Contempt Defendants' expert witnesses, Lee, does not opine that Contempt Defendants' unqualified, causal efficacy claims are substantiated. Instead, he states that Fastin, Benzedrine, Lipodrene, and Stimerex-ES "[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." Defendants' Ex. 132 ¶ 25.

650. Lee admitted at his deposition that his opinions regarding the effects of Fastin, Lipodrene, Benzedrine, and Stimerex-ES on weight loss are limited to those products' use "as part of a comprehensive program that includes diet and exercise." 3/29/17 Trial Tr. at 58:2-25. At trial, Lee attempted to change his testimony, but still only went so far as to declare that the products, "based on the mechanism of action, ***could*** cause weight loss." *Id.* at 57:17-58:1 (emphasis added).

651. Lee admitted at his deposition that his opinions regarding the effects of Fastin, Lipodrene, Benzedrine, and Stimerex-ES on fat loss are limited to those products' use "as part of a comprehensive weight management program." 3/29/17 Trial Tr. at 59:15-24. At trial, Lee attempted to change his testimony, but still only went so far as to declare that "based on the mechanisms of the products, in and of themselves[, they] ***can*** cause fat loss." *Id.* at 59:1-6 (emphasis added).

652. Contempt Defendants' expert La Puma did not opine that the Hi-Tech products would cause weight loss of any type. 3/30/17 Trial Tr. at 41:2-

11. Rather, he opined that the products would "aid in weight loss." *Id.*; *see also* 3/30/17 Trial Tr. at 44:21-25 (admitting that "aid" means "helps"). He offered no opinion regarding any claims of rapid or substantial weight loss. 3/30/17 Trial Tr. at 41:2-11.

653. La Puma also did not opine that the Hi-Tech products would cause fat loss of any type. 3/30/17 Trial Tr. at 41:12-20. Rather, he opined that the products would "aid in fat loss." *Id.*; *see also* 3/30/17 Trial Tr. at 45:1-6 (admitting that "aid" means "help"). He offered no opinion regarding any claims of rapid or substantial weight loss. 3/30/17 Trial Tr. at 41:12-20.

654. La Puma admitted at his deposition that his opinion was that the Hi-Tech products merely "aid" in the suppression of appetite, and also admitted that by "aid" he meant "help." 3/30/17 Trial Tr. at 45:11-25. At trial, he attempted to change his testimony to claim that the products suppress appetite. *See* 3/30/17 Trial Tr. at 39:23-40:13.

655. La Puma admitted at his deposition that his opinion was that the Hi-Tech products merely "aid" in increasing metabolism and that "aid" meant "help." 3/30/17 Trial Tr. at 46:4-9. At trial, he attempted to change his testimony to claim that the products increase metabolism. *Id.* at 40:14-23.

656. Another of Contempt Defendants' expert witnesses, Jacobs, admitted that he is not offering an opinion that Fastin, Lipodrene, Benzedrine, or Stimerex-ES cause rapid or substantial weight loss. 4/3/17 Trial Tr. at 67:13-20; Defendants' Ex. 129 ¶ 12(a).

657. Jacobs admitted that the only opinion he was offering with respect to rapid or substantial weight loss at his deposition is that the Hi-Tech products "will aid in rapid or substantial weight loss as part of a program of diet and exercise." 4/3/17 Trial at 67:6-12; Defendants' Ex. 132 ¶ 13(a).

658. On the witness stand, Jacobs attempted to amend his opinions, claiming for the first time that the Hi-Tech Products would aid, on their own, rapid or substantial weight loss, and that diet and exercise simply enhance the products' effects. 4/3/17 Trial Tr. at 66:2-10. Jacobs admitted that his trial testimony went beyond what had been disclosed at his expert report and even his deposition testimony. *Id.* at 66:11-20.

659. Jacobs is not offering the opinion that the Hi-Tech Products cause rapid or substantial fat loss. 4/3/17 Trial Tr. at 69:23-70:2.

660. In fact, Jacobs testified that he believes it is inappropriate to use the word "cause" in connection with any of Contempt Defendants' products. Jacobs

explained that "cause" "may not be an appropriate word with any supplement that they cause something. . . . [I]n my field we don't use the word 'cause.' It's inferring cause and effect." 4/3/17 Trial Tr. at 67:16-20. Jacobs reiterated that "cause" was inappropriate word to use on three additional occasions. *Id.* at 70:1-2 ("we would never use the word 'cause'"), 78:3 ("Again, in my field we don't use the term 'cause.'"), 179:24 ("Again, I'd never use the word 'cause.'").

661. Indeed, when asked whether it would be the norm to base a causal claim on results that were not statistically significant, Jacobs stated that "in my field we don't use the term 'cause.'" 4/3/17 Trial Tr. at 77:25-78:3.

662. Jacobs admitted at his deposition that the only opinion he is offering with respect to rapid or substantial fat loss is that the Hi-Tech products "will aid" rapid or substantial fat loss "as part of a program of diet and exercise. 4/3/17 Trial Tr. at 69:4-22; Defendants' Ex. 129 ¶ 13(b). At trial, Jacobs also admitted that at the time of his deposition, his opinion was "limited . . . to the use of the products in combination with diet and exercise." 4/3/17 Trial Tr. at 68:24-69:3; *see also id.* at 69:14-22 (Jacobs agreed that as of his

deposition, he "was not offering" the opinions offered at trial regarding the effects of the product on their own).

663. Jacobs is not offering an opinion that Fastin, Lipodrene, Benzedrine, or Stimerex-ES suppress appetite. 4/3/17 Trial Tr. at 70:5-25.

664. Jacobs' opinion that the Hi-Tech products will increase metabolism is limited to the acute context and does not apply to chronic claims. 4/3/17 Trial Tr. at 71:1-7, 72:24-74:15.

C. Contempt Defendant Wright Did Not 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 Fastin.

665. After entry of the Hi-Tech Order, Wright reviewed ingredient-specific studies to support product efficacy claims for the Hi-Tech products. Wheat Dep. at 128:12-129:14, 131:20-132:5.

666. Wright continues to disavow the need to conduct either an examination or testing of Fastin, Lipodrene, Benzedrine, or Stimerex-ES. Plaintiff's Ex. 659 at 11-13.

667. Wright admits that his opinions relating to the efficacy of Fastin, Lipodrene, Benzedrine, and Stimerex-ES are based on ingredient-specific

studies and not on product-specific, double-blind, placebo-controlled trials of the products. Plaintiff's Ex. 659 at 10-13.

668. For the reasons explained above, ingredient-specific testing is not sufficient to substantiate the unqualified, product-specific, causal efficacy claims for Fastin made in Wright's endorsement. *See* FOF ¶¶ 472-627.

D. Contempt Defendants' Arguments That Double-Blind, Placebo-Controlled, Product-Specific Studies Are Not Needed To Substantiate Their Unqualified, Causal, Product-Specific Efficacy Claims Are Baseless.

669. Contempt Defendants offered four reasons that they were not required to substantiate their unqualified, causal efficacy claims with double-blind, placebo-controlled, product-specific studies: 1) Dr. Aronne did not apply the substantiation standard contained in the Hi-Tech and Wright Orders but rather the FDA's standard for prescription drug approval, *see*, *e.g.*, Defendants' Ex. 133 ¶ 58; 2) because the products are safe product-specific testing is not required, *see, e.g.*, 3/27/17 Trial Tr. at 20:14-23; 3) product-specific studies are economically infeasible, *see, e.g.*, 4/6/17 Trial Tr. at 68:19-70:25; 4) product-specific testing is not required because Hi-Tech did not target its advertising to obese consumers, *see, e.g.*, 3/27/17 Trial Tr. at 27:25-28:5.

670. Contempt Defendants' arguments have no basis in fact. *See* FOF ¶¶ 671-860.

1. Dr. Aronne Applied The Correct Substantiation Standard.

671. As demonstrated above, Dr. Aronne used a reliable methodology to reliably apply the "competent and reliable scientific evidence" standard contained in the Hi-Tech and Wright Orders. *See* FOF ¶¶ 255-466.

672. Dr. Aronne explained that the standard he applied is not FDA's standard for the approval of drugs. *See* 3/27/17 Trial Tr. at 72:9-23. Specifically, Dr. Aronne explained that in comparison to the FDA standard, experts in the field would require "much smaller trials of shorter duration" to substantiate the types of claims made by Contempt Defendants. *Id.*

673. Similarly, Dr. Aronne explained that the standard he applied is not the same as a Phase 3 clinical trial. *See* 3/27/17 Trial Tr. at 72:24-73:16. Although Phase 3 clinical trials are, like the trials described by Dr. Aronne, randomized, double-blinded, and placebo-controlled, they are also much larger and longer than the studies necessary to substantiate Contempt Defendants' unqualified, causal efficacy claims. *Id.* at 73:10-16.

Specifically, Dr. Aronne explained that Phase 3 clinical trials for weight loss require 3,500 subjects over up to two years. *Id.* at 73:3-9.

674. Dr. Aronne also explained that in forming his opinion that there was no competent and reliable scientific evidence to substantiate Contempt Defendants' claims, he looked at the totality of the evidence. 3/28/17 Trial Tr. at 51:21-52:2.

2. Contempt Defendants Have Not Demonstrated That Their Products Are Safe.

675. Contempt Defendants contend that if their products are safe, product-specific studies are unnecessary. *See* 3/27/17 Trial Tr. at 20:14-21:7; Dkt. No. 902 at 25.

676. Dr. Aronne explained that he bases his opinions on what is necessary to demonstrate the efficacy of the products at issue, not their safety. 3/27/17 Trial Tr. at 77:3-5.

677. However, Dr. Aronne had reviewed sufficient information to form an opinion concerning the safety of the products. 3/27/17 Trial Tr. at 77:6-9. Based on the information reviewed, Dr. Aronne opined that the Hi-Tech Pharmaceuticals' products at issue are not safe. *Id.* at 77:10-11.

678. First, Dr. Aronne based his opinions on the review of various acute studies, including the studies on Fastin-XR and Fastin-RR performed by Contempt Defendants' expert and Hi-Tech Pharmaceuticals' Research and Clinical Study Chief, that demonstrated a 25 to 30 percent increase in blood pressure over a 1- to 2-hour period. *See* 3/27/17 Trial Tr. at 78:3-8, 79:2-16. Dr. Aronne explained that this magnitude of increase was "highly significant" because, given that two-thirds of the U.S. population are overweight or obese, people who are looking for rapid or substantial weight loss tend to have hypertension and would be particularly susceptible to this type of increase in blood pressure. *Id.* at 78:3-79:1.

679. Second, Dr. Aronne reviewed an article by Harvard University researcher Dr. Pieter Cohen regarding BMPEA (beta-methylphenylethylamine), an ingredient in various Hi-Tech Pharmaceuticals products including Stimerex-ES. *See* 3/27/17 Trial Tr. at 82:8-83:2, 83:15-24.

680. Dr. Aronne explained that "BMPEA is a synthetic amphetamine-like compound that was developed in the 1930s as a substitute for amphetamine," causing concerns that the product carry a risk of

"increased blood pressure, stimulation, cardiac [events], [and] heart attack." 3/27/17 Trial Tr. at 82:10-12, 84:7-10.

681. Third, Dr. Aronne reviewed information concerning DMAA (dimethylamine), an ingredient in Fastin, Lipodrene, and Stimerex-ES. 3/27/17 Trial Tr. at 84:11-19; *see also* Plaintiff's Ex. 514. Specifically, Dr. Aronne reviewed an alert from the FDA warning the public about health risks associated with DMAA. 3/27/17 Trial Tr. at 84:24-85:11; *see also* Plaintiff's Ex. 668.

682. Dr. Aronne explained that because it is an "amphetamine-like compound," DMAA "can increase pulse, [and] blood pressure, and that can lead to cardiac side effects, arrhythmias, [and] heart attack." 3/27/17 Trial Tr. at 86:12-15.

683. Dr. Aronne also explained that, based on a Department of Defense Report, "[t]he longer military people took DMAA, the more likely they were to have adverse events." 3/28/17 Trial Tr. at 90:13-14. Dr. Aronne also described the results of an epidemiological survey that found that "among cases who used the products for more than 80 days, the likelihood of having multiple adverse events was three and a half fold higher and that

adverse medical outcomes were more than twice as likely to have been reported in those using DMAA in the same year." *Id.* at 91:1-18; *see also* Defendants' Ex. 123 at 28.

684. Fourth, Dr. Aronne based his opinions on the review of various adverse events relating to the products. *See* 3/27/17 Trial Tr. at 79:17-22. One of those adverse events related to Lipodrene and was documented in a published article titled "Ventricular Fibrillation Associated With the Use of Synephrine Containing Dietary Supplement." *See id.* at 79:23-80:22; *see also* Defendants' Ex. 226.

685. In the adverse event described in that article, an otherwise healthy 28-year old female who had taken Lipodrene was doing push-ups and suffered a cardiac arrest, requiring that she be transported to an emergency room, resuscitated, and intubated. *See* 3/27/17 Trial Tr. at 80:7-15; *see also* Defendants' Ex. 226.

686. Although the authors of the article attributed the cause of the event to the synephrine that is contained in the Lipodrene, Dr. Aronne explained that it is "difficult to attribute it to one specific [component of the product],

whether its's one like synephrine or whether it's the combination . . . and the interaction between them is hard to tell." 3/27/17 Trial Tr. at 80:16-22.

687. Another researcher, Sidney Stohs, also noted that "the product in question contains at least 10 alkaloids. As a consequence, it is impossible to conclude that one of these substances, namely synephrine, was responsible for the event . . . . The case report should have correctly and appropriately been entitled – '—multi-alkaloid-containing dietary supplement.'" Defendants' Ex. 227.

688. Dr. Aronne also considered the side effects experienced by subjects in the Jacobs' Fastin-RR metabolism study in forming his opinion regarding the safety of the Hi-Tech products. *See* 3/28/17 Trial Tr. at 22:23-23:8. Specifically, he considered that 2 out of the 14 participants in the study experienced symptoms, "which is a significant number." *Id.* at 23:4-8. Moreover, he considered that Subject 9 "had cardiac symptoms, which are extremely worrisome." *Id.*

689. Dr. Aronne also responded to Contempt Defendants' contention that a relative lack of adverse event reports demonstrates that a dietary

supplement is safe. *See* 3/27/17 Trial Tr. at 87:22-90:3; *see also* Plaintiff's Ex. 581 ¶¶ 24-26.

690. Specifically, Dr. Aronne explained that adverse events are "very underreported by the public." 3/27/17 Trial Tr. at 87:22-88:2. He further explained that this underreporting occurs because consumers "don't make the connection between what they are taking" and the side effects they are experiencing because "[t]here's a misconception that supplements have been approved by the FDA." *Id.* at 88:3-8.

691. Dr. Aronne based his opinion regarding the underreporting of dietary supplement-related side effects on a New England Journal of Medicine article and a report by the Government Accountability Office (GAO). 3/27/17 Trial Tr. at 88:9-22; *see also* Plaintiff's Ex. 581 ¶¶ 24-26; Plaintiff's Exs. 670-671.

692. Dr. Aronne explained that the New England Journal of Medicine article, entitled "Emergency Department Visits for Adverse Events Related to Dietary Supplements," found that out of the 23,000 emergency room visits due to dietary-supplement related adverse events each year, 25 percent

(i.e., 6,000) were due to the consumption of weight-loss supplements. *See* 3/27/17 Trial Tr. at 88:14-89:15; Plaintiff's Ex. 581 ¶ 26.

693. Moreover, the article concluded that those patients who visited emergency rooms after consuming weight-loss supplements experienced "cardiovascular symptoms [like] chest pain, shortness of breath, [and] chest pressure." 3/27/17 Trial Tr. at 89:16-19.

694. Dr. Aronne further testified that the GAO found that "there was underreporting of adverse events to the FDA in terms of reporting health problems in the dietary supplement area." 3/27/17 Trial Tr. at 89:20-90:3.

695. GAO further concluded that "consumers may be unaware of how, and to whom, [consumers] can report their side effects." Plaintiff's Ex. 581 ¶ 25. Specifically, GAO found that "consumers, health care professionals, and others may not recognize the chronic or cumulative toxic effects of a dietary supplement or . . . assume dietary supplements to be safe and not attribute negative effects to them." Plaintiff's Ex. 581 ¶ 25.

696. Hi-Tech Pharmaceuticals produced records indicating that serious adverse events were associated with the products at issue in this case, including cardiovascular symptoms of the type described by Dr. Aronne. *See*

Plaintiff's Ex. 630; Plaintiff's Ex. 631; Plaintiff's Ex. 632; Plaintiff's Ex. 634 at 1-2; Plaintiff's Ex. 636 at 2; Plaintiff's Ex. 641 at 4; Plaintiff's Ex. 642 at 2-3; Plaintiff's Ex. 639; Plaintiff's Ex. 646 at 2; Plaintiff's Ex. 647 at 2, 3, 8-10, 12; Plaintiff's Ex. 650.

697. For example, on May 12, 2009, a consumer who consumed Lipodrene experienced "life threatening" side effects, including pulses that were "abnormal" and "absent." *See* Plaintiff's Ex. 647 at 2.

698. On June 28 and June 29, 2010, a consumer who ingested Stimerex-ES experienced symptoms including "heart palpitations" and a "racing heart." *See* Plaintiff's Ex. 632.

699. On July 9, 2010, a consumer who ingested Stimerex-ES experienced symptoms including an abnormal heart rate and "palpitations." Plaintiff's Ex. 647 at 3.

700. On March 21, 2012, a consumer who ingested Lipodrene required "hospitalization" due to "atrial fibrillation" and an increased heart rate. Plaintiff's Ex. 647 at 8.

701. On August 3, 2012, Windmill Health Products, a distributor of Hi-Tech Pharmaceuticals products, including Fastin, notified Hi-Tech of a

complaint by a consumer involving a "health related event that required hospitalization of the consumer." Plaintiff's Ex. 634 at 1. Specifically, the customer after taking Fastin for "about 30 days" she suffered a "brain bleed/stroke" necessitating hospitalization in the Intensive Care Unit of her local hospital. *Id.* at 2.

702. On February 26, 2013, a consumer who ingested Fastin experienced an increased heart rate. *See* Plaintiff's Ex. 647 at 8.

703. On July 1, 2013, a consumer who ingested Fastin experienced an increased heart rate. *See* Plaintiff's Ex. 647 at 9.

704. On December 30, 2013, a consumer who ingested Fastin experienced "serious" side effects including "chest pain." *See* Plaintiff's Ex. 647 at 10.

705. On December 12, 2014 a consumer who ingested Fastin experienced side effects including an "irregular heartbeat." *See* Plaintiff's Ex. 641 at 4.

706. On December 15, 2014, a consumer who ingested Fastin experienced side effects including an abnormal heart rate. *See* Plaintiff's Ex. 647 at 12.

707. On December 24, 2014, a consumer who ingested Fastin experienced side effects including "chest pain." *See* Plaintiff's Ex. 636 at 2.

708. On January 14, 2015, a consumer who ingested Fastin reported that the product "made me very ill with heart palpitations." *See* Plaintiff's Ex. 642 at 2-3.

709. On April 13, 2015, a consumer who ingested Lipodrene experienced side effects including an increased heart rate. *See* Plaintiff's Ex. 647 at 12.

710. On August 17, 2015, a consumer who ingested Lipodrene report that after consuming one pill the consumer "had a lot of pain and pressure in my chest . . . my blood pressure was 140 90" and the symptoms worsened until seeing a doctor. Plaintiff's Ex. 639.

711. On February 10, 2016, a consumer who ingested Fastin reported that after taking the DMAA-free version of Fastin "she had heart palpitations or it made her heart race." Plaintiff's Ex. 646 at 2.

712. Contempt Defendants' expert La Puma admitted that in an article he wrote concerning weight-loss supplements, he stated that dietary supplements can have drug-like effects. 3/30/17 Trial Tr. at 67:15-22, 68:17-22.

3. Contempt Defendants' Arguments Concerning The Feasibility of Product-Specific, Double-Blind, Placebo-Controlled , Human Clinical Studies Are Baseless.

f. The Feasibility Of A Study Is Irrelevant To What Constitutes Competent And Reliable Scientific Evidence.

713. Contempt Defendants' expert Heuer agreed that the cost of research has no bearing on the scientific standards that apply to appropriate study design because "science is science." 4/4/17 Trial Tr. at 127:17-25.

g. Product-Specific, Double-Blind, Placebo-Controlled, Human Clinical Studies Are Not Infeasible.

714. The FTC's rebuttal expert, Dr. Richard van Breemen, explained that product-specific clinical trials of dietary supplements are both feasible and routine among those who perform dietary supplement research. Defendants' Ex. 140 ¶ 31.

715. Dr. van Breemen explained that he "routinely" directs or participates "in clinical trials of botanical dietary supplements." Defendants' Ex. 140 ¶ 32. He cited the work done by his own UIC/NIH Center for Botanical Dietary Supplements – including randomized, double-blind, placebo-controlled phase II clinical trials – in addition to work carried out by other botanical centers. Defendants' Ex. 140 ¶¶ 32-33; 4/5/17 Trial Tr. at 140:23-141:10.

716. Dr. Aronne testified that appropriately-sized efficacy trials of a dietary supplement could be conducted for "tens of thousands to hundreds of thousands of dollars." 3/27/17 Trial Tr. at 56:12-16.

717. Contempt Defendant's expert Heuer has designed a 70-person clinical trial of an "energy product" to test for weight loss. 4/4/17 Trial Tr. at 125:14-20. The cost of the study, which collected data from each subject over a three-month period, was approximately $130,000. *Id.* at 125:24-25.

718. Contempt Defendants' expert Lee agreed that "it wouldn't be unreasonable to test the products at issue in this case for fat loss" or for appetite suppression. 3/29/17 Trial Tr. at 79:8-80:15.

719. Lee also admitted that it would be feasible to conduct testing on the Hi-Tech products to determine their effects on rates of metabolism in humans. 3/29/17 Trial Tr. at 80:16-81:13.

720. Contempt Defendants' expert La Puma admitted that there is no technical or ethical reason that Hi-Tech could not conduct double-blind, placebo-controlled testing of its products for weight loss, fat loss, or metabolism. 3/30/17 Trial Tr. at 85:20-86:8.

h. Contempt Defendants Had Ample Resources To Conduct Product-Specific, Double-Blind, Placebo Controlled, Human Clinical Studies.

721. The evidence demonstrates that Hi-Tech and Wheat have spent tens of millions of dollars that could have been used to conduct product-specific, double-blind, placebo-controlled human clinical trials of adequate size and duration. FOF ¶¶ 722-754.

722. On November 3, 2011, two days after the FTC initiated these contempt proceedings, Hi-Tech purchased a dietary supplement company APS Nutrition for $1.2 million. *See* Plaintiff's Ex. 292 at 13; Plaintiff's Ex. 167 at 4; 1/22/14 Trial Tr. at 97:19-23, 98:8-16.

723. APS is a wholly-owned subsidiary of Hi-Tech Pharmaceuticals. Plaintiff's Ex. 167 at 4; 1/22/14 Trial Tr. at 99:11-16.

724. Wheat testified that APS has already earned back its purchase price of $1.2 million "and then some in profit" since Hi-Tech acquired it. 1/22/14 Trial Tr. at 99:11-17.

725. In 2012, Wheat paid $2 million from his personal bank account towards the purchase of Hi-Tech Nutraceuticals, LLC. 1/23/14 Trial Tr. at 4:8-15.

726. On December 28, 2012, Hi-Tech paid $600,000 as a down payment towards the $3 million purchase of dietary supplement company ALR Industries ("ALRI"). *See* Plaintiff's Ex. 292 at 13; Plaintiff's Ex. 167 at 4; 1/22/14 Trial Tr. at 98:17-99:10.

727. ALRI is a wholly-owned subsidiary of Hi-Tech Pharmaceuticals. Plaintiff's Ex. 167 at 4; 1/22/14 Trial Tr. at 98:17-23.

728. Wheat testified that, since 2011, Hi-Tech has purchased additional dietary supplement companies, with a total purchase price of approximately $22 million. 4/6/17 Trial Tr. at 78:15-24.

729. Wheat initially testified that, he considered purchasing VPX, the manufacturer of Meltdown, in 2016 for "tens of millions of dollars." 4/5/17 Trial Tr. at 20:10-15. Later in the trial, he changed his testimony, claiming to have said "about ten million dollars." 4/6/17 Trial Tr. at 44:12-15.

730. Hi-Tech spends about $3-4 million annually on advertising. 4/6/17 Trial Tr. at 44:16-18.

731. On January 18, 2012, an official check in the amount of $425,000 was purchased using funds from, Hi-Tech's wholly-owned subsidiary,

Affiliated Distribution's Fifth Third Bank account. Plaintiff's Ex. 271 at 4; Wheat Dep. at 22:13-23:2 (testifying that Hi-Tech acquired Affiliated Distribution as a wholly-owned subsidiary "for banking purposes").

732. Wheat refused to answer questions regarding the January 18, 2012, purchase of the $425,000 official check on the basis of his Fifth Amendment privilege against self-incrimination, including questions regarding the purpose for the purchase of the check. Wheat Dep. at 258:8-259:11.

733. On January 26, 2012, an official check in the amount of $439,166.68 was purchased using funds from Affiliated Distribution's Fifth Third Bank account. Plaintiff's Ex. 271 at 4.

734. Wheat refused to answer questions regarding the January 26, 2012, purchase of the $439,166.68 official check, asserting his Fifth Amendment privilege against self-incrimination, including questions regarding the purpose for the purchase of the check. Wheat Dep. at 259:12-260:12.

735. On April 14, 2012, Wheat received a $100,000 dividend from Hi-Tech. Plaintiff's Ex. 119 at 5.

736. On July 5, 2012, Wheat received a $350,000 dividend from Hi-Tech. Plaintiff's Ex. 119 at 10.

737. On September 25, 2012, Wheat received a $280,000 dividend from Hi-Tech. Plaintiff's Ex. 265 at 3; 1/22/14 Trial Tr. at 107:9-17.

738. When asked questions concerning the $280,000 dividend from Hi-Tech, Wheat asserted his Fifth Amendment privilege against self-incrimination. 1/22/14 Trial Tr. at 107:9-17.

739. On October 22, 2012, Wheat received a $900,000 dividend from Hi-Tech. Plaintiff's Ex. 265 at 2; 1/22/14 Trial Tr. at 105:12-21, 107:5-8.

740. When asked questions concerning the $900,000 dividend from Hi-Tech, Wheat asserted his Fifth Amendment privilege against self-incrimination. 1/22/14 Trial Tr. at 105:12-20, 107:5-8.

741. On November 16, 2012, Wheat received a $360,000 dividend from Hi-Tech drawn from a Regions Bank account. Plaintiff's Ex. 265 at 1; 1/22/14 Trial Tr. at 105:3-10.

742. When asked questions concerning the $360,000 dividend from Hi-Tech, Wheat asserted his Fifth Amendment privilege against self-incrimination. 1/22/14 Trial Tr. at 103:3-11.

743. In total, in 2012, Hi-Tech paid Wheat $2,590,000 in dividends. Plaintiff's Ex. 292 at 5; 1/22/14 Trial Tr. at 107:18-20.

744. When asked questions concerning the $2,590,000 in dividends from Hi-Tech he received in 2012, Wheat asserted his Fifth Amendment privilege against self-incrimination. 1/22/14 Trial Tr. at 107:18-20.

745. On January 8, 2013, Wheat entered into a contract to purchase a 2007 Lamborghini Gallardo from Exotic Midwest Motorsports. Plaintiff's Ex. 237; 1/22/14 Trial Tr. at 102:25-103:10.

746. The purchase price of the Lamborghini was $135,087. Plaintiff's Ex. 237 at 11; 1/22/14 Trial Tr. at 103:4-6.

747. Wheat put a $2,000 deposit on the Lamborghini on January 10, 2013. Plaintiff's Ex. 237 at 3, 4, 11.

748. Wheat paid the balance of $133,087 via wire transfer on January 11, 2013. Plaintiff's Ex. 237 at 5.

749. When asked questions concerning the purchase of the Lamborghini, Wheat asserted his Fifth Amendment privilege against self-incrimination. 1/22/14 Trial Tr. at 102:25-103:10.

750. On March 11, 2013, Wheat received a $400,000 dividend from Hi-Tech. Plaintiff's Ex. 231; 1/22/14 Trial Tr. at 107:23-108:5

751. When asked questions concerning the $400,000 dividend from Hi-Tech, Wheat asserted his Fifth Amendment privilege against self-incrimination. 1/22/14 Trial Tr. at 107:23-108:5.

752. On April 25, 2013, Wheat withdrew $1 million from an East-West bank account ending in -5489. Plaintiff's Ex. 234; 1/22/14 Trial Tr. at 100:14-16, 101:17-18, 101:24-15.

753. Wheat's signature appears on the withdrawal slip. Plaintiff's Ex. 234.

754. When asked questions concerning the $1 million withdrawal, Wheat asserted his Fifth Amendment privilege against self-incrimination. 1/22/14 Trial Tr. at 101:24-102:15.

4. Contempt Defendants Have Not Demonstrated That A Different Substantiation Standard Applies Based On The Target Audience For Their Advertising.

755. The evidence demonstrates that Contempt Defendants' claim that they did not target obese and overweight individuals with their marketing, but rather, young, healthy populations who were simply seeking a bikini body, is simply untrue. FOF ¶¶ 762-775. Moreover, even if it were true, Contempt Defendants have not established any scientific basis as to why a

different standard would apply, other than their expert witnesses' *ipse dixit*. FOF ¶¶ 757-761.

756. Dr. Aronne explained that two-thirds of the population of the United States is overweight or obese. 3/28/17 Trial Tr. at 113:3-5.

757. At the hearing, counsel and experts for Contempt Defendants argued that Hi-Tech's advertising was targeted not to overweight or obese individuals, but to already healthy individuals looking to lose additional weight. Hoffman, for example testified that Hi-Tech's target audience was "young, apparently healthy individuals looking for improving their physique." 3/30/17 Trial Tr. at 146:22-147:12; *see also* 4/4/17 Trial Tr. at 120:2-24 (nutraceutical consumers are "trying to fit in their bikini and lose 5 to 10 pounds for the summer").

758. Similarly, Heuer claimed, without support, that obese people are "beyond the realm of what we're dealing with with these supplements" and that they "aren't eligible for supplements." 4/4/17 Trial Tr. at 49:11-17, 55:7-20; *see also* 4/6/17 Trial Tr. at 151:6-10 (counsel for Contempt Defendants claiming that dietary supplements are "not about obesity and the problems in the obesity area").

759. Contempt Defendants, however, never explained why, even if they were correct about Hi-Tech's target audience, that would change the standard used by experts in the field to substantiate Hi-Tech's advertising weight and fat loss claims. *See, e.g.*, 3/30/17 Trial Tr. at 146:22-149:22. Specifically, none of Contempt Defendants' experts testified as to any scientific basis as to why the standard would differ based on the audience to whom the ads were targeted rather than the general population. *Id.*

760. Hoffman did conclusorily assert that weight-loss studies lasting longer than 15 weeks are only necessary in "an obese population." 3/30/17 Trial Tr. at 132:8-13. He provided no scientific basis or explanation for why this is true, instead reiterating that the ingredients in the Hi-Tech products are, in his view, "marketed to a younger population whose primary goal is to look good on the beach." *Id.* at 132:14-20.

761. Heuer testified that obese people "need other medications" and "react differently to even weight loss things," but again did not explain how that would change what experts in the field consider competent and reliable scientific evidence. 4/4/17 Trial Tr. at 55:11-20. Nor does he cite to any

academic or scientific literature in his expert report that would support that assertion. Defendants' Ex. 133.

762. Additionally, Hoffman's interpretation of Contempt Defendants' advertising was based on incomplete information. In his expert report, Defendants' Ex. 134, he does not claim to have reviewed any of Hi-Tech's advertisements. On direct examination, Hoffman claimed that based on the "few ads" that he saw, Hi-Tech's advertisements targeted "young, apparently healthy individuals looking for improving [sic] their physique." 3/30/17 Trial Tr. at 146:22-147:1. As evidence, Hoffman noted that Hi-Tech's ads have "young women in bikinis looking pretty good." *Id.* at 147:8-12.

763. Hoffman did not offer any explanation as to why advertisements featuring "young women in bikinis looking pretty good" would not be directed at currently overweight or obese individuals. 3/30/17 Trial Tr. at 146:22-147:12.

764. Contempt Defendants did not offer Hoffman as an expert in marketing, and Hoffman, in fact, repeatedly claimed not to be an expert in marketing. 3/30/17 Trial Tr. at 113:4-10, 181:3-8, 181:17-21 ("I'm a scientist, not a

marketing person."), 185:17-186:14 ("I'm not a marketing expert . . . . [I]f you ask me a question on marketing, that's not my area of expertise.").

765. On cross examination, Hoffman admitted that he had never seen the Fastin packaging containing the statement, "Fastin is a pharmaceutical-grade dietary supplement indicated for weight loss in extremely overweight individuals." 3/30/17 Trial Tr. at 187:21-188:12; Plaintiff's Ex. 50. Upon reviewing the statement, Hoffman agreed that it was not "directed to young, apparently healthy individuals." *Id.* at 188:5-8.

766. Before Hi-Tech purchased the rights to the "Fastin" brand name, Fastin was a prescription weight-loss medication used to treat obesity. 4/6/17 Trial Tr. at 49:24-50:4. Hi-Tech's advertising strategy was to "retain" the obese consumer base.

767. In March 2010, for example, Wheat emailed Victor Kelley and Stephen Smith regarding a marketing strategy for Fastin. *See* Plaintiff's Ex. 714. Wheat wrote, "We have to play off the success of Fastin—What is that? That it has over ***40 years of brand loyalty***. ***If we get too commercialized it will get consumers to think it must not be the same as what they took years ago.***" *Id.* (emphasis added).

768. Wheat continued, "[T]he pieces that did good to this type of buyer . . . had one thing in common—***the drug-like approach***. I think whatever ad you design should play up the pill like we did with the ad in our magazine—you may want to add a picture of a girl in a bikini and/or maybe even a new picture of Dr. Wright (the weight loss doctor) as he looks more distinguished now." Plaintiff's Ex. 714. Thus, Hi-Tech planned to use pictures of bikini-clad models to target users of an obesity medication.

769. Similarly, in July 2010, Wheat expressed enthusiasm that "Fastin is one that will generate people to go get it when they see it is available without A PRESCRIPTION!" Plaintiff's Ex. 715 at 2.

770. Hi-Tech's advertising materials reflect their goal of reaching overweight and obese individuals. The April 2009 edition of Hi-Tech Health & Fitness, for example, featured an article by Defendant Wright titled "Lose Weight Fastin®!." Plaintiff's Ex. 295 at 130. In that article, disseminated by Hi-Tech, Dr. Wright wrote that Hi-Tech's Fastin was actually superior to the prescription obesity version: "As a bariatric (weight loss) physician, ***I prescribed Fastin® for decades as a prescription drug to my patients with overwhelming success***. . . . Since [prescription Fastin's] exit from the

market, Hi-Tech has been doing some exhaustive research and development on a new formula with pharmaceutical fat mobilization and apoptosis agents to create the new and improved Fastin®. . . . Unwilling to attach the name 'Fastin' to just any ole fat burning formula, ***Hi-Tech has spent a countless amount of time and resources to find a formula equal to, or superior to, the original Fastin*** . . . . Finally, after several years of research on this project, Hi-Tech developed a formula that is every bit as good (if not better) than the original Fastin formula." Plaintiff's Ex. 295 at 130 (emphasis added).

771. Later in the same article, Dr. Wright wrote that, "Fastin® is a pharmaceutical-grade dietary supplement ***indicated for weight loss in extremely overweight individuals***." Plaintiff's Ex. 295 at 130 (emphasis added).

772. That same claim—that Fastin is indicated for weight loss in "extremely overweight individuals"—is on certain Fastin packaging. Plaintiff's Ex. 50 at 4.

773. In a separate article in the April 2009 edition of Hi-Tech Health & Fitness, Dr. Wright explained that Benzedrine, like Fastin, had previously been a

prescription medication. Plaintiff's Ex. 295 at 34-35. He stated that Benzedrine "had the reputation of being the strongest pill ever to hit the Market when I began my weight loss clinics." *Id.* at 35. Dr. Wright then promised that Hi-Tech had produced a "new and improved Benzedrine" with "pharmaceutical" fat mobilization. *Id.* Wright added that "Hi-Tech developed a formula [for Benzedrine] that is so strong even Hi-Tech was hesitant to put it on the market." *Id.*

774. Wright's Benzedrine article also includes an interview by Wheat of Dr. Roy Gill. Plaintiff's Ex. 295 at 38. Gill explained to Wheat that he determines when to treat overweight patients in his medical practice by measuring percent body fat. *Id.* People with excess body fat, Gill explained, "requires some type of medical management." *Id.* When "medical treatment appears to be indicated," Dr. Gill claimed that he turns to Hi-Tech products, including Fastin, Lipodrene, Benzedrine, and Stimerex-ES. *Id.* at 39. Gill also explained that rather than "obesity," he uses the term "hypothalamic dysfunction syndrome or HDS." *Id.* at 40. Gill then described Benzedrine as "essential" for many patients with HDS. *Id.* at 42. Thus, Hi-Tech plainly positioned the Hi-Tech Products as treatments for

overweight or obese individuals needing medical treatment, and not just already healthy individuals trying to lose a few pounds.

775. Contempt Defendants have made numerous other claims that facially are not directed to healthy individuals looking to lose a few pounds. These claims include: "EXTREME WEIGHT LOSS GUARANTEED," "Increases the release of Norepinephrine and Dopamine for dramatic weight loss," and "Fastin® is a pharmaceutical-grade dietary supplement indicated for weight loss in extremely overweight individuals." *See* FOF ¶¶ 135-136.

E. Contempt Defendants' Expert Testimony Regarding Substantiation Is Neither Credible Nor Reliable.

1. Gaginella's Testimony Is Neither Credible Nor Reliable.

776. Gaginella's expert testimony is neither credible nor reliable because Gaginella's limited experience with weight loss is derived solely from his work as a consultant on behalf of Hi-Tech and because his longstanding and continuing relationship with Hi-Tech calls into question his credibility. FOF ¶¶ 777-787.

777. Outside of his work for Hi-Tech and Jared Wheat, Gaginella has never done any work in the fields of weight loss or obesity. Gaginella Tr. at

20:15-23. Gaginella is not a member of any professional societies that are focused on obesity or weight management. *Id.* at 21:25-22:8.

778. Gaginella has never conducted any human clinical trial measuring weight or fat loss. Gaginella Tr. at 20:24-21:5. Nor has Gaginella ever been an investigator on any human clinical trial. Gaginella Tr. at 22:23-23:19, 33:9-34:20.

779. Gaginella has not done any lab research, or pharmaceutical research and development work, since 1994. Gaginella Tr. at 23:24-24:5.

780. Gaginella agreed that his familiarity with dietary supplements comes solely from reading literature. Gaginella Tr. at 25:2-26:15.

781. Gaginella relied on studies that failed to show statistically significant results but that, in his view, showed a "trend" in the evidence. Gaginella Tr. at 66:2-6, 167:6-14. Gaginella, however, is not a statistician, does not know how statisticians treat "trends" of non-statistically significant results, and did not apply any guidelines regarding "trends" when forming his opinions in this case. *Id.* at 168:3-169:7.

782. Gaginella's history with Hi-Tech Pharmaceuticals raises significant concerns about the credibility of his testimony. *See* FOF ¶¶ 783-787.

783. Gaginella was a paid consultant of Hi-Tech Pharmaceuticals and other companies owned by Wheat from 1998 or 1999 through 2006. Gaginella Tr. at 157:6-20. For the last four or five years of the consulting relationship, Gaginella received $60,000 per year from Wheat or his companies. *Id.* at 157:21-158:11.

784. In exchange for the $60,000 annual salary, Gaginella spoke with Wheat, at most, every three months for approximately 10-15 minutes. Gaginella Tr. at 158:12-21, 160:11-14.

785. Although Gaginella, on his phone calls with Wheat, would offer to help with product formulation, advertising copy, and adding scientific references to mail-out brochures, Wheat never accepted those offers. Gaginella Tr. at 158:22-159:24. Gaginella felt guilty that he wasn't doing more. *Id.* at 160:4-6. Wheat would occasionally ask Gaginella questions that would require research, but Wheat generally did not follow up to get the answers. *Id.* at 160:15-23.

786. On at least two separate occasions during Gaginella's consulting relationship, Wheat or his companies forged Gaginella's signature on purported product endorsement letters. *See* Plaintiff's Exs. 540, 541. In

each case, Gaginella's name and fake signatures were placed on letters that he had never seen. Gaginella Tr. at 161:22-162:15, 162:22-164:4.

787. Despite the fact that Gaginella's consulting relationship with Hi-Tech ended in 2006, Hi-Tech continues to hold him out as their "Research & Development Group Chief." Plaintiff's Ex. 657 at 3.

2. Lee's Testimony Is Neither Credible Nor Reliable.

788. Lee's expert testimony is neither credible nor reliable because he lacks experience in the relevant areas and either ignored, or was not aware of, various concerns regarding ingredients in the Hi-Tech Products. *See* FOF ¶¶ 789-796.

789. Lee is a primary care physician who does not specialize in weight loss. 3/29/17 Trial Tr. at 52:23-25. Nor has he ever published any papers or given any presentations in the field of weight loss. 3/29/17 Trial Tr. at 53:4-9. Lee is not a member of any professional societies that focus on weight management. *Id.* at 53:1-3.

790. Lee has never conducted any human clinical trials, animal studies, or in vitro studies to measure fat loss, appetite suppression, metabolism, thermogenesis, or lipolysis. 3/29/17 Trial Tr. at 53:23-54:21.

791. Lee has never designed or been an investigator on any human clinical trial. 3/29/17 Trial Tr. at 54:22-55:2. Outside of his work on the effects of THC in mice, Lee has never designed or conducted an animal study. *Id.* at 55:3-8. Lee also has never designed or conducted an in vitro study. *Id.* at 55:9-14.

792. Lee has never published any articles, or conducted any lab research work, on dietary supplements. *Id.* at 55:15-20.

793. Lee offered no opinions regarding the following ingredients in the Hi-Tech Products: DMAA, ephedra extract, green tea, naringen, bergamottin, cassia nomame, hoodia gordonii, 5-hydroxytyptopahn, 5-methoxytryptamine, and l-tyrosine ethyl ester. 3/29/17 Trial Tr. at 60:4-64:17.

794. Bergamottin is an ingredient in Lipodrene and Stimerex-ES, Plaintiff's Ex. 569 at 2, 4, and can alter the absorption by the body of other compounds—a fact that Lee admitted at his deposition but claimed not to be aware of on the witness stand. 3/29/17 Trial Tr. at 62:1-13. Lee did no analysis to determine whether bergamottin would alter the way that the body absorbs the other ingredients in the Hi-Tech products. *Id.* at 62:14-18.

795. Although Lee considered "phenylethylamines" to be a "key ingredient" in the Hi-Tech Products, 3/29/17 Trial Tr. at 33:15-17, he admitted that he did not know which particular phenylethylamines are in the Hi-Tech products. *Id.* at 65:25-66:2. Lee also admitted that phenylethylamines are a large class of compounds, and that most have not even been studied. *Id.* at 66:3-67:6.

796. Lee also considered caffeine to be a "key ingredient" in the Hi-Tech Products. 3/29/17 Tr. at 67:13-15. Lee did not, however, consider whether individuals' habituation to caffeine would affect the products' impact on their resting energy expenditure. *Id.* at 68:7-69:1.

3. La Puma's Testimony Is Neither Credible Nor Reliable.

797. La Puma's expert testimony is neither credible nor reliable because he applied the wrong standard in evaluating whether there was adequate substantiation for Contempt Defendants' claims, relied on Contempt Defendants' other unreliable experts, changed his testimony between his deposition and his trial testimony in several material respects, misrepresented his work in this case and the materials that he relied upon,

and offered testimony that is contradicted by Contempt Defendants' other expert witnesses. FOF ¶¶ 798-809.

798. La Puma applied the incorrect standard in evaluating whether there was adequate substantiation for Contempt Defendants' advertising claims. *See* 3/30/17 Trial Tr. at 17:15-21. Specifically, he considered "the amount of substantiation that experts in the field believe is reasonable." *Id.* But, Dr. La Puma admitted that the word "reasonable" is not part of the definition of "competent and reliable scientific evidence." 3/30/17 Trial Tr. at 58:15-59:8. La Puma also admitted that "the amount of substantiation experts in the field believe is reasonable" is one of the *Pfizer* factors. *Id.* at 60:17-21.

799. In forming his opinion regarding the appropriate level of substantiation, La Puma considered the administrative law judge's (ALJ) decision in the *POM Wonderful* matter before the Federal Trade Commission. 3/30/17 Trial Tr. at 65:8-11; Defendants' Ex. 130 ¶ 12. La Puma affirmed that he continued to rely on the ALJ decision in his testimony before the Court. 3/30/17 Trial Tr. at 65:4-6. La Puma persists in his reliance on the ALJ decision, despite the fact that the decision was overturned by the Commission to find that POM needed randomized, double-blind, placebo-

controlled trials to substantiate its efficacy claims. *Id.* at 65:4-19. He also persists in relying on the overturned ALJ decision even though the United States Court of Appeals for the District of Columbia Circuit found that POM needed a randomized, placebo-controlled trial to substantiate its efficacy claims, a decision that La Puma called "nonsense and just inaccurate." *Id.* at 65:20-25.

800. In forming his opinions, La Puma relied on the opinions of Contempt Defendants' other experts, Gaginella and Jacobs. 3/30/17 Trial Tr. at 43:22-44:6. However, neither Jacobs nor Gaginella's opinions are reliable or credible. *See* FOF ¶¶ 776-787 (Gaginella), 818-837 (Jacobs).

801. At trial, La Puma claimed that statistical significance is not necessary for a study to constitute competent and reliable scientific evidence of a product's efficacy. 3/30/17 Trial Tr. at 33:9-12. He cites no scientific or academic literature that supports his position that conclusions concerning the efficacy of a substance can be drawn in the absence of statistical significance. *See* Defendants' Ex. 130; 3/30/17 Trial Tr. at 33:9-34:5. To the contrary, in his expert report he admits that "statistical analysis of results with accepted standards for statistical significance" is a "well accepted

scientific technique" that he considered in rendering his opinions. Defendants' Ex. 130 ¶ 22.

802. At his deposition, La Puma admitted that he did not make an independent determination of what constituted a "key ingredient" but rather that he relied on the list of studies provided by Hi-Tech Pharmaceuticals to identify the key ingredients. *See* 3/30/17 Trial Tr. at 87:25-88:10. However, at trial, he changed his testimony to claim that he made an independent evaluation of what constitutes a key ingredient in the Hi-Tech products. *See id.* at 87:12-24.

803. At his deposition, La Puma admitted that studies of caffeine alone were not sufficient to support his opinion that Fastin aids weight loss. 3/30/17 Trial Tr. at 89:3-10. He attempted to change his testimony at trial to claim that studies of caffeine alone were sufficient to substantiate Contempt Defendants' weight-loss claims. 3/30/17 Trial Tr. at 88:24-89:2.

804. At his deposition, La Puma admitted that the sole basis for his opinion that there were no antagonistic effects between the ingredients in the Hi-Tech products was his clinical experience, and not a review of the medical literature. 3/30/17 Trial Tr. at 90:2-11. However, at trial he attempted to

change his testimony to state that this opinion was also based on his review of the medical literature. 3/30/17 Trial Tr. at 89:11-25.

805. When discussing the Lean System 7 study, La Puma attempted to argue that because the study purported to show a statistically-significant change in hip circumference, it supported Contempt Defendants' claims. *See, e.g.*, 3/30/17 Trial Tr. at 98:21-24. Despite admitting that hip circumference was measured with a tape measure, La Puma tried to claim that it was a reliable way to measure that endpoint. *See id.* at 102:3-10. That testimony was directly contradicted by Contempt Defendants' expert Heuer, who admitted that unless the same person is measuring the exact same spot on the exact same subject in the exact same position, measurements of waist and hip circumference can vary by as much as 1-2 inches. *See* 4/4/17 Trial Tr. at 126:15-127:13.

806. La Puma admitted that his opinion that placebo-controlled studies of the product are not required is based, in part, on his understanding that the key ingredients work safely together. 3/30/17 Trial Tr. at 78:6-14. La Puma further admitted that Contempt Defendants never provided him with a single adverse event report to be considered in forming his

opinions. 3/30/17 Trial Tr. at 79:15-17. For example, Contempt Defendants did not provide La Puma with the August 3, 2012 complaint concerning the consumer who suffered a stroke requiring hospitalization in the intensive care unit after consuming Fastin. 3/30/17 Trial Tr. at 75:3-77:22. (discussing Plaintiff's Ex. 634). La Puma also admitted that he does not know how many adverse event reports Contempt Defendants possessed. *Id.* at 79:18-19.

807. Similarly, despite claiming to have conducted a PubMed search for articles involving adverse events relating to the Hi-Tech Products, 3/30/17 Trial Tr. at 70:6-21, La Puma did not find the Stephensen article concerning the military woman who had a cardiac event while doing pushups after consuming Lipodrene, *id.* at 80:15-81:13. Although La Puma argued that he couldn't definitely state that the Lipodrene consumption caused the cardiac event, he admitted he could not rule it out as the cause. *See id.* at 81:14-82:5. In his testimony, La Puma also understated the nature of the event. *Id.* at 81:17-18.

808. Despite claiming that he relied on an American College of Physicians Board of Regents set of standards regarding substantiation for dietary

supplements, *see* 3/30/17 Trial Tr. at 22:1-24, the American College of Physicians document on which La Puma relies has nothing to do with what experts in the field require to demonstrate the causal efficacy of weight-loss supplements, but instead relates to ensuring that dietary supplements generally contain the amounts of the ingredients that are identified on their labels. *See* 3/30/17 Trial Tr. at 84:24-85:1 ("Q: But this resolution is not about the causal efficacy for a dietary supplement; is that correct? A: No. It's about content and purity.").

809. La Puma considered theobromine a "key ingredient" even though none of Contempt Defendants' expert considered it to be one. 3/30/17 Trial Tr. at 21-36:2. In contrast, La Puma did not consider yohimbine a "key ingredient" even though Contempt Defendants' other experts did. *See id.*

4. Hoffman's Testimony Is Neither Credible Nor Reliable.

810. Hoffman's expert testimony is neither credible nor reliable because he admittedly lacks expertise in weight loss, refused to offer any opinion on many ingredients in the Hi-Tech products or offered opinions that were inconsistent with Contempt Defendants' other expert witnesses, misrepresented certain materials that he relied upon, and changed his

testimony between deposition and trial in a number of material respects. FOF ¶¶ 811-817.

811. Hoffman admitted that he is not an expert in the field of weight loss. 3/30/17 Trial Tr. at 168:13-16.

812. Hoffman admitted that he was giving no opinion regarding the following ingredients in the Hi-Tech productions: ephedra extract, theobromine, naringen, bergamottin, cassia nomame, 5-Methoxytryptamine, and DMAA. 3/30/17 Trial Tr. at 189:6-22.

813. Hoffman admitted that when a label reads "citrus aurantium," there is no way to tell which metabolites of citrus aurantium are present in the product. 3/30/17 Trial Tr. at 190:5-8.

814. Although Hoffman considered synephrine a "key ingredient" in the Hi-Tech Products, 3/30/17 Trial Tr. at 189:21-23, he testified at his deposition that the presence of citrus aurantium—of which synephrine is a component—is not sufficient to substantiate fat loss claims. *Id.* at 189:24-190:1, 190:21-191:2.

815. Unlike Contempt Defendants' other experts, Hoffman does not consider phenylethylamines to be a "key ingredient" of the Hi-Tech products.

3/30/17 Trial Tr. at 197:1-198:1. In fact, Hoffman wrote in his report, and confirmed at trial, that phenylethylamine "does not appear to be a primary ingredient for use in a weight loss product." Defendants' Ex. 134 ¶ 38; 3/30/17 Trial Tr. at 197:23-198:1.

816. In Hoffman's expert report, he wrote that citrus aurantium "is thought to contribute to appetite suppression, increased metabolic rate, and lipolysis." Defendants' Ex. 134 ¶ 32. In support of that proposition, Hoffman cited Defendants' Exhibit 192, a 2004 journal article. The authors of that article, however, actually wrote that, "***Little evidence supports the use of [citrus aurantium] for weight loss***, despite its inclusion in over-the-court weight-loss products." Defendants' Ex. 192 at 701 (emphasis added). Later, the authors added, "In summary, the only pushed trial of a citrus aurantium-containing weight-loss product found that ***the product was not superior to placebo for weight loss***. There is no evidence that synephrine and octopamine in levels that would be found in weight-loss products would have any lipolytic effect on human adipocytes." *Id.* (emphasis added). They also wrote, "There is little evidence that C. aurantium-containing products would be effective for weight loss, but a

dearth of clinical trials is no deterrent to consumers eager to lose weight. No clinical trials have been performed with C. aurantium alone. The one clinical trial (of a high-caffeine combination product) did not appear to affect weight loss more than placebo." *Id.* at 702.

817. Hoffman also repeatedly changed his deposition testimony at trial, including by asserting that advertising claims he previously considered to be unsubstantiated he now viewed as puffery, and by claiming that at his deposition he "wasn't aware of the ingredients." *See* FOF ¶¶ 404, 421, 644, 646-647.

5. Jacobs' Testimony Is Neither Credible Nor Reliable.

818. Jacobs' expert testimony is neither credible nor reliable. As discussed above, Jacobs repeatedly misstated information concerning his own studies in the formal and informal write-ups of his testing on the Hi-Tech products and, most importantly, in his expert report. FOF ¶¶ 482-483, 490-492, 500-501, 505, 511-514. Jacobs also applied an unduly low standard to his determination of whether advertising claims were substantiated. Furthermore, he misstated facts concerning his expert analysis in his report, including by repeatedly concealing data that was unfavorable to

Hi-Tech Pharmaceuticals in the process. Despite his denials, moreover, he is an officer of Hi-Tech Pharmaceuticals and has a financial interest in maintaining his ongoing relationship with the company. FOF ¶¶ 834-837.

819. Jacobs testified at his deposition that he would only have considered advertising claims to be unsubstantiated based on a "total lack of evidence" or "absolutely no evidence." 4/3/17 Trial Tr. at 136:14-137:12.

820. Jacobs only cited studies in his expert report that, in his view, supported his conclusions. He reviewed, but omitted, other studies that showed no efficacy or otherwise did not support his conclusions. 4/3/17 Trial Tr. at 140:2-8; FOF ¶¶ 822-827.

821. The Guide, however, directs that "[a]dvertisers should consider ***all*** relevant research relating to the claimed benefit of their supplement and should not focus only on research that supports the effect, while discounting research that does not. . . . Wide variation in outcomes of studies and inconsistent or conflicting results will raise serious questions about the adequacy of an advertiser's substantiation." Defendants' Ex. 3 at 14 (emphasis added).

822. Jacobs reviewed, but did not cite, Defendants' Ex. 192, a journal article titled, "Citrus Aurantium, an Ingredient of Dietary Supplements Marketed for Weight Loss: Current Status of Clinical and Basic Research." Jacobs ignored the article's finding that "the ***only published trial of C. aurantium-containing weight-loss product found that the product was not superior to placebo for weight loss***. . . . There is no evidence that synephrine and octopamine in levels that would be found in weight-loss products would have any lipolytic effect on human adipocytes." Defendants' Ex. 192 at 500; 4/3/17 Trial Tr. at 141:1-142:23 (emphasis added).

823. Jacobs also reviewed, but did not cite, Defendants' Exhibit 225, an article titled "Effect of Lean System 7 on Metabolic Rate and Body Composition." In that study, Zenk examined a product called Lean System 7 that contained both synephrine (as part of citrus aurantium) and caffeine (from guarana)—two of the four ingredients that Defendants have identified as "key." Defendants' Ex. 225 at 2; 3/30/17 Trial Tr. at 95:6-16; 4/3/17 Trial Tr. at 143:15-17. Zenk found that eight weeks of Lean System 7 treatment resulted in no statistically significant effect of the product (as compared to

placebo) on BMI, body weight, or body fat. Defendants' Ex. 225 at 4 (Table 2); 4/3/17 Trial Tr. at 143:18-144:23.

824. Jacobs also reviewed, but did not cite, Defendants' Exhibit 151, an article titled "Human Pharmacology of a Performance-Enhancing Dietary Supplement Under Resting and Exercise Conditions." In that study, Haller examined a dietary supplement containing both synephrine and caffeine. Defendants' Ex. 151 at 1; 4/3/17 Trial Tr. at 145:4-9. The study concluded that "[n]o treatment difference in exercise-related oxygen consumption, serum lactate, or insulin were observed." Defendants' Ex. 151 at 1.

825. Jacobs also reviewed, but did not cite, Defendants' Exhibit 183, an article titled "Thermogenic Effect from Nutritionally Enriched Coffee Consumptions." That study, authored by Contempt Defendants' expert Hoffman, compared the effects of a "nutritionally enriched coffee," containing synephrine (citrus aurantium) and caffeine, to traditional coffee, which lacks synephrine but contains caffeine. Defendants' Ex. 183 at 1; 4/3/17 Trial Tr. at 149:2-150:18. Hoffman found no statistically

significant difference between the JavaFit and coffee groups. 4/3/17 Trial Tr. at 151:2-12; Defendants' Ex. 183 at 3.

826. Jacobs also reviewed, but did not cite, an article titled "Yohimbine Does Not Affect Fat Distribution in Men." That study, authored by Sax, examined the effects of yohimbine on 47 men over six months. 4/3/17 Trial Tr. at 153:2-9. The study found that yohimbine did not cause a statistically significant loss of weight or fat. *Id.* at 153:10-18.

827. Jacobs also reviewed, but did not cite, an article titled "Safety and Efficacy of Citrus Aurantium for Weight Loss." That article, authored by Bent, included a systematic review of studies of citrus aurantium, after which Bent concluded that that there was "no evidence that the herb, citrus aurantium, is effective for weight loss." 4/3/17 Trial Tr. at 153:24-154:21.

828. Jacobs also misrepresented in his expert report a serious adverse event involving Lipodrene and an otherwise healthy 27-year-old servicewoman. Jacobs's expert report, Defendants' Ex. 129 ¶ 67, omitted that the servicewoman was found with "no pulse," *see* Defendants' Ex. 226 at 1, instead claiming that she had a "weak pulse." Jacobs also relied on a report by Stohs claiming to identify potential other causes of the

servicewoman's adverse event. Defendants' Ex. 129 ¶ 67; Defendants' Ex. 227. Jacobs, however, completely omitted Stohs's discussion of the fact that Lipodrene "contains at least 10 alkaloids" and therefore it was "impossible to conclude that one of these alkaloids, mainly synephrine, was responsive for the event." Defendants' Ex. 227 at 1. Instead, Jacobs highlighted every other potential cause of the adverse event identified by Stohs. 4/3/17 Trial Tr. at 171:5-173:6.

829. In both his 2012 and 2015 expert reports, Jacobs claims to have "researched the adverse events database" and found "no reports of a serious adverse event involving either Fastin, Benzedrine, and Stimerex-ES." Defendants' Ex. 128 ¶ 8; Defendants' Ex. 129 ¶ 8.

830. Jacobs, however, conducted no such search. In fact, Contempt Defendants previously admitted they "ha[d] no documents reflecting such a search" and that Jacobs had not "personally search[ed] a database," but rather had reviewed, in 2012, documents reflecting a search purportedly done by Hi-Tech. Plaintiff's Ex. 710 at 1. Dr. Jacobs did not even select the "FDAble" database that Contempt Defendants searched. 4/3/17 Trial Tr. at 178:10-22. Rather, Hi-Tech selected the database. *Id.*

831. Jacobs admitted that Hi-Tech had not provided him with any adverse event reports other than "the couple that [he] knew about." *Id.* at 179:4-6. Notably, the FDAble database apparently did not include, and Hi-Tech failed to disclose to Jacobs, the adverse event reports admitted into evidence as Plaintiff's Exhibits 632-651.

832. Jacobs identified synephrine or citrus aurantium as a "key ingredient" in the Hi-Tech Product and as contributing to lipolysis, or fat burning. Defendants' Ex. 129 ¶ 27.

833. Outside of his work in this case, however, Jacobs has given the exact opposite opinion. In the protocol he submitted for the Fastin-XR study, Jacobs admitted that "[c]laims of increased 'fat burning'" for synephrine "have not been consistently supported by research." Plaintiff's Ex. 596 at SUP003587; 4/3/17 Trial Tr. at 181:15-182:18. Over one year later, Jacobs included the same admission in a Fastin-RR study protocol. Plaintiff's Ex. 598 at 7; 4/3/17 Trial Tr. at 182:18-183:21.

834. Hi-Tech continues to identify Jacobs as its Research and Clinical Study Chief. Plaintiff's Ex. 673 at 4; 4/3/17 Trial Tr. at 86:15-87:13.

835. Jacobs has advised Wheat on how to use Jacobs' studies in Hi-Tech's advertising. Plaintiff's Ex. 699 (Jacobs telling Wheat that he has "the ability to use the [Fastin-RR study] abstract directly in your marketing" and explaining how other companies have used study abstracts in marketing materials); 4/3/17 Trial Tr. at 87:25-89:16.

836. In 2015, over half of the revenue for Jacobs' company, Superior Performance Research, came from Hi-Tech. 4/3/17 Trial Tr. at 91:20-92:2, 97:7-11.

837. 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." Plaintiff's Ex. 696 at 1; 4/3/17 Trial Tr. at 92:16-94:25.

6. Heuer's Testimony Is Neither Credible Nor Reliable.

838. Heuer's expert testimony is neither credible nor reliable. First, he did not apply the correct standard for determining what constitutes competent and reliable scientific evidence for the weight-loss products at issue. Second, he repeatedly attempted to change his deposition testimony at trial. Third, his opinions are utterly unsupported by any reference to

academic or scientific literature. Fourth, his expert report makes material misstatements, including by misquoting the sources he cites and improperly offering legal opinions.

839. Heuer testified that in considering what constitutes competent and reliable scientific evidence, he did not consider weight-loss products specifically, but rather applied a standard that he would apply to dietary supplements in general. 4/4/17 Trial Tr. at 129:6-11.

840. Although Heuer admitted at his deposition that he does not feel that there are standards that apply to weight-loss products that do not apply to other types of dietary supplements, he attempted to change his testimony at trial to claim that he had, in fact, considered standards that only applied to weight loss products. 4/4/17 Trial Tr. at 129:12-24.

841. Heuer admitted that in formulating his opinions regarding what constitutes competent and reliable scientific evidence, he applied "no exact criteria." 4/4/17 Trial Tr. at 131:6-9. He further admitted that "whether there is specific evidence or not, it doesn't matter." *Id.* at 131:15-16.

842. Heuer also admitted that he does not know of anyone who applies the criteria he used to determine whether something was competent and

reliable scientific evidence in the same way that he did. 4/4/17 Trial Tr. at 135:10-20 ("I don't know how other scientists come to their conclusions . . . . I do that in my – what I think is a logical way and come to my conclusion.").

843. Heuer admitted that each time he encountered conflicting evidence concerning efficacy, he concluded that the Hi-Tech advertising claims were substantiated. 4/4/17 Trial Tr. at 135:21-136:10. This conflicts with the Dietary Supplement Guide, which states: "Wide variation in outcome of studies and inconsistent results raise serious questions about the adequacy of an advertiser's substantiation." Defendants' Ex. 3 at 14.

844. Despite testifying at his deposition without qualification that Dr. Aronne was an expert in the dietary supplement field, Heuer attempted to change his testimony at trial by claiming that Dr. Aronne's expertise in dietary supplements was limited to people who were "extremely overweight" or extremely obese. *Compare* 4/4/17 Trial Tr. at 113:15-20 *with id.* at 114:5-19.

845. Heuer admitted that he is not offering any opinions relating to acacia, a phenylethylamine compound and one of the so-called "key ingredients" in the Hi-Tech products. 4/4/17 Trial Tr. at 123:6-10. He further admitted

that he does not have an opinion as to the efficacy of acacia for weight loss. *Id*. at 123:11-14.

846. Heuer also admitted that he is not offering any opinion relating to phenylethylamines, another of the so-called "key ingredients" in the Hi-Tech products, in relation to the company's advertising claims. 4/4/17 Trial Tr. at 124:3-6.

847. Heuer also admitted he is not offering any opinions relating to ephedra extract. 4/4/17 Trial Tr. at 123:25-124:2.

848. Although Heuer testified that eight weeks was "a good interval" for a weight loss study, his report is silent as to the appropriate duration of a properly conducted weight loss study, and he cites no support for that opinion in either his testimony or his expert report. *Compare* 4/4/17 Trial Tr. at 65:20-24 *with* Defendants' Ex. 133.

849. Heuer offered the opinion that the studies of the "key ingredients alone" are sufficient to substantiate Hi-Tech's advertising claims. 4/4/17 Trial Tr. at 66:18-21 (citing expert report paragraph 65). However, Heuer cited no ingredient-specific studies that would support that opinion and offered no basis for that opinion. *See* Defendants' Ex. 133 ¶ 65 (listing "ingredients

commonly found in weight loss dietary supplements"). Contempt Defendants' expert Heuer admitted that studies of caffeine on their own do not substantiate weight loss claims. 4/4/17 Trial Tr. at 137:15-17. Heuer also admitted that caffeine studies alone are not sufficient to substantiate fat loss claims. 4/4/17 Trial Tr. at 138:8-20.

850. Heuer admitted that his opinion concerning yohimbine's effect on fat is based on his "personal thinking." 4/4/17 Trial Tr. at 88:25-89:12.

851. Heuer testified that a number of the claims being challenged are "puffery." *See* 4/4/17 Trial Tr. at 100:5-8, 10-14; *id.* at 104:10-24; *id.* at 107:1-9; *id.* at 107:19-25; *id.* at 108:5-9; *id.* at 109:6-12; *id.* at 110:12-19; *id.* at 112:14-113:2; *id.* at 157:2-5, 11-16.

852. Heuer's opinions concerning the standards for claim substantiation in the "dietary supplement industry" were specifically in reference to dietary supplement manufacturers, and not scientists, researchers, and clinicians. 4/4/17 Trial Tr. at 37:19-38:12; *id.* at 57:19-58:9 (testifying as to practices of dietary supplement manufacturers).

853. Heuer considered Jared Wheat a "professional in the relevant area" when forming his opinions. 4/4/17 Trial Tr. at 128:20-24; FOF ¶ 80 (defining

CRSE by reference to professional in the relevant area). In contrast, Contempt Defendants' expert La Puma testified that people who market or manufacture dietary supplements would only be considered "professionals in the relevant area" if they were also clinicians or scientists, and, as a result, he does not consider Wheat a professional in the relevant area for determining what constitutes competent and reliable scientific evidence. 3/30/17 Trial Tr. at 51:2-10.

854. In contrast to Contempt Defendants' expert La Puma, who testified that clinicians in the area of obesity are "professionals in the relevant area," Heuer disagreed that obesity was a relevant area. 4/4/17 Trial Tr. at 49:11-17.

855. Heuer admitted that the product-specific testing is "extremely rare" because "number one, the dietary industry ***companies*** tend to see it not as a requirement." 4/4/17 Trial Tr. at 10-19 (emphasis added).

856. Although Heuer testified that dietary supplement industry companies change their formulations every three to nine months, 4/4/17 Trial Tr. at 70:24-71:3, this is not the case for the Hi-Tech products, *see id.* at 138:24-140:3; *see also* Plaintiff's Exs. 513 and 514.

857. Heuer claimed that the FTC Dietary Supplement Guide does not reference RCTs being required to substantiate weight loss claims. *See* 4/4/17 Trial Tr. at 59:2-8. However, Example 19, which is the only portion of the Guide that discusses substantiation for claims that a product "will substantially reduce body fat," specifically references product-specific, double-blind clinical trials. Defendants' Ex. 3 at 14-15. Specifically, the example concludes that where there are multiple controlled double-blind studies of the product that produce conflicting results, the claims are likely unsubstantiated when considering the totality of the evidence. *Id.* Heuer did not reference Example 19 in his expert report, despite claiming to have relied on the Dietary Supplement Guide. *See* Defendants' Ex. 133.

858. Heuer purported to rely upon statements by the National Advertising Division of the Better Business Bureau in forming his opinions regarding the use of studies of "key ingredients" as substantiation. *See* 4/4/17 Trial Tr. at 151:11-18. Specifically, in his report, Heuer (purporting to quote from a law review article titled "Regulation of Dietary Supplement Advertising: Current Claims of Interest to the Federal Trade Commission and National Advertising Division"), wrote: "Although the NAD is a self-

regulatory agency and does not have legal authority over advertising claims, in accord with First Amendment cases, the NAD has even recognized, 'in the absence of direct testing on a product, an advertiser can make claims based on key ingredients supported in the scientific community and are clearly limited to the key ingredients.'" Defendants' Ex. 133 ¶ 59.

859. In fact, the quoted portion of the articles reads as follows: "In accord with First Amendment cases, the NAD has recognized that, 'in the absence of direct testing on a product, an advertiser can make claims that are supported in the scientific community and are clearly limited to the ingredients, ***but must be careful to avoid making any express or implied product performance claims***.'" Defendants' Ex. 258 at 713 (emphasis added).

860. When confronted with the fact that the words "key ingredients" never appears in the quote and the omission of the caution not to make product-specific claims based on ingredient studies, Heuer attempted to justify his blatant misrepresentation of the article's contents by claiming that he based the statement in his report off a draft of the law review article –

despite the fact that it was published in 2007, nearly 8 years before Heuer's expert report in this case. 4/4/17 Trial Tr. at 154:4-18.

V. Lack of Yohimbine Health-Risk Warning

A. Contempt Defendants' Liability Is Undisputed.

861. Hi-Tech sells Fastin in 60-count, 30-count, 20-count, and 3-count SKUs. Plaintiff's Ex. 37 at 9; Plaintiff's Exs. 46-51 (copies of Fastin product packaging and labels).

862. Hi-Tech sells Lipodrene in 100-count, 20-count, and 2-count SKUs. Plaintiff's Ex. 37 at 9; Plaintiff's Exs. 54-56 (copies of Lipodrene product packaging and labels).

863. Hi-Tech sells Benzedrine in a 60-count SKU. Plaintiff's Ex. 37 at 9; Plaintiff's Exs. 59-60 (copies of Benzedrine product packaging and labels).

864. Hi-Tech sells Stimerex-ES in 90-count, 20-count, and 2-count SKUs. Plaintiff's Ex. 37 at 9; Plaintiff's Exs. 63-65 (copies of Stimerex-ES product packaging and labels).

865. Fastin, Lipodrene, Benzedrine, and Stimerex-ES all contain yohimbine. *See* Plaintiff's Ex. 7 ¶ 17; Plaintiff's Ex. 8 ¶ 17; Plaintiff's Exs. 46-51 (Fastin product packaging and labels), 54-56 (Lipodrene product packaging and

labels), 59-60 (Benzedrine product packaging and labels), 63-65 (Stimerex-ES product packaging and labels).

866. The Fastin, Lipodrene, Benzedrine, and Stimerex-ES product packaging and labels all make efficacy claims. Plaintiff's Exs. 46-51, 54-56, 59-60, 63-65, 146; *see also* FOF ¶¶ 134-136, 139-144, 148-153, 155-158, 162, 178-180, 186-188, 194-196, 200-202, 204-207, 217, 222, 226-227, 242, 248-250.

867. Michelle Harris testified that Hi-Tech places the labels on product bottles as part of the manufacturing process. 1/21/14 Trial Tr. at 148:10-12.

868. The product packaging and labels for Fastin, Lipodrene, Benzedrine, and Stimerex-ES in use from January 1, 2009 through late 2012 did not contain the words: "**WARNING**: This product can raise blood pressure and interfere with other drugs you may be taking. Talk to your doctor about this product." Plaintiff's Exs. 46-51, 54-56, 59-60, 63-65.

869. Instead, Contempt Defendants included other warning language, which did not comply with Section VI of the Hi-Tech Order, on their product packaging and labels. *See* FOF ¶¶ 990-991.

870. The non-compliant warning language on Contempt Defendants' product packaging and labels was not displayed "clearly and prominently." In

particular, the non-compliant warning language was not in a "type size and location sufficiently noticeable for an ordinary consumer to read and comprehend it." Plaintiff's Ex. 1 at 6 (Definitions ¶ 4(C)); *see also* Plaintiff's Exs. 46-51, 54-56, 59-60, 63-65.

871. Instead, the non-compliant language was in small font and in a large block of all capital letters, rendering it difficult for consumers to read. *See* Plaintiff's Exs. 46-51, 54-56, 59-60, 63-65. In addition, the non-compliant language was placed on the back of the product packaging or the inside of the product labels, frequently requiring consumers to "peel back" the label to find the warning. *Id.* The non-compliant language, despite being on the back or inside of the product packaging and labels, was not "within a border." Plaintiff's Ex. 1 at 6 (Definitions ¶ 4(C)).

872. The non-compliant language also contradicts, is inconsistent with, or is in mitigation of, the Court-ordered warning. *Compare* FOF ¶¶ 990-991 *with* FOF ¶ 76.

873. Wheat admitted that, after this Court issued the Hi-Tech Order on December 16, 2008, Contempt Defendants' product packaging and labels did not incorporate the yohimbine warning required by Section VI of the

Hi-Tech Order until late 2012. Wheat Dep. at 124:5-125:25, 153:1-13; 1/22/14 Trial Tr. at 67:23-69:18.

874. On August 2, 2013, more than a year after Wheat claims Hi-Tech began to place the yohimbine warnings on its product packaging, Federal Trade Commission Investigator Ronald Lewis was able to purchase Fastin that did not contain the required yohimbine health-risk warning on the packaging. 1/21/14 Trial Tr. at 44:25-45:24; Plaintiff's Ex. 146.

875. In granting the FTC's Motion Seeking Entry of Contempt Judgment and the Imposition of Compensatory and Coercive Sanctions, the Court found that the product packaging and labels did not contain the required health-risk warning. Dkt. No. 524 at 23-24.

876. Contempt Defendants admit that they did not challenge the Court's findings with respect to their violations of Section VI of the Hi-Tech Order on appeal. *See* Plaintiff's Ex. 500 at 11 ("Contempt Defendants did not appeal the contempt finding as to Section VI of the injunction, which required a specific warning on products that contained yohimbine.").

B. Contempt Defendants' Claim That FDA Reviewed And Approved The Labels For Compliance With The Hi-Tech Order Is False.

877. Wheat admits that the FDA's review of Hi-Tech's product labels and packaging in 2008 was not to determine whether the labels and packaging complied with the Hi-Tech Order, but to determine whether the labels and packaging complied with the 2003 consent decree between Hi-Tech and the FDA. Wheat Dep. at 163:21-164:11.

C. Contempt Defendants' Claim That The Warning Was Available From Other Sources Between January 1, 2009 And September 2010 Is False.

878. Contempt Defendants claim not to have maintained a website or disseminated any print ads from January 2009 through September 2010. 1/21/14 Trial Tr. at 98:2-12; 1/22/14 Trial Tr. at 12:14-12:23, 45:6-45:14; 1/23/14 Trial Tr. at 67:1-2; Plaintiff's Ex. 75 at 3 (5/24/2010 e-mail noting Hi-Tech website had been taken down); Plaintiff's Ex. 101 at 3 (7/8/2010 e-mail noting Hi-Tech website had been down for "some time").

879. The print ads that Contempt Defendants did publish during that time did not contain the yohimbine-health risk warning. *See* FOF ¶¶ 880-899.

880. The April 2009 edition of Hi-Tech Health & Fitness includes a two-page print advertisement titled "Fat Loss." Plaintiff's Ex. 295 at 2, 51.

881. The April 2009 "Fat Loss" print ad includes efficacy claims for Fastin, Lipodrene, Benzedrine, and Stimerex-ES. Plaintiff's Ex. 295 at 2, 51.

882. The April 2009 "Fat Loss" print ad does not contain the words: "**WARNING**: This product can raise blood pressure and interfere with other drugs you may be taking. Talk to your doctor about this product." Plaintiff's Ex. 295 at 2, 51; *compare id. with* Plaintiff's Ex. 1 at Section VI.

883. The April 2009 edition of Hi-Tech Health & Fitness contains a one-page print ad for Benzedrine. Plaintiff's Ex. 295 at 23.

884. The April 2009 Benzedrine print ad contains efficacy claims. Plaintiff's Ex. 295 at 23.

885. The April 2009 Benzedrine print ad does not contain the words: "**WARNING**: This product can raise blood pressure and interfere with other drugs you may be taking. Talk to your doctor about this product." Plaintiff's Ex. 295 at 23; *compare id. with* Plaintiff's Ex. 1 at Section VI.

886. The April 2009 edition of Hi-Tech Health & Fitness contains a ten-page print ad for Lipodrene, titled "Liposuction In a Pill?" Plaintiff's Ex. 295 at 81-85.

887. The April 2009 "Liposuction In A Pill?" print ad contains efficacy claims for Lipodrene. Plaintiff's Ex. 295 at 81-85.

888. The April 2009 "Liposuction In A Pill?" print ad does not contain the words: "**WARNING**: This product can raise blood pressure and interfere with other drugs you may be taking. Talk to your doctor about this product." Plaintiff's Ex. 295 at 81-85; *compare id. with* Plaintiff's Ex. 1 at Section VI.

889. The April 2009 edition of Hi-Tech Health & Fitness contains three print advertisements authored by Mark Wright, M.D, two of which involve challenged products. Plaintiff's Ex. 295 at 4.

890. The first print ad authored by Wright is titled: "Benzedrine A Diet Aid That Pushes the Nutraceutical Envelope." Plaintiff's Ex. 295 at 4, 19.

891. The "Benzedrine A Diet Aid That Pushes the Nutraceutical Envelope" print ad contains efficacy claims for Benzedrine.

892. The "Benzedrine A Diet Aid That Pushes the Nutraceutical Envelope" print ad does not contain the words: "**WARNING**: This product can raise blood pressure and interfere with other drugs you may be taking. Talk to

your doctor about this product." Plaintiff's Ex. 295 at 19-20; *compare id. with* Plaintiff's Ex. 1 at Section VI.

893. The second print advertisement authored by Wright is titled: "Lose Weight Fastin®!" Plaintiff's Ex. 295 at 4, 71-73.

894. The "Lose Weight Fastin" print ad contains efficacy claims for Fastin. Plaintiff's Ex. 295 at 4, 71-73.

895. The "Lose Weight Fastin" print ad does not contain the words: "**WARNING**: This product can raise blood pressure and interfere with other drugs you may be taking. Talk to your doctor about this product." Plaintiff's Ex. 295 at 71-73; *compare id. with* Plaintiff's Ex. 1 at Section VI.

896. The April 2009 edition of Hi-Tech Health & Fitness contains three advertisements authored by Stephen Smith, including one entitled "Nutraceutical Advancements in 2009." Plaintiff's Ex. 295 at 4; *see also id.* at 38-44.

897. The "Nutraceutical Advancements in 2009" print ad is subtitled "What Consumers and Retailers Should Know About These New Products." Plaintiff's Ex. 295 at 38.

898. The "Nutraceutical Advancements in 2009" print ad contains efficacy claims for Lipodrene and Stimerex-ES. Plaintiff's Ex. 295 at 38-44.

899. The "Nutraceutical Advancements in 2009" print ad does not contain the following words: "**WARNING**: This product can raise blood pressure and interfere with other drugs you may be taking. Talk to your doctor about this product." Plaintiff's Ex. 295 at 38-44; *compare id. with* Plaintiff's Ex. 1 at Section VI.

D. Even After September 2010, Not All Of Contempt Defendants' Print And Website Advertising Contained The Yohimbine Warning Is False.

900. Even after September 2010, when Contempt Defendants admit that they resumed print and website advertisements, some of their print advertisements and webpages lacked the required yohimbine safety warning. *See* FOF ¶¶ 901-913.

901. The January 2011 edition of Hi-Tech Health & Fitness includes a 2-page print advertisement titled "Fat Loss." Plaintiff's Ex. 296 at 2.

902. The January 2011 "Fat Loss" print ad includes efficacy claims for Fastin, Lipodrene, Benzedrine, and Stimerex-ES. Plaintiff's Ex. 296 at 2.

903. The January 2011 "Fat Loss" print ad does not contain the words: "**WARNING**: This product can raise blood pressure and interfere with other drugs you may be taking. Talk to your doctor about this product." Plaintiff's Ex. 296 at 2; *compare id. with* Plaintiff's Ex. 1 at Section VI.

904. The January 2011 edition of Hi-Tech Health & Fitness includes a 10-page print ad authored by "Dr. Mark Wright" and titled: "Weight Loss Supplements What's Hot In The Weight Loss Industry!" Plaintiff's Ex. 296 at 5-12.

905. The "Weight Loss Supplements What's Hot In The Weight Loss Industry!" print ad contains efficacy claims for Fastin, Lipodrene, and Stimerex-ES. Plaintiff's Ex. 296 at 5-12.

906. The "Weight Loss Supplements What's Hot In The Weight Loss Industry!" print ad does not contain the words: "**WARNING**: This product can raise blood pressure and interfere with other drugs you may be taking. Talk to your doctor about this product." Plaintiff's Ex. 296 at 5-12; *compare id. with* Plaintiff's Ex. 1 at Section VI.

907. The January 2011 edition of Hi-Tech Health & Fitness contains a one-page ad for Stimerex-ES and Lipodrene that includes efficacy claims. Plaintiff's Ex. 296 at 19.

908. The one-page Stimerex-ES/Lipodrene print ad does not contain the words: "**WARNING**: This product can raise blood pressure and interfere with other drugs you may be taking. Talk to your doctor about this product. Plaintiff's Ex. 296 at 19; *compare id. with* Plaintiff's Ex. 1 at Section VI.

909. The January 2011 edition of Hi-Tech Health & Fitness contains an eight-page print ad authored by Jared Wheat titled: "The 2nd Coming Of Ephedra!" Plaintiff's Ex. 296 at 18-22.

910. The "2nd Coming of Ephedra!" print ad contains efficacy claims for Lipodrene.

911. The "2nd coming of Ephedra!" print ad does not contain the words: "**WARNING**: This product can raise blood pressure and interfere with other drugs you may be taking. Talk to your doctor about this product." Plaintiff's Ex. 296 at 18-22; *compare id. with* Plaintiff's Ex. 1 at Section VI.

912. Additionally, a Lipodrene product order webpage accessed on August 15, 2013 contains efficacy claims for Lipodrene, including "Helps Promote

Weight Loss and Extreme Energy" and "Extremely Potent Thermogenic Intensifier." Plaintiff's Ex. 150.

913. The Lipodrene order webpage from August 15, 2013, does not contain the words: "**WARNING**: This product can raise blood pressure and interfere with other drugs you may be taking. Talk to your doctor about this product." Plaintiff's Ex. 150; *compare id. with* Plaintiff's Ex. 1 at Section VI.

VI. Consumer Injury Resulting From Contempt Defendants' Sale Of Fastin, Lipodrene, Benzedrine, And Stimerex-ES.

A. Consumer Injury Resulting From Contempt Defendants' Unsubstantiated Efficacy Claims.

1. Contempt Defendants Have Widely Disseminated Their Unsubstantiated Advertisements.

914. Contempt Defendants' unsubstantiated efficacy claims appeared in print advertisements, product pages on the www.hitechpharma.com website, product labels, and product packaging. *See* Plaintiff's Exs. 43-65, 146-148, 272, 274, 276, 284, 286-288, 290.

915. As discussed above, Contempt Defendants widely disseminated unsubstantiated advertising claims for Fastin through national magazines, through the www.hitechpharma.com website, and through product

packaging and labels distributed both directly by Contempt Defendants and through retail outlets. *See* FOF ¶¶ 128-132.

916. As discussed above, Contempt Defendants widely disseminated unsubstantiated advertising claims for Lipodrene through national magazines, through the www.hitechpharma.com website, and through product packaging and labels distributed both directly by Contempt Defendants and through retail outlets. *See* FOF ¶¶ 171-175.

917. As discussed above, Contempt Defendants widely disseminated unsubstantiated advertising claims for Benzedrine through national magazines, through the www.hitechpharma.com website, and through product packaging and labels distributed both directly by Contempt Defendants and through retail outlets. *See* FOF ¶¶ 209-213.

918. As discussed above, Contempt Defendants widely disseminated unsubstantiated advertising claims for Stimerex-ES through national magazines, through the www.hitechpharma.com website, and through product packaging and labels distributed both directly by Contempt Defendants and through retail outlets. *See* FOF ¶¶ 229-233.

2. Hi-Tech, Wheat, And Smith Caused Approximately $40 Million In Consumer Injury Through Their Unsubstantiated Efficacy Claims.

919. Contempt Defendants have sold Fastin, Lipodrene, Benzedrine, and Stimerex-ES continuously since January 1, 2009. Wheat Dep. at 49:25-50:11; *see also* Plaintiff's Ex. 18 at 7.

920. For the period January 1, 2009, through August 31, 2013, Contempt Defendants' total billings from the sale of Fastin, Lipodrene, Benzedrine, and Stimerex-ES were $40,120,950. *See* Dkt. No. 905 ¶ 27; Defendants' Ex. 65 at 19 (Table 2).

921. Fastin and Lipodrene were Hi-Tech's top selling weight-loss products for 2009. Wheat Dep. at 49:19-24.

922. Fastin and Lipodrene were Hi-Tech's top selling weight-loss products for 2010. Wheat Dep. at 49:15-18.

923. Fastin was Hi-Tech's top selling weight-loss product for 2011. Wheat Dep. at 49:12-14.

924. Fastin was Hi-Tech's top selling weight-loss product for 2012. Wheat Dep. at 49:9-11.

925. Hi-Tech's 2012 U.S. Income Tax Return for an S Corporation reported $42,185,651 in gross receipts or sales less returns and allowances. Plaintiff's Ex. 292 at 2.

926. In 2012, Hi-Tech's total billings for the four products - Benzedrine, Fastin, Lipodrene, and Stimerex-ES – less customer remittance deductions totaled $8,600,763. Dkt. No. 905 ¶ 20; Defendants' Ex. 65 at 19 (Table 2).

927. In 2012, Hi-Tech's total billings for the four products less customer remittance deductions accounted for 20 percent of Hi-Tech's gross receipts or sales less returns and allowances. *See* FOF ¶¶ 925-926.

B. Wright Caused Approximately $21 Million In Consumer Injury Through His Unsubstantiated Fastin Endorsement.

928. Hi-Tech began to disseminate the print ad featuring Wright's unsubstantiated Fastin endorsement in October 2010. Plaintiff's Ex. 7 ¶ 1; Plaintiff's Ex. 8 ¶ 1; Plaintiff's Ex. 18 at 10-13; Plaintiff's Ex. 20 at 4; Plaintiff's Ex. 32 at 5-10; Plaintiff's Ex. 43 at 3.

929. Hi-Tech, Wheat, Smith, and Wright also disseminated the violative Fastin print ads through the website www.hitechpharma.com through at least December 30, 2013. Plaintiff's Ex. 272 at 3, 29.

930. For the period October 2010, through August 26, 2013, during which Hi-Tech used Wright's endorsement to advertise Fastin, Hi-Tech Pharmaceuticals' gross revenues from the sale of Fastin were approximately $22,140,976.90. Dkt. No. 534-1 ¶ 5.

931. Hi-Tech issued approximately $647,519.26 in refunds during the same period. Plaintiff's Ex. 167 at 4.

932. Hi-Tech's net revenues (gross revenues less refunds) from the sales of Fastin for the period Hi-Tech disseminated the Fastin print ad containing Wright's endorsement, are $21,493,557.64. *See* FOF ¶¶ 930-931.

C. Contempt Defendants' Profit Calculation Is Fundamentally Flawed And Provides No Basis To Reduce The Consumer Harm Caused By Contempt Defendants' Unsubstantiated Efficacy Claims.

933. Contempt Defendants' expert, James Hart, testified that Wheat directed Hart to analyze Hi-Tech's various components of profitability, beginning with Hi-Tech's gross billings for each of the four products. 1/23/14 Trial Tr. at 146:16-25.

934. Hart testified that it was his opinion that the proper amount of compensatory damages could span anywhere along the range of numbers

that he provided in his declaration, from Hi-Tech's gross revenues to profit before tax after advertising. 1/23/14 Trial Tr. at 147:6-11.

935. From January 1, 2009 to August 31, 2013, Hi-Tech's gross revenues for Fastin, Lipodrene, Benzedrine, and Stimerex-ES were $46,233,396. Defendants' Ex. 65 at 19.

936. From January 1, 2009 to August 31, 2013, Hi-Tech's gross revenues less refunds and returns for those four products were $40,120,950. *See* Dkt. No. 905 ¶ 27; Defendants' Ex. 65 at 19.

937. Hart applied two different "relevant periods," each with different starting and ending dates, to his analysis: the "Hi-Tech Relevant Period" and the "FTC Relevant Period." Defendants' Ex. 65.

938. Hart defined the Hi-Tech Relevant Period as follows:

- For Fastin: September 1, 2010 through May 31, 2012;
- For Benzedrine: September 1, 2010 through September 30, 2012; and
- For Lipodrene and Stimerex-ES: January 1, 2011 through September 30, 2012.

Defendants' Ex. 65 at 5.

939. Hart testified that Wheat told him to narrow the Hi-Tech Relevant Period by the period of time that Hi-Tech ran violative advertising in print media, such as magazines. 1/23/14 Trial Tr. at 148:18-149:8.

940. Hart testified that he did not do anything to verify the starting and ending dates that Wheat provided to him in narrowing the Hi-Tech Relevant Period. 1/23/14 Trial Tr. at 149:9-11.

941. In defining the starting and ending dates for the Hi-Tech Relevant Period, Hart testified that Wheat asked Hart to consider only Hi-Tech's print media advertising. 1/23/14 Trial Tr. at 149:25-150:2.

942. Hart testified that he did not review Hi-Tech's website, labels, or packaging to determine whether they contained violative advertising. 1/23/14 Trial Tr. at 149:21-24, 150:12-16, 150:23-151:1.

943. In defining the starting and ending dates for the Hi-Tech Relevant Period, Hart testified that he did not take into account whether Hi-Tech ran violative advertisements on Hi-Tech's website, whether Hi-Tech distributed products with violative labels or packaging, or Contempt Defendants' failure to include the required yohimbine warning on Hi-Tech's labels. 1/23/14 Trial Tr. at 149:16-20, 150:3-7, 150:17-22, 151:6-9.

944. Hart testified that he never discussed the required yohimbine warning with Wheat. 1/23/14 Trial Tr. at 151:10-12.

945. The Fastin claim "Warning: Extremely Potent Diet Aid! Do Not Consume Unless Rapid Fat and Weight Loss Are Your Desired Result!" appears only on Contempt Defendants' product packaging. *Compare* Plaintiff's Exs. 46, 50 *with* Plaintiff's Exs. 43-45.

946. The Fastin claim "Extreme Weight Loss Guaranteed!" only appears on Contempt Defendants' product packaging. *Compare* Plaintiff's Ex. 46 *with* Plaintiff's Exs. 43-45.

947. The Fastin claim "Rapid Fat Burner" only appears on Contempt Defendants' product packaging. *Compare* Plaintiff's Exs. 46, 48, 50, 146, 274, 290 *with* Plaintiff's Exs. 43-45.

948. The Fastin claim "Increases the metabolic rate promoting thermogenesis (The Burning of Stored Body Fat)" only appears on Contempt Defendants' product packaging. *Compare* Plaintiff's Exs. 46, 48, 50, 146, 274, 290 *with* Plaintiff's Exs. 43-45.

949. The Fastin claim "Fastin has both immediate and delayed release profiles for appetite suppression, energy and weight loss" only appears on

Contempt Defendants' product packaging. *Compare* Plaintiff's Ex. 50 *with* Plaintiff's Exs. 43-45.

950. The Lipodrene claim "Increases the metabolic rate promoting thermogenesis (the burning of stored body fat)" only appears on Contempt Defendants' product packaging. *Compare* Plaintiff's Ex. 56 *with* Plaintiff's Exs. 44, 52-53.

951. The Lipodrene claim "slows the absorption of serotonin, which helps in weight management by controlling food cravings and suppressing the appetite" only appears on Contempt Defendants' product packaging. *Compare* Plaintiff's Ex. 56 *with* Plaintiff's Exs. 44, 52-53.

952. The Stimerex-ES claim "High Performance Thermogenic Intensifier for Maximum Fat Loss," only appears on Contempt Defendants' product packaging. *Compare* Plaintiff's Ex. 65 *with* Plaintiff's Exs. 44, 61-62.

953. Hart testified that he defined the starting and ending dates for the Hi-Tech Relevant Period for Lipodrene—January 1, 2011, through September 30, 2012—based on what Wheat told him, and did not do anything to verify that Hi-Tech did not disseminate violative advertising for Lipodrene prior

to the starting or after the ending dates that Wheat provided. 1/23/14 Trial Tr. at 152:17-153:3, 158:10-24.

954. The print advertisement dissemination schedule for Lipodrene provided by the Contempt Defendants to the FTC identifies a Lipodrene advertisement that ran in October 2010. Plaintiff's Ex. 18 at 17.

955. Hart testified that he did not review the print advertisement dissemination schedule for Lipodrene provided by the Contempt Defendants to the FTC. 1/23/14 Trial Tr. at 153:24-154:5.

956. Hart testified that he did not review Wheat's declaration dated December 14, 2012, which stated that Hi-Tech continued to disseminate a combination ad featuring Lipodrene, Fastin, and Stimerex-ES as of December 14, 2012. 1/23/14 Trial Tr. at 156:21-25.

957. Hart testified that he defined the starting and ending dates for the Hi-Tech Relevant Period for Stimerex-ES—January 1, 2011, through September 30, 2012—based on what Wheat told him, and did not do anything to verify that Hi-Tech did not disseminate violative advertising for Stimerex-ES prior to the starting or after the ending dates that Wheat provided. 1/23/14 Trial Tr. at 154:12-25, 159:12-22.

958. The print advertisement dissemination schedule for Stimerex-ES provided by the Contempt Defendants to the FTC identifies a Stimerex-ES advertisement that ran in October 2010. Plaintiff's Ex. 18 at 28.

959. Hart testified that he did not review the print advertisement dissemination schedule for Stimerex-ES provided by the Contempt Defendants to the FTC. 1/23/14 Trial Tr. at 155:9-13.

960. Hart testified that he defined the ending date for the Hi-Tech Relevant Period for Fastin—May 31, 2012—based on what Wheat told him, and did not do anything to verify that Hi-Tech did not disseminate violative advertising for Fastin after the ending date that Wheat provided. 1/23/14 Trial Tr. at 156:7-20.

961. Hart testified that the Food, Drug, and Mass entry in his declaration consists of payments that Hi-Tech made to Stephen Smith, Mike Smith, and other brokers. 1/24/14 Trial Tr. at 7:16-18.

962. Hart testified that Wheat and Stephen Smith told him that broker payments were very important to getting product into stores. 1/24/14 Trial Tr. at 7:19-21.

963. Wheat testified that "brokers are a necessary evil in the dietary supplement world." 1/21/14 Trial Tr. at 175:17-19.

964. Wheat testified that brokers work with large chain retailers to decide what planogram goes on the retailers' shelves. 1/21/14 Trial Tr. at 175:17-23.

965. Wheat testified that brokers and large chain retailers determine the planogram layout as follows: for "a better selling product, you are going to get eye level type placement [on the planogram]. If it is not selling good[], you are going to get the bottom shelf or the top shelf [placement on the planogram]." 1/21/14 Trial Tr. at 175:24-176:5.

966. From January 1, 2009 through August 31, 2013, Hi-Tech paid Stephen Smith $989,242 in broker payments. Defendants' Ex. 65 at 23.

967. Payments to Stephen Smith totaled nearly half of Hi-Tech's total broker payments for January 1, 2009 to August 2013. Defendants' Ex. 65 at 23; 1/24/14 Trial Tr. at 8:2-8.

968. As discussed below, Smith used JPEG and PDF images of the violative product packaging to market Hi-Tech's weight-loss products to retailers. *See* FOF ¶ 37.

969. From January 1, 2009 through August 31, 2013, Hi-Tech spent $3,975,699 on advertising for Fastin, Lipodrene, Benzedrine, and Stimerex-ES. Defendants' Ex. 65 at 19; 1/24/14 Trial Tr. at 8:11-9:20.

970. Hart testified that the nearly $4 million that Hi-Tech attributed to advertising costs did not include the costs to maintain Hi-Tech's website. 1/24/14 Trial Tr. at 9:2-8.

971. Hart testified that the nearly $4 million that Hi-Tech attributed to advertising costs did not include the costs of Hi-Tech's labels. 1/24/14 Trial Tr. at 9:9-15.

972. Hart testified that the nearly $4 million that Hi-Tech attributed to advertising costs did not include the costs of Hi-Tech's packaging. 1/24/14 Trial Tr. at 9:16-20 ("This is solely print media advertising costs.").

973. Hart testified that the nearly $4 million that Hi-Tech attributed to advertising costs did not include the costs or fees paid to expert endorsers. 1/24/14 Trial Tr. at 8:19-9:1.

974. Victor Kelley, Hi-Tech's former CEO, testified that during the period Hi-Tech purportedly ceased advertising "the company was losing revenues." 1/21/14 Trial Tr. at 99:13-100:1.

975. Kelley testified that "it is difficult to run a company like [Hi-Tech] unless you get the word out about your product and advertise." 1/21/14 Tr. at 99:18-100:1.

976. On March 16, 2010, Wheat wrote to his managers, including Stephen Smith, "In order to come out the other side of the FTC verdict since they are not willing to back off on the dollar amount—we are going to have to advertise and increase revenue and profit margin. I am analyzing what all we can do now to increase revenue and profits." Plaintiff's Ex. 94 at 3.

977. On March 28, 2010, Wheat wrote to Stephen Smith, "I would love to advertise as I think we could grow Fastin to the point of running 24-7 to keep up . . . I believe if we advertised and launched in the magazines in June you would be able to run the rest of the table." Plaintiff's Ex. 96 at 3.

978. On March 30, 2010, Wheat wrote to Arthur Leach and Stephen Smith, "With no advertising we are bulletproof but as you and I discussed the

downside is brand erosion as we have seen with Stamina and Lipodrene." Defendants' Ex. 98 at 3.

979. On July 15, 2010, Wheat wrote to Stephen Smith, "kepp [sic] up the good work and we are going to run the table with Fastin and get our money back in spades on the ads as Fastin is one that will generate people to go get it when they see it is available without A PRESCRIPTION!" Plaintiff's Ex. 90 at 4.

980. On July 19, 2010, Wheat wrote to his managers, including Stephen Smith, that he believed that advertising would increase sales for Lipodrene by 30 to 40 percent. Plaintiff's Ex. 91 at 3.

D. Contempt Defendants Caused Approximately $34 Million In Consumer Injury Through Their Failure To Include The Required Yohimbine Health-Risk Warning.

981. From at least January 1, 2009 through December 31, 2012, Contempt Defendants failed to include the required yohimbine health-risk warning on their packaging for Fastin, Lipodrene, Benzedrine, and Stimerex-ES. *See* FOF ¶¶ 861-874.

982. In 2009, Hi-Tech's total billings for Fastin, Lipodrene, Benzedrine, and Stimerex-ES – less customer remittance deductions – totaled $6,459,393. Dkt. No. 905 ¶ 5; Defendants' Ex. 65 at 19.

983. In 2010, Hi-Tech's total billings for Fastin, Lipodrene, Benzedrine, and Stimerex-ES – less customer remittance deductions – totaled $6,011,475. Dkt. No. 905 ¶ 10; Defendants' Ex. 65 at 19.

984. In 2011, Hi-Tech's total billings for Fastin, Lipodrene, Benzedrine, and Stimerex-ES – less customer remittance deductions – totaled $13,369,596. Dkt. No. 905 ¶ 15; Defendants' Ex. 65 at 19.

985. In 2012, Hi-Tech's total billings for Fastin, Lipodrene, Benzedrine, and Stimerex-ES – less customer remittance deductions – totaled $8,600,763. Dkt. No. 905 ¶ 20; Defendants' Ex. 65 at 19.

986. In total, between January 1, 2009, and December 31, 2012, Hi-Tech's total billings for Fastin, Lipodrene, Benzedrine, and Stimerex-ES – less customer remittance deductions – totaled $34,441, 227. Dkt. No. 905 ¶ 21; Defendants' Ex. 65 at 19.

E. Contempt Defendants' Evidence Is Unreliable And Does Not Provide A Basis To Reduce The Amount Of Consumer Harm Caused By Contempt Defendants' Failure To Include The Required Yohimbine Health-Risk Warning.

1. Contempt Defendants' Witnesses Offer No Testimony Regarding The Purchasers Of The Products At Issue.

987. Contempt Defendants' warnings expert, Gerald M. Goldhaber, offers no opinion as to whether Hi-Tech's product labels affected actual consumers' purchasing decisions. *See* Defendants' Ex. 131.

988. Contempt Defendants' consumer research survey expert, Linda Gilbert, offers no opinion on the effect that product labels had on actual Hi-Tech consumers' purchasing decisions. 3/31/17 Trial Tr. at 133:20-23. In fact, Gilbert did not survey Hi-Tech consumers and cannot identify how any actual Hi-Tech "consumers interpret the language on the labels of the products at issue." 3/31/17 Trial Tr. 133:12-134:13.

2. The Non-Compliant Safety Warnings Used By Contempt Defendants Are Substantially Different From The Court-Ordered Yohimbine Health-Risk Warning.

989. The product packaging and labels for Fastin, Lipodrene, Benzedrine, and Stimerex-ES in use from January 1, 2009 through late 2012 did not contain the words "**WARNING:** This product can raise blood pressure and interfere with other drugs you may be taking. Talk to your doctor about

this product." *See* FOF ¶¶ 861-874; Plaintiff's Exs. 46-51, 54-56, 59-60, 63-65.

990. Instead, Contempt Defendants included non-compliant warning language on their product packaging and labels. That language did not tell consumers that the products "can raise blood pressure" or "interfere with other drugs" they may be taking, as required by the Hi-Tech Order. *Compare* Plaintiff's Exs. 46-51, 54-56, 59-60, 63-65 *with* Plaintiff's Ex. 1 at Section VI. It also did not direct all consumers to "[t]alk to [their] doctor about this product," as also required by the Hi-Tech Order. *Compare* Plaintiff's Exs. 46-51, 54-56, 59-60, 63-65 *with* Plaintiff's Ex. 1 at 18.

991. For example, on their Fastin, Lipodrene, and Benzedrine product packaging and labels, Contempt Defendants included the following non-compliant warning language, or a close variation thereof, in small print, as part of a much longer block of warning text, on the inside of their product labels – such that consumers had to peel back before purchase – or on the back of their product packaging:

a. "Consult with your physician prior to use if you have a medical condition, including but not limited to, heart, liver, kidney or

thyroid disease, psychiatric or epileptic disorders, difficulty urinating, diabetes, high blood pressure, cardiac arrhythmia, recurrent headaches, enlarged prostate or glaucoma;" and

b. "Consult with your physician prior to use if you are taking medication, including but not limited to MAOI inhibitors, antidepressants, aspirin, nonsteroidal anti-inflammatory drugs or products containing phenylephrine ephedrine, pseudoephedrine, or other stimulants."

See, e.g., Plaintiff's Exs. 46, 54, 60.

992. Contempt Defendants' Stimerex-ES product label, Plaintiff's Ex. 63, does not even contain the non-compliant language quoted in Paragraph 991. It does not mention "blood pressure" at all and directs only those "individuals who are sensitive to the effects of caffeine" to consult a "licensed health care professional" before using the product. *Id.*

3. Goldhaber's Opinion That Consumers Understand The Non-Compliant Warning To Have The Same Meaning As The Court-Ordered Warning Is Unsupported And Contradicts The Established Science In The Field.

993. On cross examination, Dr. Goldhaber admitted that he is not opining that the Hi-Tech product labels "by themselves would have communicated to

all consumers who read them the contents of the Court-ordered warning." 3/31/17 Trial Tr. at 47:15-20.

994. Nevertheless, on direct examination, Goldhaber opined that "while the language [on the Hi-Tech labels] is different, the meaning is the same" as the Court-ordered warning. 3/31/17 Trial Tr. at 37:3-14.

995. Other than generally referencing his "experience as an expert in the area of warnings," Goldhaber provides no evidence that the warning labels communicated the content of the Court-ordered warning to consumers who purchased Hi-Tech's products. Defendants' Ex. 131 ¶ 21.

996. The FTC presented rebuttal testimony from Dr. Susan J. Blalock. Dr. Blalock obtained her Ph.D. in public health from the University of North Carolina in 1987. She is the chair of the FDA's Risk Communication Advisory Committee, on which she has served since 2013. She is also a professor in, and vice-chair of, the University of North Carolina's Eshelman School of Pharmacy's Division of Pharmaceutical Outcomes and Policy. 4/5/17 Trial Tr. at 58:1-14, 58:21-66:18; Plaintiff's Ex. 589 ¶¶ 3-5.

997. Dr. Blalock reviewed Goldhaber's expert report and concluded that Goldhaber's opinion is inconsistent with established literature and

evidence, and that there is no scientific support for his opinion that Contempt Defendants' non-compliant warning language would have communicated the content of the Court-ordered warning. 4/5/17 Trial Tr. at 74:4-76:11; Plaintiff's Ex. 589 ¶¶ 15, 24.

998. Dr. Blalock explained, with citations to the relevant academic literature, that messages targeted to a particular subset of consumers are not likely to attract the attention of individuals outside that subset. 4/5/17 Trial Tr. at 75:24-76:11, 79:15-80:8, 81:1-83:18; Plaintiff's Ex. 589 ¶ 21.

999. Dr. Blalock further explained that if consumers have a difficult time finding the warning on a label, the warning is not likely to attract the attention of consumers. 4/5/17 Trial Tr. at 80:9-81:8.

1000. Dr. Blalock concluded that because Contempt Defendants' warning labels speak only to the subset of consumers who already have high blood pressure or the other listed conditions, most readers of the Fastin, Lipodrene, and Benzedrine labels who do not have high blood pressure or the other listed conditions would disregard the message advising users to consult a physician. 4/5/17 Trial Tr. at 79:15-80:8, 81:1-13, 84:10-85:3; Plaintiff's Ex. 589 ¶ 28.

1001. Goldhaber agreed that "a warning that's targeted to a particular group" may suggest to people "who are not in that group . . . that they're not at risk." 3/31/17 Trial Tr. at 55:19-23.

1002. Goldhaber also testified that the "blood pressure" language on the Fastin, Lipodrene, and Benzedrine labels is "[o]bviously . . . to a targeted audience"—those who already have high blood pressure. 3/31/17 Trial Tr. at 39:7-8.

1003. The warning label for Stimerex-ES does not mention blood pressure at all, and therefore fails to inform users that the product may raise blood pressure, irrespective of whether a person has existing high blood pressure. 3/31/17 Trial Tr. at 148:21-149:3; 4/5/17 Trial Tr. at 75:12-23; Plaintiff's Ex. 589 ¶ 26.

1004. Even Goldhaber agreed that the Stimerex-ES label "doesn't mention blood pressure" and "isn't very specific." 3/31/17 Trial Tr. at 43:10-44:4. He offered the limited opinion that "one would ***hope*** that and expect that if the consumer read the label, that they ***might*** draw from that the conclusion that it has to do with blood pressure ***possibly***." *Id.* (emphasis added).

4. Goldhaber's Opinion That Consumers Could Have Understood The Court-Ordered Warning By Other Means Is Unsupported And Contradicts The Established Science In The Field.

1005. Goldhaber opines that, in addition to the information contained on the product labels, "[c]onsumers would have obtained information from product ads and Hi-Tech's website, and other sources of information from the information environment" and that "consumers rely on product names, ads and website information, in addition to product labels, in making purchasing decisions regarding dietary supplements." Defendants' Ex. 131 ¶ 25.

1006. Other than generally referencing his experience in the area of warnings and communications, including his own 1974 textbook, Goldhaber cites no support for this conclusion. Defendants' Ex. 131 ¶ 25; 4/5/17 Trial Tr. at 74:12-15**;** Plaintiff's Ex. 589 ¶ 33.

1007. Goldhaber offers no opinion regarding how many actual purchasers of Hi-Tech's products saw or relied upon sources outside of the product labels and packaging, such as Hi-Tech's website and print advertisements. 3/31/17 Trial Tr. at 51:8-52:7.

1008. In fact, Goldhaber's opinion about the "information environment" providing the Court-ordered warning to consumers is based, in part, on an unsupported assumption: that all of Contempt Defendants' print advertisements and web pages from 2009-2012 contained the Court-ordered warning. 3/31/17 Trial Tr. at 63:1-64:8; Defendants' Ex. 131 ¶ 8 ("I have also been advised by counsel for Hi-Tech that the [Court-ordered] warning was included in all of Hi-Tech's print advertising and web site advertising during the relevant time period. . . .").

1009. That assumption, however, ignores that Contempt Defendants claim not to have maintained a website or disseminated any print ads from January 2009 through September 2010. *See* FOF ¶ 878. Thus, consumers could not have obtained the Court-ordered warning from those sources in that time period. Counsel for Contempt Defendants neglected to inform Goldhaber that they claim to have run no advertising in this time period. 3/31/17 Trial Tr. at 66:25-67:6. Contempt Defendants' no-advertising claim is also false, and, in fact, the print advertisements that Contempt Defendants ran during the January 2009-September 2010 time period did not have the required warning. *See* FOF ¶¶ 878-899. Counsel also did not provide

Goldhaber with copies these non-compliant advertisements. 3/31/17 Trial Tr. at 68:5-69:6.

1010. Even outside of the January 2009-September 2010 time period, Contempt Defendants' advertisements frequently lacked the required warnings. *See* FOF ¶¶ 900-913. Counsel also concealed these advertisements from Goldhaber. 3/31/17 Trial Tr. at 69:7-70:16

1011. Even assuming that the Court-ordered warning was present on Hi-Tech's website and print advertisements for some period of time after September 2010, the non-compliant product packaging and labels conflict or is inconsistent with the information on the websites and in the print ads. 4/5/17 Trial Tr. at 85:15-87:1; Plaintiff's Ex. 589 ¶¶ 28, 34; *see also* FOF ¶ 872.

1012. Dr. Blalock concluded, with citations to the relevant academic literature, that exposure to conflicting information can create confusion and backlash to health recommendations and regulations designed to protect consumers. 4/5/17 Trial Tr. at 86:5-87:2-8; Plaintiff's Ex. 589 ¶ 34.

1013. Goldhaber offers no opinion regarding conflicting or inconsistent information sources, but admitted that "[i]f a message contains

inconsistent or even conflicting appeals, its effectiveness is greatly reduced," and that "[m]ore information in a warning, particularly inconsistent information, may actually reduce the accuracy of . . . judgments while at the same time increasing a person's confidence that his or her judgment is accurate." 3/31/17 Trial Tr. at 58:21-59:1, 59:11-14.

1014. Goldhaber also admitted that "warning messages tend to be more effective when there are fewer pieces of information on the packaging." 3/31/17 Trial Tr. at 56:20-23. Indeed, Goldhaber further admitted that "when people are confronted with a lot of information in a warning, they may not be motivated to process the entire set of information and as a result may make an erroneous judgment." *Id.* at 56:24-57:3. Goldhaber previously testified before a Senate subcommittee that "people remember more important information from a warning containing fewer pieces of information than a warning with more information." *Id.* at 57:16-58:12.

1015. Goldhaber also agreed that "information contained in a package warning should be short, limited, and concise." 3/31/17 Trial Tr. at 56:16-19

5. Goldhaber's Opinion Regarding Industry Standards Is Irrelevant And Unsupported.

1016. Goldhaber opined that the warnings on the product labels are all well-designed and consistent with the standard of care in the dietary supplement industry, or the "state of the art." Defendants' Ex. 131 ¶ 21; 3/31/17 Trial Tr. at 36:10-18.

1017. Goldhaber agreed that "'state of the art' doesn't mean that a bad warning is acceptable just because other people are using it." 3/31/17 Trial Tr. at 54:7-15.

6. Gilbert's Survey Is Fundamentally Flawed And Unreliable.

1018. Contempt Defendants offered rebuttal testimony to Dr. Blalock from Linda Gilbert, who designed and executed a survey that she claimed was intended to determine whether language on the warning labels "successfully communicate[s] that this supplement can increase one's blood pressure" and "that consumers should consult with their doctor before using this supplement." Plaintiff's Ex. 590 ¶ 9

1019. Gilbert admitted that on March 29, 2013, she provided deposition testimony in a separate case where she admitted that she did not consider

herself to be "an expert in survey design or analytics," and that she "hire[s] people to do that sort of thing." 3/31/17 Trial Tr. at 87:23-89:1.

1020. Gilbert admitted that her survey was not designed to test whether or not people would read the warning label, but rather to test how consumers would understand the language presented to them if they had noticed and read the statements on the label. 3/31/17 Trial Tr. at 109:13-15; 133:4-11.

1021. Gilbert testified that she is not offering any opinion on whether the language on the product label was displayed clearly and prominently. 3/31/17 Trial Tr. at 132:24-133:3.

1022. The FTC offered sur-rebuttal expert testimony from Dr. Kenneth L. Bernhardt. Dr. Bernhardt is a Regents Professor of Marketing Emeritus at the J. Mack Robinson College of Business at Georgia State University. He served on the marketing faculty of the business school from 1972-2013. 4/5/17 Trial Tr. at 170:24-171:10; Plaintiff's Ex. 590 ¶ 1.

1023. Dr. Bernhardt also served as Chairman of the Board for the 45,000-member American Marketing Association, as President of the Association for Consumer Research, and as Chair of the U.S. Census Bureau Marketing

Advisory Committee. 4/5/17 Trial Tr. at 172:12-173:1; Plaintiff's Ex. 590 ¶¶ 4-5.

1024. Dr. Bernhardt has published more than a dozen books and monographs and numerous articles on marketing and consumer behavior in various marketing, business, and research journals. He has also designed, conducted, and analyzed over 100 surveys throughout his career. 4/5/17 Trial Tr. at 173:18-174:9; Plaintiff's Ex. 590 ¶¶ 6-7.

1025. From 1978-1980, Dr. Bernhardt served as a Consumer Research Advisor for the Federal Trade Commission, with responsibility for the design and implementation of the FTC's consumer research activity. Upon leaving the FTC, Dr. Bernhardt received the Chairman's Award for Meritorious Service. 4/5/17 Trial Tr. at 171:11-21; Plaintiff's Ex. 590 ¶ 3.

1026. Dr. Bernhardt reviewed Gilbert's survey and concluded that her survey results are unreliable, and cannot be used to provide reliable evidence of what consumers would have gathered from Contempt Defendants' product packaging and labels, because of major methodological and design flaws that are inconsistent with accepted practices of survey research. 4/5/17 Trial Tr. at 175:17-176:6**;** Plaintiff's Ex. 590 ¶¶ 12-13.

1027. Dr. Bernhardt identified several major flaws in Gilbert's study design and execution that render it unreliable. *See* 4/5/17 Trial Tr. at 177:1-9; Plaintiff's Ex. 590 ¶¶ 13-42.

1028. First, Gilbert's survey does not replicate marketplace conditions. 4/6/17 Trial Tr. at 4:21-5:15; Plaintiff's Ex. 590 ¶¶ 14-18.

1029. Rather than show survey respondents Contempt Defendants' actual, non-compliant product labels, Gilbert showed them excerpted language from the labels, presented in isolation from the rest of the labels' statements and in an easier-to-read format. 3/31/17 Trial Tr. at 108:10-18; 4/6/17 Trial Tr. at 5:16-6:25; Plaintiff's Ex. 590 ¶¶ 16.

1030. Gilbert admitted that she did not see the actual product labels and pulled the language used in the survey directly from Goldhaber's expert report without verifying the actual language used on the product labels. 3/31/17 Trial Tr. at 137:1-14.

1031. Gilbert also admitted that she did not try to replicate marketplace conditions, and her goal was not to determine how consumers would interact with the products in the marketplace. 3/31/17 Trial Tr. at 150:8-11.

1032. Gilbert further admitted that the decisions she made on how to display the non-compliant warning language was to make that language "readable" and "to focus consumers' attention on those things that we felt were most important." 3/31/17 Trial Tr. at 150:12-16. For example, Gilbert admitted that she:

a. Presented the label statements in mixed case to improve the readability of the statements. 3/31/17 Trial Tr. at 143:6-25, 146:11-16, 148:17-20, 149:24-150:3. The actual labels at issue presented language in upper case letters. *See* Plaintiff's Exs. 46-51, 54-56, 59-60, 63-65.

b. Presented respondents with language in a larger font size than that on the product labels at issue. 3/31/17 Trial Tr. at 142:24-143:5, 146:7-10, 148:14-16, 149:21-23.

c. Did not present respondents with the all of the language on the product labels in its entirety. 3/31/17 Trial Tr. at 142:1-6; 145:9-12; 147:17-20; 149:11-13.

d. Did not include any scenarios where a consumer would have to "lift" or "peel" the label to see the warning, in contrast with most of the product labels at issue. 3/31/17 Trial Tr. at 145:4-8, 149:4-10; *see* Plaintiff's Exs. 46-51, 54-56, 59-60, 63-65.

e. Presented warning language in separate sections, in contrast with the product labels at issue, which presented warning language in one single block with no breaks. 3/31/17 Trial Tr. at 142:7-15, 145:13-23, 147:21-148:9, 149:14-17.

f. Presented language in a different order than the language on the product labels at issue. 3/31/17 Trial Tr. at 142:20-23, 146:4-6, 148:10-13, 149:18-20.

1033. Dr. Bernhardt explained that by focusing respondents' 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 would understand warnings from having actually experienced them. *See* Plaintiff's Ex. 590 ¶ 29; 4/5/17 Trial Tr. at 186:1-24.

1034. Third, the survey suffers from several types of bias, including the "priming" of survey participants by asking them certain questions and "telegraphing" to consumers the researchers' interest. 4/5/17 Trial Tr. at 179:15-180:9; Plaintiff's Ex. 590 ¶¶ 22-26. Dr. Bernhardt explains that this bias may cause respondents to be more likely to agree that Contempt Defendants' products could increase one's blood pressure when asked the question later in the survey. *Id*; 4/5/17 Trial Tr. at 181:15-182:16.

1035. In an article relied on by Dr. Bernhardt in forming his opinions, survey researcher Jon Krosnick explains some of the effects of priming: "[R]espondents may interpret each question superficially and select what they believe will be a reasonable answer to the interviewer and researcher. Yet this answer is selected without referring to any internal psychological cues relevant to the attitude, belief, or event of interest. Instead, the respondent may look to the wording of the question for a cue, pointing to a response that can be easily selected and defended if necessary." Plaintiff's Ex. 691 at 548.

1036. Fourth, the survey encouraged guessing. 4/5/17 Trial Tr. at 187:11-188:8, 189:16-190:10; Plaintiff's Ex. 590 ¶¶ 30-37. The questions were asked in a

"true," "false," or "don't know" format, with no instructions mentioning the "don't know" option. Plaintiff's Ex. 590 ¶¶ 30-37; *see also* 4/5/17 Trial Tr. at 193:10-194:8.

1037. As explained by Professor Shari Seidman Diamond in the Federal Judicial Center's *Reference Manual on Scientific Evidence*: "One form of closed-ended question format that typically produces some distortion is the popular agree/disagree, true/false, yes/no question. Although this format is appealing because it is easy to write and score these questions and their responses, the format is also seriously problematic. With simplicity comes acquiescence, '[T]he tendency to endorse any assertion made in a question, regardless of its content . . . .'" Plaintiff's Ex. 571 at 394.

1038. Fifth, Gilbert's survey does not use a control group or control questions. 3/31/17 Trial Tr. at 113:3-10; Plaintiff's Ex. 590 ¶¶ 38-42. As explained in the *Reference Manual on Scientific Evidence*: "It is possible to adjust many survey designs so that causal inferences about the effect of . . . allegedly deceptive [material] become clear and unambiguous. By adding one or more appropriate control grounds the survey expert can directly test the

inference of the stimulus" – here, the warning language. Plaintiff's Ex. 571 at 398.

1039. In other words, as Dr. Bernhardt explained, the control group reduces guessing, acquiescence, and other forms of error, in order to determine whether respondents are answering in a particular way because of the survey design rather than their actual attitudes or beliefs. 4/5/17 Trial Tr. at 194:20-196:19; Plaintiff's Ex. 590 ¶ 38. Where, as here, the survey relies on true/false questions, "[o]nly when control groups or control questions are added to the survey design can this question format provide reasonable response estimates." Plaintiff's Ex. 571 at 394.

1040. Gilbert claimed that she did not need a control for the survey because she was not trying to understand why consumer held the types of beliefs that they did. She also testified that "we weren't at all trying to understand why people believed what they did, so we weren't looking for any sort of causality." 3/31/17 Trial Tr. at 112:11-113:10. This testimony, however, directly contradicts her expert report, in which she claimed that her survey was designed to test whether Contempt Defendants' warning language

communicated certain information to consumers. Defendants' Ex. 135 ¶¶ 7-8.

VII. Contempt Defendants Repeatedly Lied And Omitted Material Information When Responding To The FTC's Requests For Information Concerning Their Compliance With The Hi-Tech Order.

A. Contempt Defendants Lied About The Nature Of Their Advertising Claims As Early As February 2009.

1041. In their initial compliance reports to the Federal Trade Commission on February 17, 2009, which were submitted by Novotny, Contempt Defendants stated that "Defendants Hi-Tech and NUG have reviewed all current marketing practices to ensure that they have eliminated any unsubstantiated claims for weight loss . . . and that for any representation they have competent and reliable scientific evidence." Plaintiff's Ex. 12 at 3-4.

1042. As of February 17, 2009, Contempt Defendants were marketing Fastin, Lipodrene, Benzedrine, and Stimerex-ES through their product labels and packaging with claims that the products cause rapid or substantial loss of weight or fat and affect human metabolism, appetite, or body fat without having double-blind, placebo-controlled studies of the products to substantiate the claims. Plaintiff's Ex. 18 at 12, 17, 23, and 28; Plaintiff's

Exs. 46-51, 54-56, 59-60, 63-65; Dkt. No. 524 at 18-22; *see also* 1/22/14 Trial Tr. at 109:18-23, 110:11-15.

1043. On February 17, 2009, Contempt Defendants stated that "Hi-Tech and NUG . . . have reviewed all current marketing and ***labeling*** practices to ensure they include the required warning label for products with Yohimbine." Plaintiff's Ex. 12 at 4 (emphasis added).

1044. As of February 17, 2009, Contempt Defendants did not include the required yohimbine warning on any of their product packaging or labels for Fastin, Lipodrene, Benzedrine, and Stimerex-ES. Plaintiff's Ex. 18 at 12, 17, 23, and 28; Plaintiff's Exs. 46-51, 54-56, 59-60, 63-65; Dkt. No. 524 at 23-24.

B. Contempt Defendants Lied About The Nature Of Hi-Tech Publishing's Business Activities.

1045. On August 19, 2013, the FTC made a compliance demand on Contempt Defendants that requested:

"A report identifying any entity in which Hi-Tech or Wheat is an officer, director, principal, owner or shareholder with five percent or more ownership. For each entity identified, the report should describe the business of the entity, whether the entity manufactures, labels, advertises,

promotes, offers for sale, sells, or distributes any weight loss product, the date upon which the company was acquired and to the extent not reported to the FTC 30 days prior to the acquisition as required by Section XI of the Hi-Tech Order, the reason for the failure to report the acquisition." Plaintiff's Ex. 165 at 3.

1046. The August 19, 2013, demand letter requested materials for the period January 1, 2009, through the date of Contempt Defendants' response. Plaintiff's Ex. 165 at 2.

1047. Contempt Defendants responded to the FTC's August 19, 2013, demand letter on August 29, 2013, and September 11, 2013. *See* Plaintiff's Exs. 166 and 167.

1048. In their September 11, 2013, response, Contempt Defendants stated: "Hi-Tech Publishing, Inc. . . . do[es] not sell or advertise weight loss products." Plaintiff's Ex. 167 at 5.

1049. Hi-Tech Publishing, Inc. is a corporation wholly-owned by Jared Wheat. *See* Plaintiff's Ex. 167 at 4.

1050. Hi-Tech Health & Fitness is a catalog that was published by Hi-Tech Publishing, Inc. for use in its advertising. 1/22/14 Trial Tr. at 130:21-24, 131:8-11; *see also* Plaintiff's Ex. 295 at 3; Plaintiff's Ex. 296 at 3.

1051. Hi-Tech Health & Fitness identifies Jared Wheat as its editor-in-chief. Plaintiff's Ex. 295 at 3; Plaintiff's Ex. 296 at 3.

1052. Wheat admitted that Hi-Tech disseminated copies of Hi-Tech Health & Fitness to retailers. 1/22/14 Trial Tr. at 130:21-131:4.

1053. Wheat admitted that Hi-Tech Health & Fitness was sent to retailers so that the retailers could offer copies to their customers "to educate them on our products." 1/22/14 Trial Tr. at 130:25-131:7.

C. Contempt Defendants Repeatedly Failed To Produce All Print Ads, Product Labels, And Packaging For Fastin, Lipodrene, Benzedrine, And Stimerex-ES.

1054. On November 3, 2011, the FTC made a compliance demand on Contempt Defendants that requested for all Fastin, Lipodrene, Benzedrine, and Stimerex-ES products:

> Copies of each unique version of advertisements for each . . . in any medium, including newspapers, ***magazines***, television, radio,

telephone, direct mail, ***product packaging (including labels)***, the Internet, or electronic mail.

Plaintiff's Ex. 17 at 3 (emphasis added).

1055. The November 3, 2011, demand letter requested materials for the period "beginning January 1, 2009," through the date of Contempt Defendants' response. Plaintiff's Ex. 17 at 2.

1056. Contempt Defendants responded to the FTC's November 3, 2011, demand letter on December 15, 2011. Plaintiff's Ex. 18; *see also* Plaintiff's Exs. 23-24.

1057. Apart from the advertising materials included in the FTC's Motion for an Order to Show Cause Why Contempt Defendants Hi-Tech Pharmaceuticals, Jared Wheat, and Stephen Smith Should Not Be Held in Contempt For Violating the Final Judgment and Permanent Injunction, Contempt Defendants provided no additional advertising materials to the Federal Trade Commission in its December 15, 2011, response to the FTC's November 3, 2011 demand. *See generally* Plaintiff's Ex. 18.

1058. With regard to Contempt Defendants' response to the November 3, 2011, compliance report demand, Wheat attested under oath: "[T]o the best of my knowledge, complete and accurate copies of all information and

documents requested by the FTC have been provided in response to the FTC's various information demands and I have no reason to believe that any information was not provided or is inaccurate." Plaintiff's Ex. 26 at 5.

1. Contempt Defendants Withheld Product Packaging From Their Compliance Demand Responses And Only Produced Them Pursuant To Specific, Subsequent Requests from the FTC.

1059. On May 17, 2012, the FTC requested an additional compliance report from Contempt Defendants and enclosed the packaging for the 3-count SKU of Fastin. Plaintiff's Ex. 27 at 2-3, 5.

1060. The May 17, 2012, demand letter requested:

a. That Contempt Defendants explain their failure to produce the packaging for the 3-count Fastin SKU as part of their response to the November 3, 2011, demand letter. Plaintiff's Ex. 27 at 3.

b. Copies of each unique version of advertisements for Fastin, Lipodrene, Benzedrine, or Stimerex-ES, in any medium, including newspapers, ***magazines***, television, radio, telephone, direct mail, ***product packaging (including product labels)***, the Internet, or electronic mail, that have not been previously identified in response

to Demand 4.b to the FTC's November 3, 2011, Demand Letter. Plaintiff's Ex. 27 at 3 (emphasis added).

1061. The May 17, 2012, demand letter covered the period January 1, 2009, through the date of Contempt Defendants' response. Plaintiff's Ex. 27 at 2.

1062. Wheat and Hi-Tech responded to the May 17, 2012, demand letter on May 27, 2012, and on June 5, 2012. *See* Plaintiff's Exs. 28 and 29.

1063. In their May 27 and June 5 responses to the May 17, 2012 demand letter, Contempt Defendants identified no additional product packaging, labels, or magazine advertisements for Fastin, Lipodrene, Benzedrine, or Stimerex-ES. *See* Plaintiff's Ex. 28 at 2 ("Hi-Tech is not aware of any other advertisements at this time."); Plaintiff's Ex. 29 at 2 ("Hi-Tech is not aware of any additional promotional materials that were sent via direct mailings to consumers.").

1064. In their May 17, 2012, demand letter response, Contempt Defendants claimed that the 3-count Fastin packaging was only used "for a very short period of time during August of 2010." Plaintiff's Ex. 28 at 2.

1065. With regard to Contempt Defendants' response to the May 17, 2012, compliance report demand, Wheat attested under oath: "[T]o the best of

my knowledge, complete and accurate copies of all information and documents requested by the FTC have been provided in response to the FTC's various information demands and I have no reason to believe that any information was not provided or is inaccurate." Plaintiff's Ex. 37 at 11, 13.

1066. In fact, Contempt Defendants sold Fastin using the 3-count packaging through both 2011 and 2012. *See* Defendants' Ex. 65 at 20 (Table 2-1).

1067. On August 30, 2012, the FTC requested an additional compliance report based on information revealed at the depositions of Jared Wheat and Stephen Smith. *See* Plaintiff's Ex. 36.

1068. Based on Hi-Tech's failure to provide advertisements for the 3-count Fastin SKU, the August 30, 2012, demand letter requested the following: "Please provide copies of the product packaging and labels for the 30-count Fastin SKU, as well as any other packaging, labels, print or internet advertising of any of the Identified [P]roducts that has not been provided to date. Your clients' response must include each unique package or label for each SKU of the Identified Products that has not been previously produced." Plaintiff's Ex. 36 at 3.

1069. Wheat and Hi-Tech responded to the August 30, 2012, demand letter on September 20, 2012. *See* Plaintiff's Ex. 37.

1070. In the September 20, 2012, response, Contempt Defendants provided copies of the product label and packaging for the 30- and 60-count Fastin SKUs as well as the advertisements used at the GNC trade show, but no other product packaging or advertising. Plaintiff's Ex. 37 at 1, 3-7.

1071. On September 20, 2012, the FTC sent Hi-Tech and Wheat a notice of deficiency stating the following:

> "[W]e note that your client has never provided product packaging for the following SKUs:
>
> (a) Lipodrene, 20 count;
>
> (b) Lipodrene, 2 count blister packs;
>
> (c) Lipodrene 24-2 count blister packs;
>
> (d) Stimerex-ES, 20 count;
>
> (e) Stimerex-ES, 2 count blister packs; and
>
> (f) Stimerex ES, 24-2 count blister packs."

Plaintiff's Ex. 38 at 3.

1072. Contempt Defendants responded to the September 20, 2012, notice of deficiency on October 19, 2012, three days prior to the Court's deadline for summary judgment motions. Plaintiff's Ex. 41; *see also* Dkt. No. 399 ¶ 6 (setting summary judgment schedule).

1073. In their October 19, 2012, response, Contempt Defendants produced, for the first time, packaging for the 2-count blister packs of Lipodrene and Stimerex-ES. Plaintiff's Ex. 41 at 6.

1074. The Lipodrene 2-count packaging included advertising claims for the product not previously disclosed to the FTC, including:

a. Increases the metabolic rate, promoting thermogenesis (the burning of stored body fat). Plaintiff's Ex. 41 at 6; *compare id. with* Plaintiff's Exs. 44, 52-55 (Lipodrene advertising).

b. Slows the absorption of serotonin, which helps in weight management by controlling food cravings and suppressing the appetite. Plaintiff's Ex. 41 at 6; *compare id. with* Plaintiff's Exs. 44, 52-55 (Lipodrene advertising).

1075. The Stimerex-ES 2-count packaging included product advertising claims not previously disclosed to the FTC, including: "High Performance Thermogenic Intensifier for Maximum Fat Loss." Plaintiff's Ex. 41 at 12; *compare id. with* Plaintiff's Exs. 44, 61-64.

2. Contempt Defendants Withheld Unique Print Advertisements From Their Compliance Demand Responses and Never Produced Those Advertisements In Response To The FTC Compliance Report Demands.

1076. Wheat falsely testified that he ceased advertising for all Hi-Tech products for the 18 months following entry of the Hi-Tech Order. 1/22/14 Trial Tr. at 45:6-12; *see also id.* at 11:8-13, 12:14-23.

1077. Contempt Defendants did not produce either the April 2009 or the January 2011 editions of Hi-Tech Health & Fitness in response to the FTC's numerous compliance demands. *See* Plaintiff's Exs. 11-16, 18, 22-24, 26, 28-29, 32, 34-35, 37, 41, 166-167 (Contempt Defendants' compliance report responses).

1078. Those catalogs contained numerous ads authored by Wheat, Smith, and Wright that contained unique advertising claims that had not been disclosed to the FTC, such as:

a. "After Fastin . . . Lipogenesis Enzymes controlling fat storage are inhibited thus less fat is stored . . . Lipolysis Cellular energy is elevated thus more fat is released (burned)." Plaintiff's Ex. 295 at 71 (inset box at bottom of page); *compare id. with* Plaintiff's Exs. 43-51 (challenged Fastin advertisements).

b. "Lipodrene brings forth . . . a novel approach to fat loss through triggering fat cell death (apoptosis). " Plaintiff's Ex. 295 at 82; *compare id. with* Plaintiff's Exs. 44, 52-56 (challenged Lipodrene advertisements).

c. "Benzedrine The First Anorectic Dietary Supplement Ever Produced! Anorexics, anorexigenics or appetite suppressants are substances (dietary supplements or drugs) that reduce the appetite and cause a person to eat less. The word comes from the greek [sic] an- = 'without' and –orexi- = 'appetite.'" Plaintiff's Ex. 295; *compare id. with* Plaintiff's Ex. 57-60 (challenged Benzedrine advertisements).

d. "Stimerex-ES exerts its mechanism of action through several metabolic pathways that result in fat loss." Plaintiff's Ex. 296 at 2;

compare id. with Plaintiff's Exs. 44, 61-65 (challenged Stimerex-ES advertisements).

See also generally Plaintiff's Exs. 295-296.

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Proposed Conclusions of Law

I. The FTC Has Proven By Clear And Convincing Evidence That Hi-Tech, Wheat, Smith, And Wright Are In Contempt.

1. The Court has authority to enforce its own orders through civil contempt. *See Shillitani v. United States*, 384 U.S. 364, 370 (1966); *Citronelle-Mobile Gathering, Inc. v. Watkins*, 943 F.2d 1297, 1301 (11th Cir. 1991).

2. As a party to the original action, the FTC may invoke the Court's order-enforcement power by initiating civil contempt proceedings in the same action. *Gompers v. Buck's Stove and Range Co.*, 221 U.S. 418, 444-45 (1911).

3. Contempt is established where there is clear and convincing evidence that the "violated order was valid and lawful; . . . the order was clear and unambiguous; and the . . . alleged violator had the ability to comply." *Fed. Trade Comm'n v. Leshin*, 618 F.3d 1221, 1232 (11th Cir. 2010) ("*Leshin I*") (ellipses original).

4. The clear and convincing evidence standard does not require evidence beyond a reasonable doubt. *See Essex Ins. Co. v. Tina Marie Entm't, LLC*, 602 F. App'x 471, 473 (11th Cir. 2015); *see also Cruzan v. Dir. Missouri Dep't of Health*, 497 U.S. 261, 286 n.11 (1990).

5. The standard for clear and convincing evidence is met where the party bearing the burden of proof introduces "evidence that produces in the mind of the trier of fact a firm belief or conviction, without hesitancy, as to the truth of the allegations sought to be established." *Essex Ins. Co.*, 602 F. App'x at 473 (internal quotation marks omitted).

6. The clear and convincing evidence standard can be met even where facts are in dispute and even where there is conflicting expert testimony. *See, e.g., Ward Labs., Inc. v. Fed. Trade Comm'n*, 276 F.2d 952, 954 (2d Cir. 1960) ("It is indeed a rare case where medical experts are called which does not involve disagreement. Here, however, the examiner is supported by clear and convincing testimony from well qualified witnesses. His decision and findings are the antithesis of 'arbitrary and capricious.'").

A. The Hi-Tech and Wright Orders Are Valid And Lawful Orders.

7. On June 4, 2008, this Court entered summary judgment in favor of the FTC against Hi-Tech, Wheat, Smith, and Wright. *See Fed. Trade Comm'n v. Nat'l Urological Grp.*, 645 F. Supp. 2d. 1167 (N.D. Ga. 2008), *aff'd*, 356 F. App'x 368 (11th Cir. 2009).

8. Finding a risk of recurrent violations that "could cause significant harm to consumers," the Court found that permanent injunctions were warranted against the defendants. *See Nat'l Urological Grp.*, 645 F. Supp. 2d at 1209-1210 (addressing Hi-Tech, Wheat, and Smith); *id.* at 1214 (addressing Wright).

9. The Eleventh Circuit Court of Appeals affirmed the judgment of the court. *Cf. TiVo, Inc. v. EchoStar Corp.*, 646 F.3d 869, 880 (Fed. Cir. 2011) ("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.") (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.")).

10. Thus, the Hi-Tech and Wright Orders are valid and lawful orders of the Court.

B. The Hi-Tech And Wright Orders Are Clear And Unambiguous.

1. The Substantiation Requirement Is Clear And Unambiguous.

11. An order is clear and unambiguous under Federal Rule of Civil Procedure 65(d) if "an ordinary person reading the court's order [is] 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); *Abbott Labs. v. Unlimited Beverages, Inc.*, 218 F.3d 1238, 1240 (11th Cir. 2000).

12. This standard for the enforceability of an injunction is essentially the same as the standard for constitutional vagueness. *Compare Eastern Air Lines*, 920 F.2d at 730 *with Nat'l Urological Grp.*, 645 F. Supp. 2d at 1186 (finding that competent and reliable scientific evidence standard was not constitutionally vague because it is sufficient "to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits").

13. Because the Orders' definition of "competent and reliable scientific evidence" is sufficient to "give people of ordinary intelligence a reasonable opportunity to understand what evidence is required to substantiate their health-related claims," *see Nat'l Urological Grp.*, 645 F. Supp. 2d at 1186, it

meets the standard for enforceability under Rule 65(d), *see Eastern Air Lines*, 920 F.2d at 730.

14. In determining whether an order is clear and unambiguous, the Court may also look to "whether the parties subject thereto understand their obligations under the order." *Planetary Motion v. Techsplosion, Inc.*, 261 F.3d 1188, 1203-04 (11th Cir. 2001) (collecting cases); *see also United States v. Sarcona*, 457 F. App'x 806, 811 (11th Cir. 2012) (rejecting challenge to injunction under Rule 65(d) and upholding criminal conviction where "the government presented evidence that [the defendant] understood [the injunction's] obligations well").

2. The Orders Are Not Obey The Law Injunctions.

15. The Orders are not improper "obey the law" injunctions because the substantiation requirement is a specific term of the injunction with a specific definition that put Defendants on fair notice of what was required to comply. *See Sec. & Exch. Comm'n v. Goble,* 682 F.3d 934, 952 (11th Cir. 2012).

16. Moreover, where the public interest is at stake, "a broad, but properly drafted injunction, which largely uses 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 to do." *Sec & Exch. Comm'n v. North Am. Clearing, Inc.*, 656 F. App'x 969, 972 (11th Cir. 2016) (citing *Goble*, 682 F.3d at 952).

17. However, the language of the injunction is neither statutory nor regulatory. To the extent that the Orders' definition of competent and reliable scientific evidence is also found in the FTC's Dietary Supplement Guide: An Advertising Guide for Industry, that document is, at most, an interpretative rule, 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).

18. Thus, the Court may enforce the Orders' substantiation requirement against Hi-Tech, Wheat, Smith, and Wright.

C. Defendants Have Violated The Hi-Tech And Wright Orders.

1. Hi-Tech, Wheat, And Smith's Unsubstantiated Advertising Claims Violated The Hi-Tech Order.

19. Section II of the Hi-Tech Order prohibits Hi-Tech, Wheat, and Smith 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. *See* FOF ¶ 75, *supra*.

20. Section VII of the Hi-Tech Order prohibits Hi-Tech, Wheat, and Smith from making "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." *See* FOF ¶ 77.

21. "When assessing the meaning and representations conveyed by an advertisement, the court must look to the advertisement's overall, net impression rather than the literal truth or falsity of the words in the advertisement." *Nat'l Urological Grp.*, 645 F. Supp. 2d at 1189 (citing *Fed.*

Trade Comm'n v. Peoples Credit First, LLC, 2005 WL 3468588, at *5-6 (M.D. Fla. Dec. 18, 2005)).

22. "If the advertisement explicitly states or clearly and conspicuously implies a claim, the court need not look to extrinsic evidence to ascertain whether the advertisement made the claim." *Nat'l Urological Grp.*, 645 F. Supp. 2d at 1189 (citing *In re Thompson Med. Co.*, 104 F.T.C. 648, ¶¶ 311-12 (1984) and *Fed. Trade Comm'n v. QT, Inc.*, 448 F. Supp. 2d 908, 958 (N.D. Ill. 2006)).

23. Contempt Defendants are obligated to substantiate all interpretations that reasonable consumers may take from 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).

24. Small print, non-proximate disclaimers are insufficient to overcome the net impression of an advertisement. *See, e.g.*, *Fed. Trade Comm'n v. Cyberspace.Com LLC*, 453 F.3d 1196, 1200-01 (9th Cir. 2006); *see also Fed. Trade Comm'n v. Lanier Law, LLC*, 194 F. Supp. 3d 1238, 1275 (M.D. Fla. 2016) (rejecting argument that disclaimers "buried in lengthy paperwork"

could cure more prominent misrepresentations); *Washington Data Res.*, 856 F. Supp. 2d at 1275 (holding that "inconspicuous" disclaimer "fail[ed] to sufficiently change the deceptive 'net impression'"); *Fed. Trade Comm'n v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 42-43 (D.C. Cir. 1985) (finding that "fine-print" disclosure placed in an "inconspicuous" location could not cure deceptive net impression).

25. Based on the Court's review of the advertisements, Hi-Tech, Wheat, and Smith have made express claims that Fastin, Lipodrene, and Stimerex-ES cause rapid or substantial loss of weight. *See* FOF ¶¶ 134-137, 176-181, 234-237.

26. Based on the Court's review of the advertisements, Hi-Tech, Wheat, and Smith have made express claims that Fastin, Lipodrene, Benzedrine, and Stimerex-ES cause rapid or substantial loss of fat. *See* FOF ¶¶ 138-145, 182-189, 214-223, 238-243.

27. Based on the Court's review of the advertisements, Hi-Tech, Wheat, and Smith have made express claims that Fastin, Lipodrene, Benzedrine, and Stimerex-ES affect body fat. *See* FOF ¶¶ 146-154, 190-197, 219-223, 244-251.

28. Based on the Court's review of the advertisements, Hi-Tech, Wheat, and Smith have made express claims that Fastin and Lipodrene affect human metabolism. *See* FOF ¶¶ 155-159, 198-203.

29. Based on the Court's review of the advertisements, Hi-Tech, Wheat, and Smith have made express claims that Fastin, Lipodrene, and Benzedrine affect appetite. *See* FOF ¶¶ 160-163, 204-208, 224-228.

30. Based on the Court's review of the Stimerex-ES print advertisement, Hi-Tech, Wheat, and Smith made an express claim that Stimerex-ES has comparable efficacy to supplements containing banned ephedrine alkaloids. *See* FOF ¶¶ 252-254.

31. As this Court has recognized, what constitutes competent and reliable scientific evidence "depend[s] on what pertinent professionals would require for the particular claim made." *See Nat'l Urological Grp.*, 645 F. Supp. 2d at 1186.

32. Based on the testimony of the FTC's expert, Dr. Louis J. Aronne, the FTC has established by clear and convincing evidence that for the products and claims at issue, competent and reliable scientific evidence consists of "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" to substantiate claims that a dietary supplement causes rapid or substantial weight or fat loss or affects human metabolism, appetite, or body fat. *See* FOF ¶¶ 255-466.

33. The FTC's Dietary Supplement Guide does not preclude the Court from finding that double-blind, placebo-controlled, product-specific trials are required to substantiate Contempt Defendants' advertising claims. *See, e.g.*, *Fed. Trade Comm'n v. Coorga Nutraceuticals Corp.*, 201 F. Supp. 3d 1300, 1311 (D. Wy. 2016) ("While . . . 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.").

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

35. Contempt Defendants' experts have provided no evidence that Contempt Defendants' unqualified claims that the products cause rapid or substantial fat or weight loss are substantiated. *See* FOF ¶¶ 467-664.

36. Contempt Defendants' experts have provided no evidence that Contempt Defendants' unqualified claims that the products affect body fat are substantiated. *See* FOF ¶¶ 467-664.

37. Contempt Defendants' experts have provided no evidence that Contempt Defendants' unqualified claims that the products cause an increase in metabolism are substantiated. FOF ¶ 467-664.

38. Contempt Defendants' experts have provided no evidence that Stimerex-ES has comparative efficacy to ephedrine-containing supplements. *See* FOF ¶¶ 467-664.

39. Accordingly, the FTC has proven by clear and convincing evidence, COL ¶¶ 3-6, that Hi-Tech, Wheat, and Smith have violated the Hi-Tech Order through their unsubstantiated advertising claims.

2. Hi-Tech, Wheat, And Smith's Omission Of The Court-Ordered Safety Warning Violated The Hi-Tech Order.

40. Section VI of the Hi-Tech Order requires Hi-Tech, Wheat, and Smith, on any product packaging or labels that make efficacy claims for yohimbine-containing products, to "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." *See* FOF ¶ 76.

41. Fastin, Lipodrene, Benzedrine, and Stimerex-ES all contain yohimbine. *See* FOF ¶ 865.

42. Each of the product packages and labels for Fastin, Lipodrene, Benzedrine, and Stimerex-ES make express efficacy claims. *See* FOF ¶ 866.

43. For the period January 1, 2009 through December 31, 2012, none of the product packaging or labels for Fastin, Lipodrene, Benzedrine, and Stimerex-ES contained the required warning. *See* FOF ¶ 868.

44. Thus, the FTC has proven to clear and convincing evidence that Hi-Tech, Wheat, and Smith violated Section VI of the Hi-Tech Order.

3. Wright's Unsubstantiated Fastin Endorsement Violated The Wright Order.

45. Section II of the Wright Order prohibits him from "making any representation, in any manner, expressly or by implication, including through the use of endorsements, that" a covered weight loss product "causes rapid or substantial loss of weight or fat" or that such product "affects human metabolism, appetite, or body fat," unless the representation is true and substantiated by competent and reliable scientific evidence. *See* FOF ¶ 123.

46. Based on the Court's review of the Fastin print advertisement, Wright's endorsement is an express representation that Fastin affects body fat. *See* FOF ¶ 147.

47. For the reasons discussed above, *see* COL ¶¶ 19-24, 31-39, the FTC has proven to clear and convincing evidence that Wright lacked competent and reliable scientific evidence to substantiate his endorsement.

48. Thus, the FTC has proven to clear and convincing evidence that Wright has violated Section II of the Wright Order.

4. Defendants Had The Ability To Comply With The Orders.

49. Defendants had the ability to comply with the Orders by refraining from selling their products or refraining from making claims without the appropriate level of substantiation. *See CFTC v. Wellington Precious Metals, Inc.*, 950 F.2d 1525, 1529 (11th Cir. 1992) (per curiam) (to prove inability to comply, contemnor must demonstrate that "he has made 'in good faith all reasonable efforts' to meet the terms of the court order he is seeking to avoid" (citations omitted)).

II. Contempt Defendants' Defenses Are Meritless.

50. The Eleventh Circuit has held that there is no "good faith" defense to contempt liability, stating: "[S]ubstantial, diligent, or good faith efforts are not enough; the only issue is compliance." *See Leshin I*, 618 F.3d at 1232-33 (collecting cases).

51. "As a general rule, laches or neglect of duty on the part of officers of the Government is no defense to a suit by it to enforce a public right or protect a public interest." *Nevada v. United States,* 463 U.S. 110, 141 (1983); *Immigration & Naturalization Servs. v. Hibi*, 414 U.S. 5, 8 (1973); *see also United States v. Duboc*, 694 F.3d 1223, 1228 (11th Cir. 2012) ("[T]he United

States is generally not subject to the defense of laches when it enforces its rights.").

52. Neither "feasibility" nor "reasonableness" are part of the definition of competent and reliable scientific evidence 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 competent and reliable scientific evidence is necessary. *See, e.g., POM Wonderful, LLC v Fed. Trade Comm'n*, 777 F.3d 478, 490-91 (D.C. Cir. 2015) (listing *Pfizer* factors); *ECM BioFilms, Inc. v. Fed. Trade Comm'n*, 851 F.3d 599, 613 (6th Cir. 2017) (finding that where determination has been made that competent and reliable scientific evidence is necessary to substantiate claim, application of *Pfizer* factors is moot).

53. "Statements made for the purpose of deceiving prospective purchasers cannot properly be characterized as mere puffing." *Nat'l Urological Grp.*, 645 F. Supp. 2d at 1206 (quoting *Fed. Trade Comm'n v. U.S. Sales Corp.*, 785 F. Supp. 737, 746 (N.D. Ill. 1992)). "Thus, the Eleventh Circuit has

concluded that when an advertiser places 'otherwise general assertions about the value [of a product] into a concrete factual setting,' the advertiser creates representations that are either true or false, not mere puffery." *Id.* (quoting *United States v. Simon*, 839 F.2d 1461, 1468 (11th Cir. 1988)).

54. In fact, in the weight-loss context, the case law makes clear that non-mathematical claims are often actionable statements of fact. For example, in *Federal Trade Commission v. Trudeau*, the Seventh Circuit found that claims that a weight-loss program was "easy" and the "easiest method known on planet earth" were actionable given their context. 662 F.3d 947, 950 (7th Cir. 2011).

III. Contempt Defendants' Expert Witnesses Are Neither Credible Nor Reliable.

55. "Where expert testimony is in conflict, the expert testimony is not binding on the trier of fact and may be given only such weight as circumstances warrant[.] [I]n addition, the trier of fact has the discretion to accept or disregard portions of the testimony." *Brabham v. Hendrickson*, 2007 WL 708882, at *4 (S.D. Fla. Mar. 8, 2007).

56. "Under Rule 702 and *Daubert*, district courts must act as 'gatekeepers' which admit expert testimony only if it is both reliable and relevant." *Rink v. Cheminova, Inc.*, 400 F.3d 1286, 1291 (11th Cir. 2005).

57. "[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 Medical Corp.*, 184 F.3d 1300, 1316-17 (11th Cir. 1999).

58. The Court's gatekeeping function "requires more than simply 'taking the expert's word for it.'" *United States v. Frazier,* 387 F.3d 1244, 1261 (11th Cir. 2004) (quoting Fed. R. Evid. 702 advisory committee note). As such, even where an expert is "admittedly qualified," reliability cannot "be established merely by the *ipse dixit*" of the expert. *Id.*

59. "[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. 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).

60. "If the [expert] 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." *Frazier,* 387 F.3d at 1261 (emphasis added).

61. "If an expert does not have an explanation behind or empirical support for his opinion, he offers merely a bare conclusion." *Bowers v. Norfolk S. Corp.*, 537 F. Supp. 2d 1343, 1373 (M.D. Ga. 2007), *aff'd*, 300 F. App'x 700 (11th Cir. 2008).

62. A trial court "may exclude expert testimony that is imprecise and unspecific, or whose factual basis is not adequately explained." *Cook ex rel. Estate of Tessier v. Sheriff of Monroe Cnty.*, 402 F. 3d 1092, 1111 (11th Cir. 2005) (internal quotation marks omitted).

63. Expert opinions that are "belied by the evidence . . . do nothing to assist the trier of fact in understanding the evidence or determining a fact in issue." *Ferguson v. Bombardier Servs. Corp.*, 244 F. App'x 944, 949 (11th Cir. 2007).

64. "[G]aps in an expert's qualifications or knowledge . . . generally go to the weight of the witness's testimony . . . ." *Trilink Saw Chain, LLC v. Blount, Inc.*, 583 F. Supp. 2d 1293, 1304 (N.D. Ga. 2008) (Pannell, J.) (quoting *Leathers v. Pfizer, Inc.*, 233 F.R.D. 687, 692 (N.D. Ga. 2006)).

65. "As a general principle, testifying experts may not offer legal conclusions." *R.W. v. Bd. of Regents of the Univ. Sys. of Georgia*, 114 F. Supp. 3d 1260, 1274-75 (N.D. Ga. 2015).

66. "In order to be reliable, . . . expert testimony relating to survey research must be supported by knowledge grounded in the methods and procedures of science." *Nightlight Sys., Inc. v. Nitelites Franchise Sys., Inc.*, 2007 WL 456873, at *5 (N.D. Ga. July 17, 2007).

67. In particular, a survey that "fails to adequately replicate marketplace conditions, is entitled to little weight, if any." *Smith v. Wal-Mart Stores, Inc.*, 537 F. Supp. 2d 1302, 1323 (N.D. Ga. 2008); *see also Native Am. Arts, Inc. v. Bud K World Wide, Inc.*, 2012 WL 1833877, at *6 (M.D. Ga. May 18, 2012) ("In order to be considered reliable, a survey must resemble the way consumers would view the products in the marketplace.").

IV. Compensatory Sanctions In The Amount Of Gross Revenues Less Refunds And Returns Are Warranted.

68. Compensatory sanctions are an appropriate remedy for Contempt Defendants' contumacious conduct. *See United States v. United Mine Workers,* 330 U.S. 258, 303-04 (1947) ("Judicial sanctions in civil contempt proceedings may . . . be employed for either or both of two purposes: to coerce the defendant into compliance with the court's order, and to compensate the complainant for losses sustained."); *Nat'l Union Fire Ins. Co. of Pittsburgh, Pa. v. Olympia Holding Corp.*, 140 F. App'x 860, 863 (11th Cir. 2005) ("To achieve compliance, courts can impose both coercive and compensatory sanctions.").

69. Compensatory sanctions must be "based upon evidence of complainant's actual loss." *United Mine Workers*, 330 U.S. at 304.

70. The measure of compensatory sanctions must only be proven by a preponderance of the evidence. *See McGregor v. Chierico*, 206 F.3d 1378, 1387 (11th Cir. 2000).

71. Good faith is irrelevant to the determination of compensatory sanctions. *See McComb v. Jacksonville Paper Co.*, 336 U.S. 187, 191 (1949). ("Since the

purpose is remedial, it matters not with what intent the defendant did the prohibited act.").

72. Ability to pay is irrelevant to the determination of the amount of the compensatory sanction. *Fed. Trade Comm'n v. Leshin*, 719 F.3d 1227, 1234 (11th Cir. 2013) ("*Leshin II*") ("For a compensatory contempt sanction . . . inability to pay is no defense.").

A. Gross Revenues Less Refunds And Returns Is The Appropriate Compensatory Baseline.

73. Proof of individual consumer injury is unnecessary because "[i]t 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." *McGregor*, 206 F.3d at 1388 (citations omitted); *see also Fed. Trade Comm'n v. Kuykendall*, 371 F.3d 745, 765 (10th Cir. 2004) (en banc) ("To the extent the large number of consumers affected by the defendants' deceptive trade practices creates a risk of uncertainty, the defendants must bear that risk.").

74. Instead, once the FTC "[1] has proved that the defendant made material misrepresentations, [2] that they were widely disseminated, and [3] that consumers purchased the defendant's product," each consumer is presumed to have relied on the misrepresentation. *McGregor,* 206 F.3d

1188 (citing *Fed. Trade Comm'n v. Figgie, Int'l, Inc.*, 994 F.2d 595, 605-06 (9th Cir. 1993) and *Fed. Trade Comm'n v. Sec. Rare Coin & Bullion Corp.*, 931 F.2d 1312, 1316 (8th Cir. 1991)); *see also Leshin I*, 618 F.3d at 1237 (awarding gross revenues as compensatory contempt sanction and rejecting profits as an alternative measure of sanctions); *Fed. Trade Comm'n v. BlueHippo Funding, LLC*, 762 F.3d 238, 244 (2d Cir. 2014); *Trudeau*, 662 F.3d at 950; *Kuykendall*, 371 F.3d at 765.

75. The presumption of consumer reliance applies not only to misrepresentations, but also to omissions. *See, e.g.*, *BlueHippo Funding*, 762 F.3d at 244 (holding, in a contempt case, that "the FTC is entitled to a presumption of consumer reliance upon showing," *inter alia*, that "the defendant made material misrepresentations or omissions"); *Sec. Rare Coin*, 931 F.2d at 1316 ("[T]he FTC need merely show that the misrepresentations or omissions were of a kind usually relied upon by reasonable and prudent persons.").

76. Here, Contempt Defendants' violations of Sections II, VI, and VII of the Hi-Tech Order, and Section II of the Wright Order, were material and

widespread, and consumers purchased the Hi-Tech Products. Therefore, the presumption applies.

77. Express claims are presumptively material. *See Nat'l Urological Grp.*, 645 F. Supp. 2d at 1190.

78. In addition, claims that "significantly involve health, safety, or other issues that would concern reasonable consumers" are also presumptively material. *Nat'l Urological Grp.*, 645 F. Supp. 2d at 1190; *see id.* at 1191 (explaining that it is "hard to imagine that any reasonable customer would find claims regarding how a product affects his or her health or safety immaterial").

79. More specifically, "when a customer makes a decision to purchase a health product that he or she will ingest for purported health benefits, any claim on the label regarding the health benefits (i.e., any product efficacy claims) or any claims regarding the safety of the product can be presumed material." *Nat'l Urological Grp.*, 645 F. Supp. 2d at 1191.

80. The claims that violate Sections II, VI, and VII of the Hi-Tech Order and Section II of the Wright Order are both express and involve health or safety, and are, thus, material.

81. All of the violative print advertisements, webpages, product, packaging, and labels were widely disseminated. *See* FOF ¶¶ 128-133, 171-175, 209-213, 229-233.

82. Consumers actually purchased Defendants' products. *See* FOF ¶¶ 920.

83. Accordingly, the presumption of consumer reliance applies.

84. Where the presumption applies, gross revenues, less refunds and returns, is the appropriate baseline for compensatory sanctions. *See McGregor*, 206 F.3d at 1387-89; *Leshin I*, 618 F.3d at 1239; *see also Kuykendall*, 371 F.3d at 765 (citing *McGregor*, 206 F.3d at 1387-88).

85. An award of gross revenues, less refunds and returns, is compensatory, and remedial, because it "attempts to restore the status quo" by placing consumers in the position they would have been but for the defendants' order violations. *See Leshin I*, 618 F.3d at 1239; *see also Trudeau*, 662 F.3d at 950 (award of gross revenues appropriate because it "might come close to putting [the contempt] victims in the same position they would have been" but for the contemnor's "flagrant[] and repeated[]" order violations); *cf. Nat'l Urological Grp.*, 645 F. Supp. 2d at 1212-13 (award of gross revenues

less refunds and returns appropriate remedy "to restore victims to their position prior to the deceptive sales").

86. Because Contempt Defendants "join[ed] together" to evade the orders against them, they are "jointly and severally liable for the amount of damages resulting from the contumacious conduct." *Leshin I*, 618 F.3d at 1236-37.

B. The Parties Have Stipulated To Contempt Defendants' Gross Revenues For The Periods In Which The Order Violations Have Occurred.

87. Between January 1, 2009, and August 31, 2013, Contempt Defendants' gross revenues from the sale of Fastin, Lipodrene, Benzedrine and Stimerex-ES, less refunds and returns, are $40,120,950. *See*, FOF ¶ 920.

88. For the period Hi-Tech disseminated the Fastin print ad containing Wright's endorsement, Contempt Defendants' gross revenues from the sale of Fastin, less refunds and returns, are $21,493,557.64**.** *See* FOF ¶ 932.

89. Between January 1, 2009 and December 21, 2012, Contempt Defendants' gross revenues from the sale of Fastin, Lipodrene, Benzedrine and Stimerex-ES – less customer remittance deductions – totaled $34,441,227. *See* FOF ¶ 986.

C. Contempt Defendants Have Failed To Rebut The FTC's Compensatory Sanction Calculations.

90. Once the presumption of reliance applies and the compensatory baseline is set, the burden shifts to the defendants to demonstrate that the baseline consumer loss should be offset. *See Kuykendall*, 371 F.3d at 766; *BlueHippo Funding*, 762 F.3d at 246.

91. However, evidence sufficient to rebut the presumption is not unbounded. Specifically, Contempt Defendants are only permitted to demonstrate "that ***individual*** transactions were atypical and resulted in a lower-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).

92. Critically, the presumption of consumer reliance is not that all consumers in the aggregate relied on the misrepresentation, but rather that each individual consumer relied on the misrepresentation and was injured as a result. *See McGregor*, 206 F.3d at 1388 ("[T]he seller's misrepresentations tainted ***the customer's*** purchasing decisions." (emphasis added)); *see also BlueHippo Funding*, 762 F.3d at 245 ("[W]hen an injury by misrepresentation or omission precedes a purchase, the full amount paid

by the ***injured consumer*** must serve as the baseline for calculating damages . . . ." (emphasis added))).

93. To the extent that evidence shows that an individual consumer did not rely on the misrepresentation or omission to his or her detriment, the presumption is rebutted, but only as to that individual consumer, not to the thousands of others who were subject to the same misrepresentation and presumed to rely on it. *See, e.g., Fed. Trade Comm'n v. Amy Travel Serv., Inc.*, 875 F.2d 564, 572 (7th Cir. 1989) (holding that existence of some uninjured consumers allows offset for only those consumers); *Fed. Trade Comm'n v. Rensin*, --- F. App'x ---, 2017 WL 1363866, at *2 (2d Cir. Apr. 12, 2017) (summary order) (in case involving omission, rejecting speculative offset and finding that defendant must actually trace funding to uninjured consumers to establish offset).

94. Accordingly, even in instances where courts have permitted defendants to adduce evidence that individual consumers did not rely on the misrepresentations to their detriment, they have not shifted the burden of proving each injured consumer's individual reliance back to the FTC. Rather, they have uniformly treated that evidence as individual offsets to

gross revenues. *See, e.g.*, *Kuykendall*, 371 F.3d at 766-67 ("The defendants may then put forth evidence showing offset is required because certain consumers . . . were satisfied with their purchases.") (emphasis added); *Amy Travel Serv.*, 875 F.2d 564, 572 (7th Cir. 1997) ("Contrary to defendants' claims, the FTC need not provide that every consumer was injured. The existence of some satisfied consumers does not constitute a defense under the FTCA. The magistrate correctly acknowledged the existence of satisfied customers in computing the amount of defendants' liability. . . .") (emphasis added); *Fed. Trade Comm'n v. Bronson Partners, LLC*, 674 F. Supp. 2d 373, 386 (D. Conn. 2009) (noting that, where presumption of reliance applies, evidence that "repeat customers did not rely on the deceptive advertising" would entitle defendants to an "offset against the restitutionary baseline" for sales made to those customers) (emphasis added), *aff'd*, 654 F.3d 359 (2d Cir. 2011).

1. Contempt Defendants' Profits Calculation Does Not Rebut The FTC's Sanctions Calculation For Defendants' Failure To Substantiate Their Unqualified, Causal Efficacy Claims.

95. An award of Contempt Defendants' profits is not compensatory because it "would be the equivalent of making the consumer bear the defendants'

expenses." *Nat'l Urological Grp.*, 645 F. Supp. 2d at 1213; *see also Bronson Partners,* 654 F.3d at 374-75 (noting that defendants in a disgorgement action are "not entitled to deduct costs associated with committing their illegal acts") (citations omitted).

96. Therefore, Contempt Defendants have not presented evidence that rebuts the FTC's sanctions calculation for Hi-Tech, Wheat, and Smith's violations of Sections II and VII of the Hi-Tech Order, and for Wright's violation of Section II of the Wright Order.

2. Contempt Defendants' Have Failed To Rebut The FTC's Sanctions Calculation For Contempt Defendants' Failure To Include The Yohimbine Health-Risk Warning On Their Product Packaging And Labels.

97. Contempt Defendants do not even suggest that they have any evidence about specific Hi-Tech consumers who did not rely upon Contempt Defendants' misrepresentations or omissions. Instead, they put forward expert witness testimony that, even if it were reliable, relates solely to consumers in general or to the U.S. population as a whole, rather than to any actual Hi-Tech consumers. FOF ¶¶ 987-988.

98. In addition, Goldhaber's unsupported testimony is unreliable and not credible and, thus, provides no basis for reducing the compensatory baseline. *See* FOF ¶¶ 993-1015; *see also* COL ¶¶ 55-65.

99. Gilbert's survey is unreliable and not credible and, thus, provides no basis for reducing the compensatory baseline. *See* FOF ¶¶ 1018-1040; COL ¶¶ 66-67.

100. Thus, Contempt Defendants are unable, as a matter of law, to rebut the presumption that each individual consumer of their products relied on their misrepresentations and omissions, and the FTC is entitled to an award of gross revenues, less refunds and returns. *See McGregor*, 206 F.3d at 1388; *Kuykendall*, 371 F.3d at 765; *Bronson Partners*, 654 F.3d at 369.

V. Conclusion

101. To compensate consumers for their violations of Sections II and VII of the Hi-Tech Order, Hi-Tech, Wheat, and Smith are ordered to pay compensatory sanctions, jointly and severally, in the amount of $40,120,950.

102. Through their violations of Section VI of the Hi-Tech Order, Hi-Tech, Wheat, and Smith have caused consumer injury in the amount of

$34,441,227. This amount is the amount that would be necessary to compensate consumers solely for Contempt Defendants' violations of Section VI and is a subset of, and not in addition to, the $40,120,950 sanctions resulting from Contempt Defendants' violations of Section II and VII of the Hi-Tech Order.

103. To compensate consumers for his violations of Section II of the Wright Order, Wright is ordered to pay compensatory sanctions, jointly and severally with Hi-Tech, Wheat, and Smith, in the amount of $21,493,557.64.

CERTIFICATE OF COMPLIANCE WITH L.R. 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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