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1 2 3 4 5 6 7 8 9	JONATHAN E. NUECHTERLEIN GENERAL COUNSEL LAURA FREMONT, Calif. Bar No. 159670 KENNETH H. ABBE, Calif. Bar No. 172416 JACOB A. SNOW, Calif. Bar No. 270988 AUSTIN A.B. OWNBEY, Calif. Bar No. 27219 Federal Trade Commission 901 Market Street, Suite 570 San Francisco, CA 94103 415-848-5100 (voice); 415-848-5184 (fax) Ifremont@ftc.gov, kabbe@ftc.gov, jsnow@ftc.gov Attorneys for Plaintiff Federal Trade Commission	ov, aownbey@ftc	
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12 13 14 15 16 17 18 19 20 21 22 23	FEDERAL TRADE COMMISSION, Plaintiff, v. WELLNESS SUPPORT NETWORK, INC., a corporation, ROBERT HELD, individually and as an officer of Wellness Support Network, Inc., and ROBYN HELD, individually and as an officer of Wellness Support Network, Inc., Defendants.	Case No. 3:10-c FEDERAL TR MOTION FOR JUDGMENT Hearing Date: Hearing Time: Location:	ADE COMMISSION'S R SUMMARY February 14, 2014
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NOTICE OF MOTION FOR SUMMARY JUDGMENT

On February 14, 2014, at 9:30 a.m., pursuant to Federal Rule of Civil Procedure 56, the Federal Trade Commission ("FTC") will move this Court for summary judgment against Defendants Wellness Support Network, Inc., Robert Held, and Robyn Held for violations of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a), 52.

The FTC respectfully requests this Court to grant summary judgment against all Defendants as to all issues in this case. As explained below, the FTC has established sufficient material facts, about which there is no genuine dispute, to support a finding that Defendants are liable as a matter of law. Judgment as to each Defendant should include a permanent injunction to prevent future violations of the law, and an award of monetary relief for injured consumers.

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MEMORANDUM OF POINTS AND AUTHORITIES 1 2 Q: What did you read on our website that caused you to decide on getting the Diabetic Pack? 3 You claimed that it worked. A: 4 — Defendants' customer survey¹ "I would tell [my patients]: do the diet thing; do the 5 exercise thing; do the sleep thing; save your money and don't 6 buy the Diabetic Pack." — W. Timothy Garvey, M.D.² 7 8 I. INTRODUCTION Diabetes afflicts millions of Americans and can cause serious disability and death. 9 Wellness Support Network, Inc. capitalized on this public-health problem by marketing 10 11 unproven remedies for diabetes and insulin resistance, a diabetes-related condition. The company persuaded thousands of consumers to purchase its "breakthrough" products by 12 promising lower blood sugar and "life changing results"; by publishing dramatic customer 13 "success" stories; and by suggesting the products were "validated" by the Nobel Prize. Among 14 15 other things, Wellness Support Network's ads claimed that their products prevent or treat diabetes, that customers could reduce or throw away their diabetes medications, and that 16 scientific studies proved these claims. Yet there is no proof that the company's products work. 17 The Federal Trade Commission ("FTC") brought this case against Wellness Support 18 19 Network and its owners, Robert and Robyn Held (collectively, "WSN" or "Defendants") to stop 20 their deceptive advertising, prevent future deception, and obtain redress for injured consumers. 21 22 Declaration of FTC Investigator Kelly Ortiz ("Ortiz Dec."), Exhibit 8 ("Ortiz Ex. 8" or "Ex. 8") 23 ("WSN Diabetes Pack Purchaser Survey"); see also Ortiz Ex. 6 at 119:3-7, 18-21; 121:5-8, 22-25; 123:13-124:16 (Deposition of Deborah Gilleard ("Gilleard Dep.")). 24 ² Ortiz Ex. 11 at 239:1-4 (Deposition of Dr. W. Timothy Garvey ("Garvey Dep.")). Dr. Garvey

28 ("Garvey Report")).

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² Ortiz Ex. 11 at 239:1-4 (Deposition of Dr. W. Timothy Garvey ("Garvey Dep.")). Dr. Garvey is Butterworth Professor and Chair of the Department of Nutrition Sciences at the University of Alabama at Birmingham, and director of the NIH-funded UAB Diabetes Research and Training Center. Since 2003 he has also served as Staff Physician and Geriatric Research, Education, and Clinical Center Investigator at the Birmingham Veterans Affairs Medical Center. Declaration of W. Timothy Garvey, M.D. ("Garvey Dec."), Ex. A at 1-2 (Expert Report of W. Timothy Garvey

To prove that WSN's ads are deceptive under the FTC Act, the FTC must show: (1) there is a representation, omission, or practice; (2) that is likely to mislead consumers acting reasonably under the circumstances; and (3) the representation, omission, or practice was material.³ Expert testimony, Defendants' admissions, and corporate records make clear that there is no genuine dispute as to any of these elements, the individual defendants' personal liability, the amount of consumer injury, or any other material fact. Summary judgment is therefore appropriate.

II. FACTUAL BACKGROUND

A. The Defendants

Defendant Wellness Support Network, Inc., is a California corporation co-owned by individual defendants Robert and Robyn Held.⁴ The Helds exercise complete control over Wellness Support Network, and have actively participated in the conduct at issue in this case.⁵

B. Background On Diabetes And Insulin Resistance

Diabetes mellitus is a group of disorders that affect 25 million adults in the United States.⁶ The disorders are characterized by abnormal glucose metabolism, in particular "hyperglycemia," which refers to high levels of glucose (or sugar) in the blood.⁷ Insulin is a hormone, produced in the pancreas, that helps to unlock the body's cells so that glucose in the blood can be absorbed by the cells and used for energy.⁸ When the pancreas does not produce enough insulin, or if the cells do not respond normally to the insulin that is produced (known as "insulin resistance"), glucose builds up in the blood.⁹ Over time, high levels of blood glucose

³ FTC v. Pantron I Corp., 33 F.3d 1088, 1095 (9th Cir. 1994); FTC v. Stefanchik, 559 F.3d 924, 928 (9th Cir. 2009).

⁴ Joint Statement of Undisputed Material Facts (Dkt. #162) ("SOF") 2, 4, 9; Ortiz Ex. 12 at 15 ("Defendants' Response to Plaintiff's First Set of Requests for Production of Documents and Tangible Things" ("1st RFP Resp."), #27)); Ortiz Ex. 13 (e-mail) (referenced in Ortiz Ex. 12 at 15 (1st RFP Resp. #27).

⁵ See Sec IV.C., *infra*.

⁶ Garvey Report at 9.

⁷ Garvey Report at 9.

⁸ Garvey Report at 9.

⁹ Garvey Report at 9. For a description of insulin resistance, see Garvey Report at 9-11.

can cause serious complications, including heart disease, stroke, blindness, kidney disease, and loss of limbs.¹⁰ It is therefore critical for diabetics and prediabetics to keep their blood sugar in a range that will minimize damage to the body.¹¹

C. WSN's Products

WSN has sold the Diabetic Pack ("DP") and the Insulin Resistance Pack ("IRP") (collectively, the "Products") since 2004. DP and IRP are the same product under different names, containing the exact same ingredients. WSN advertised the Products as containing vitamins, minerals, and botanical extracts, formulated into three components: the Glucose Support Formula (capsules), the Vitamin-Mineral Formula (tablets), and the Calcium-Magnesium Formula (tablets). The company advertised and sold the Products until at least 2011. Although WSN stopped marketing the products as the "Diabetic Pack" and "Insulin Resistance Pack" in 2011, they continue to sell similar products, and to make claims similar to those made for DP. 16

WSN sold the Products on the WSN website, Amazon.com, eBay.com, and over the phone. A 30-day supply averaged \$62.65. After subtracting money returned to customers,

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¹⁰ Garvey Report at 9.

¹¹ Garvey Report at 17. Blood sugar levels in healthy adults are generally less than 100 milligrams per deciliter (mg/dl), while a blood sugar level between 100 mg/dl and 125 mg/dl indicates prediabetes, and over 125 mg/dl indicates diabetes. Garvey Report at 13.

¹² SOF 24, 60; see also SOF 95-98 (Diabetic Pack instructions for use).

¹³ SOF 93, 95.

¹⁴ Ortiz Ex. 1 at 25:14-26:12 (Deposition of Robert "Bob" Held ("B. Held Dep.")).

¹⁵ Ortiz Ex. 1 at 25:14-26:4 (B. Held Dep.). The company rebranded its products and sells the components under new names. SOF 25, 26, 56, 79. The Glucose Support Formula ("GSF") component retains that name, while the Calcium-Magnesium Formula and Vitamin and Mineral Formula have been combined into the "Life Support Formula" ("LSF"). SOF 56, 79. GSF and LSF are sold separately. SOF 56. Although WSN no longer advertises a "Diabetic Pack," it still sells the three components of the product to customers who ask for it. SOF 67; Ortiz Ex. 4 at 40:5-20 (Deposition of Robyn Held ("R. Held Dep.")).

¹⁶ Second Declaration of David Gonzalez ("2d Gonzalez Dec."), Ex. 2.

¹⁷ SOF 71; Ortiz Ex. 4 at 32:17-33:9 (R. Held Dep.); Ortiz Ex. 1 at 28:8-12 (B. Held Dep.).

¹⁸ Declaration of David Gonzalez ("Gonzalez Dec."), Ex. A at 4.

WSN's sales revenue for the Products between 2004 and 2012 totaled \$2,198,612.12.¹⁹ 1 D. WSN's Advertising 2 WSN advertised its Products primarily through online "pay-per-click" ("PPC") 3 campaigns, ²⁰ in which WSN's ads were displayed when consumers performed certain searches 4 on the Internet.²¹ Defendants chose "keywords" they thought consumers might use as search 5 terms, including such phrases as "cure diabetes," "natural diabetes cure," and "diabetes 6 treatment."22 Two of WSN's most lucrative PPC ads read as follows: 7 8 Can't Lower Your Blood Sugar? Clinically Proven Drug Free 9 Solution That Lowers Blood Sugar 10 Control Blood Sugar Level 11 Clinically Proven Natural Solution To Diabetes With A 90% Success Rate²³ 12 Consumers clicking on WSN's PPC ads would land on WSN's website, 24 which 13 contained numerous pages advertising the Products.²⁵ The design and content of these webpages 14 15 16 ¹⁹ Gonzalez Dec. Ex. A at 4. See also Gonzalez Dec. at 2-3. 17 ²⁰ SOF 102-103. ²¹ Ortiz Ex. 4 at 105:23-106:12 (R. Held Dep.); Ortiz Ex. 15 at 4 ("Defendants' Response to 18 Plaintiff's First Set of Interrogatories" ("1st Rog Resp."), #1). 19 ²² Ortiz Ex. 4 at 107:25-108:11, 127:1-128:23 (R. Held Dep.). 20 ²³ Ortiz Ex. 9 ("RealFoodNutrients Diabetes campaign setup"); Ortiz Ex. 6 at 134:7-18 (Gilleard Dep.); see also SOF 106; Ortiz Ex. 10 at 60:17-61:13, 128:9-23 (Deposition of Ted Huffman 21 ("Huffman Dep.")); Ortiz Ex. 10-A (e-mail); Ortiz Ex. 10-B (Declaration of Craig Kauffman Re Internet Search Term Research) (substantially similar representations). 22 ²⁴ Ortiz Ex. 15 at 4-6 (1st Rog Resp., #1-3); Ortiz Ex. 4 at 107:2-8, 111:4-14, 129:16-130:3 (R. 23 Held Dep.). 24 ²⁵ Printouts of some of Defendants' webpages appear as Exhibits 17 to 48 to the Ortiz Declaration. The HTML files from which the printouts were made were provided by the 25 Defendants during discovery, and are lodged as Ortiz Ex. 49 (see also Ortiz Dec. ¶ 33). See Ortiz Dec. ¶ 22-32, Ortiz Ex. 16 at 4-5 ("Defendants' Third Supplemental Response to 26 Plaintiff's First Set of Requests for Production of Documents and Tangible Things" ("3rd Supp. 27 RFP Resp.") #1, #5). Website ads preserved by the FTC are also provided as Exhibits 1 and 2 to the Second Gonzalez Declaration. Website ads also appear as Exhibits A-C (Dkt. 27-1 to 27-5) 28 to the First Amended Complaint ("FAC") (Dkt. 27). These exhibits were authenticated by

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were strikingly consistent over the years. Three key themes were lower blood sugar levels,
reduced dependency on medication, and scientific proof of these benefits. For example,
webpages for DP included a picture of the product next to a large headline announcing a
"Diabetes Breakthrough." Stating that the product is "specifically formulated for the dietary
management of diabetes," the website promised to "lower [] blood sugar, safely and effectively
with absolutely NO SIDE EFFECTS!! GUARANTEED!!" ²⁷ Checklists of "breakthrough
benefits" included "lower blood glucose levels" and "less dependency on medications." The
website also contained testimonials, including this one from customer "Barbara Culver":

This is the first time that I have ever ordered a product that really did what it said it would do! I was taking 50 units of insulin plus pills twice a day and my blood sugar just kept going up. I was tired all of the time and I could fall asleep as soon as I sat down. I also kept gaining weight. Since I've been using the Diabetic Pack I have lost 9 pounds, I have all kinds of energy and my sugar is down in the low 100s. Also I don't take insulin any more!²⁹

Another prominently-featured testimonial stated, "[m]y blood sugar went from 230 to 117 in just 21 days." Among numerous other testimonials³¹ was one from "Jeff Rice," who ignored his doctors' advice and "threw all the medicines out the window":

It has been a transformation of my sugar's running in the 300 to 250 range to 120 and lower...The first doctor put me on Glucotrol 10 mg. The second doctor put me on Glucophage 2000 mg along with the

Defendants. See Ortiz Ex. 14 at 4 ("Defendants' Response to Plaintiff's First Set of Requests for Admissions" ("1st RFA Resp.") #1-3).

- ²⁶ FAC Ex. A at Dkt. 27-1, p. 2 (2009 website); Ortiz Exs. 42-46 at 1 (2007-2010 websites).
- ²⁷ FAC Ex. A at Dkt. 27-1, p. 2 (2009 website); Ortiz Ex. 42 at 1 (2007), Ex. 43 at 1 (2008), Ex. 45 at 1 (2010).
- ²⁸ FAC Ex. A at Dkt. 27-1, p. 3 (2009 website); Ortiz Ex. 42 at 1-2 (2007), Ex. 43 at 1-2 (2008), Ex. 44 at 2 (2009), Ex. 45 at 2 (2010).
- ²⁹ FAC Ex. A at Dkt 27-2, p. 1 (2009 website); FAC Ex. B at Dkt. 27-3, p. 5 to Dkt 27-4, p.1 (2010 website); Ortiz Ex. 43 at 2-3 (2008 website) (substantially similar). *See also* Ortiz Ex. 42 at 2-3 (2007 website); Ex. 44 at 2-3 (2009); Ex. 45 at 2-3 (2010); Ex. 46 at 2-3 (2010) (substantially similar).
- ³⁰ FAC Ex. A at Dkt. 27-1, p. 2. (2009 website); Ortiz Exs. 42-46 at 1 (2007-2010 websites).
- ³¹ Ortiz Ex. 47 (2009 website), Ex. 48 (2010).

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Glucotrol. Also Neurontin 300 mg, Tricor 160 mg, Lipitor 200 mg, Diovan 80 mg and Avandia. I was taking all this and on the second visit he walked in the room, never looked at my sugar readings, and said you need insulin... I started searching and found your site on the Internet...Now, with all those pills, you can imagine what was happening to my body, I was being poisoned. I threw all the medicines out the window and went a month with no medicine and just the Diabetic Pack supplements. I leveled off in the 120 range....³²

The website contained repeated references to science, including the headline, "Nobel Prize Validates Amazing Technology," followed by references to the "Foodform" process underlying DP.³³ The website claimed that the "superiority of Foodform technology" had been confirmed by "Nobel Prize winning science and over 60 independent American university studies,"34 and referred to studies that purportedly showed a 31.9% drop in blood sugar levels.35

WSN's webpage for IRP closely resembled those for DP. The webpage consistently heralded an "Insulin Resistance Breakthrough" in large, bold type. 36 The list of "breakthrough" benefits" included "Reduced Insulin Resistance," "Improved Utilization of Glucose," and "Helps Prevent Diabetes."³⁷ The website promised "reverse Insulin Resistance, safely and effectively

³² Ortiz Ex. 47 at 1-2, Ex. 48 at 1-2.

³³ FAC Ex. A at Dkt. 27-1, p.3 (2009 website); Ortiz Ex. 42 at 2 (2007 website); Ex. 44 at 2 (2009); Ex. 45 at 2, (2010); see also FAC Ex. B at Dkt. 27-3, p. 4 (2010 website) ("Nobel Prize Winning Technology Validates WSN Diabetic Pack Ingredients!"); FAC Ex. A at Dkt. 27-1, p. 2 (2009 website); Ortiz Exs. 42-45 at 1 (2007-2010 websites); Ex. 46 at 2 (2010).

³⁴ FAC Ex. A at Dkt. 27-1, p. 3 (2009 website); Ortiz Exs. 42-45 at 2 (2007-2010 websites); see also FAC Ex. B at Dkt. 27-3, p. 5 (2010 website); Ortiz Ex. 46 at 2 (2010 website) (citing Nobel Prize support for the superiority of Foodform *nutrients*).

³⁵ FAC Ex. A at Dkt. 27-1, pp. 2, 3 (2009 website); Ortiz Exs. 24-27 at 3-4 (2007-2010 websites); Ex. 28 at 4 (2011); Ex. 29 at 3-4 (2012).

³⁶ FAC Ex. C at Dkt. 27-5, p. 3 (2010 website); Ortiz Exs. 19-23 at 1 (2007-2011 websites); Ex. 28 at 1 (2011); Ex. 30 at 1 (2007); Ex. 32 at 1 (2009); Ex. 33 at 1 (2010); Exs. 35-41 at 1 (2007-2011).

³⁷ FAC Ex. C, Dkt. 27-5, p. 3 (2010 website); Ortiz Ex. 17 at 1 (2008 website), Ex. 18 at 1 (2011), Ex. 19 at 1 (2007), Ex. 20 at1 (2008) Ex. 21 at 1 (2009), Ex. 23 at 1 (2011), Exs. 30-32 at 1 (2007-2009), Ex. 34 at 1 (2011), Ex. 35 at 1 (2007); see also Ortiz Ex. 22 at 1 (2010 website), Ex. 33 at 1 (2010), Ex. 38 at 1 (2010) ("health benefits" rather than "breakthrough benefits").

with absolutely no side effects,"³⁸ and referred to IRP as "specifically formulated for the dietary management of insulin resistance."³⁹ The superiority of Foodform was touted via references to the Nobel Prize and "60 independent American university studies."⁴⁰ The IRP ads also cited the study that purportedly showed a 31.9% drop in blood sugar levels.⁴¹ Lastly, some webpages promised that "a new breakthrough can protect you from becoming diabetic."⁴²

III. LEGAL STANDARDS

A. Summary Judgment Standard

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." A party moving for summary judgment must show the absence of a genuine dispute as to any material fact with respect to an essential element of the non-moving party's claim, or to a defense on which the non-moving party will bear the burden of persuasion at trial. The burden then shifts to the opposing party to designate "specific facts showing there is a genuine issue for trial."

B. Deceptive Advertising Under The FTC Act

Section 5(a) of the FTC Act prohibits unfair or deceptive acts and practices in or

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³⁸ FAC Ex. C, Dkt. 27-5, p. 3 (2010 website); Ortiz Exs. 17-23 at 1 (2008-2011 websites); Ortiz Exs. 30-41 at 1 (2007-2011 websites).

³⁹ FAC Ex. C; Dkt. 27-5, p. 3 (2010 website); Ortiz Exs. 19-22 at 1 (2007-2010 websites); Ex. 30 at 1 (2007); Ex. 32 at 1 (2009), Ex. 33 at 1 (2010); Ex. 35 at 1 (2007); Ex. 38 at 1 (2010); Ex. 40 at 1 (2008); Ex. 41 at 1 (2011); *see also* FAC Ex. C, Dkt. 27-6, p. 3 (2010 website); Ortiz Ex. 40 at 4 (2008 website); Ex. 41 at 4 (2011) (similar statements).

⁴⁰ FAC Ex. C, Dkt. 27-5, p. 4 (2010 website); Ortiz Ex. 17 at 2 (2008 website); Ex. 18 at 2 (2011); Ex. 19 at 2-3 (2007); Ex. 20 at 2 (2008); Ex. 21 at 2 (2009); Ex. 23 at 1 (2011); Ex. 30 at 1-2 (2007); Ex. 31 at 2 (2008); Ex. 32 at 2 (2009); Ex. 34 at 2 (2011); Ex. 35 at 2-3 (2007).

⁴¹ FAC Ex. C, Dkt. 27-5, p. 4 (2010 website); Ortiz Ex. 17 at 2 (2008 website); Ex. 18 at 2 (2011); Ex. 19 at 2 (2007); Ex. 20 at 2 (2008); Ex. 21 at 2 (2009); Ex. 23 at 2 (2011); Ex. 28 at 4 (2011); Exs. 30-32 at 2 (2007-2009); Ex. 34 at 2 (2011); Ex. 35 at 2 (2007).

⁴² Ortiz Ex. 17 at 1 (2008 website); Ex. 18 at 1 (2011); Ex. 31 at 1 (2008); Ex. 34 at 1 (2011).

⁴³ FED. R. CIV. P. 56(a).

⁴⁴ Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986).

⁴⁵ *Id.* at 324.

affecting commerce,⁴⁶ while Section 12 prohibits false advertisements for any food, drug, device, or cosmetic.⁴⁷ To prove that WSN's ads are deceptive under Sections 5(a) and 12, the FTC must show that: (1) there is a representation, omission, or practice; (2) that is likely to mislead consumers acting reasonably under the circumstances; and (3) the representation, omission, or practice was material.⁴⁸ In this case, the FTC must satisfy these elements with respect to the nine claims set forth in the First Amended Complaint (the "challenged claims").⁴⁹

1. Determining Whether The Claims Were Made

The FTC's first step in proving deception is establishing that WSN's ads made the challenged claims. The Court can ascertain the meaning of WSN's ads by examining the ads themselves.⁵⁰ Both express and implied claims may violate the FTC Act,⁵¹ and deception may be found based on the "net impression" created by an ad.⁵²

To prove that a claim was made, the FTC need not prove that WSN acted in bad faith or intended to deceive consumers.⁵³ That is, advertisers are liable for all claims reasonably conveyed by their advertising, whether they intended to make the claims or not.⁵⁴ Finally, an ad "capable of being interpreted in a misleading way should be construed against the advertiser."⁵⁵ In Section IV.A.1., below, the FTC applies these standards to the nine challenged claims.

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⁴⁶ 15 U.S.C. § 45(a).

⁴⁷ 15 U.S.C. § 52; see also 15 U.S.C. § 55 (providing definitions for Sec. 12).

⁴⁸ FTC v. Wellness Support Network, Inc., No. C-10-04879JCS, 2011 U.S. Dist. LEXIS 36453, at *17-18 (N.D. Cal. Apr. 4, 2011) (citing FTC v. Pantron I Corp., 33 F.3d 1088, 1095 (9th Cir. 1994)).

⁴⁹ FAC (Dkt. 27) ¶¶ 24, 26.

⁵⁰ FTC v. US Sales Corp., 785 F. Supp. 737, 745 (N.D. Ill. 1992) (citing FTC v. Colgate-Palmolive Co., 380 U.S. 374 (1965)).

²⁴ || ⁵¹ FTC v. Gill, 71 F. Supp. 2d 1030, 1043 (C.D. Cal. 1999), aff'd, 265 F.3d 944 (9th Cir. 2001).

⁵² Stefanchik, 559 F.3d at 928; see also Gill, 71 F. Supp. 2d at 1043.

⁵³ FTC v. World Travel Vacation Brokers, Inc., 861 F.2d 1020, 1029 (7th Cir. 1988).

⁵⁴ See, e.g., Chrysler Corp. v. FTC, 561 F.2d 357, 363, 363 n.5 (D.C. Cir. 1977).

⁵⁵ Simeon Mgmt. v. FTC, 579 F.2d 1137, 1146 (9th Cir. 1978) (citing Resort Car Rental Sys., Inc. v. FTC, 518 F.2d 962 (9th Cir. 1975)).

2. Determining Whether The Claims Were Likely To Mislead

Next, the FTC must show that the challenged claims are likely to mislead reasonable consumers. The FTC can make this showing by demonstrating *either* that the claims are false (known as asserting a "falsity" theory) *or* that WSN lacked a reasonable basis for making the claims (known as a "reasonable basis" or "substantiation" theory). ⁵⁶ Under a falsity theory, the FTC must show that the given claim is false. ⁵⁷ Under a substantiation theory, the FTC must prove that the defendant lacked a reasonable basis for its claims —that is, lacked sufficient substantiation for them. ⁵⁸ The FTC need not, however, conduct or present studies proving that WSN's products do not work as claimed. ⁵⁹ In this case, the FTC alleges that all nine challenged claims are unsubstantiated, and that some of them are also false.

To assess whether an advertiser has sufficient substantiation for a claim, the court first determines what level of substantiation an advertiser must have, then determines whether the advertiser possessed that level of substantiation. When an ad claims that a particular level of substantiation exists (e.g., "tests prove," "studies show") the advertiser must possess that level of substantiation. (Such claims are sometimes known as "establishment claims." Here, the FTC asserts that WSN lacks the level of substantiation claimed in its ads; therefore, WSN's establishment claims (i.e., Claims 3, 4, 8, and 9 as listed below) are both false and unsubstantiated.

If an ad does not reference a specific level of support, the court determines the appropriate level of substantiation. Here, the proper level of substantiation for WSN's health-

 $^{^{56}}$ FTC v. Medlab, Inc., 615 F. Supp. 2d 1068, 1079 (N.D. Cal. 2009) (citing Pantron I, 33 F.3d at 1096).

⁵⁷ Pantron I, 33 F.3d at 1096.

 $^{|^{58}}$ *Id*.

^{25 | &}lt;sup>59</sup> FTC v. QT, Inc., 448 F. Supp. 2d 908, 959 (N.D. Ill. 2006), aff'd, 512 F.3d 858 (7th Cir. 2008); see also Pantron I, 33 F.3d at 1096.

⁶⁰ *Pantron I*, 33 F.3d at 1096.

⁶¹ Removatron Int'l Corp. v. FTC, 884 F.2d 1489, 1492 n.3 (1st Cir. 1989).

⁶² See, e.g., Sterling Drug, Inc. v. FTC, 741 F.2d 1146, 1150 (9th Cir. 1984).

1	related efficacy claims is "competent and reliable scientific evidence." The FTC asserts that
2	WSN's non-establishment claims relating to the effectiveness of its products (i.e., Claims 1, 2, 5,
3	6, and 7) are unsubstantiated.
4	3. Determining Whether The Claims Are Material
5	Finally, the FTC must prove that the claims are material. Certain types of advertising
6	claims are presumptively material, including express product claims, ⁶⁴ health and safety
7	claims, 65 and claims that are likely to affect consumers' choice of a product. 66
8	IV. ARGUMENT
9	A. WSN's Advertisements Violated The FTC Act
10	1. WSN's Advertisements Make The Challenged Claims
11	At the core of the FTC's case are the nine claims identified in the FAC ⁶⁷ :
12	Claim 1. DP is an effective treatment for diabetes (FAC Count 1a);
13	Claim 2. Scientific studies prove that DP is an effective treatment for diabetes (FAC Count 1c);
14	Claim 3. DP reduces or eliminates the need for insulin and other diabetes medications (FAC Count 1b);
15	Claim 4. DP is clinically proven to cause an average drop in blood glucose levels of 31.9% (FAC Count 1d);
16	Claim 5. IRP reverses insulin resistance (FAC Count 2a);
17	Claim 6. IRP manages insulin resistance (FAC Count 2b); Claim 7. IRP prevents diabetes (FAC Count 2c);
18	Claim 8. Scientific studies prove IRP is an effective treatment for insulin
19	resistance (FAC Count 2d); and Claim 9. IRP is clinically proven to cause an average drop in blood glucose
20	levels of 31.9% (FAC Count 2e).
21	The following nine sections explain why there is no genuine dispute that WSN's ads
22	convey each of the challenged claims.
23	
24	63 See QT, 448 F. Supp. 2d at 959 (citing Sterling Drug, Inc. v. FTC, 741 F.2d 1146, 1156-57
25	(9th Cir. 1984)).
26	⁶⁴ Pantron I, 33 F.3d at 1095-96.
	⁶⁵ <i>QT</i> , <i>Inc.</i> , 448 F. Supp. 2d at 960, 965-66.
27	66 FTC v. Cyberspace.com, LLC, 453 F.3d 1196, 1201 (9th Cir. 2006).
28	⁶⁷ FAC (Dkt. 27) ¶¶ 24, 26.

a. WSN Claimed that DP Is An Effective Treatment For Diabetes

WSN's ads claimed that DP is an effective treatment for diabetes. As noted above, WSN's ads for DP repeatedly touted DP's ability to lower blood sugar—a key treatment goal for diabetics. For example, one PPC ad promoted a "[c]linically proven drug-free solution that lowers blood sugar," while another told consumers they could "have normal blood sugar levels." WSN's webpage for DP announced a "diabetes breakthrough" that would "lower your blood sugar, safely and effectively, with absolutely no side effects!!" The webpage also listed "lower blood glucose levels" as one of DP's "breakthrough benefits." Lastly, customer testimonials described dramatic drops in blood sugar.

The effective treatment claim was also conveyed by representations that DP could do the same job as diabetes medications. As discussed further below, WSN's website featured DP users who achieved lower blood sugar while eliminating medication, including, in one instance,

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⁶⁸ Garvey Report at 17 (identifying controlling blood sugar as a key treatment goal).

⁶⁹ SOF 102, 105, 106.

⁷⁰ Ortiz Ex. 9 ("RealFoodNutrients Diabetes campaign setup"); Ortiz Ex. 6 at 134:7-18 (Gilleard Dep.). *See also* Ortiz Ex. 10 at 60:17-61:13, 128:9-23 (Huffman Dep.); Ortiz Ex.10-A (e-mail); Ortiz Ex. 10-B (Declaration of Craig Kauffman re Internet Search Term Research)(substantially similar representations).

⁷¹ FAC Ex. A at Dkt. 27-1, p. 2 (2009 website); Ortiz Ex. 42 at 1 (2007 website); Ex. 43 at 1 (2008); Ex. 44 at 1 (2009); Ex. 45 at 1 (2010); *see also* FAC Ex. B at Dkt. 27-3, p. 3 (2010 website). Although in 2010 some webpages said that DP "maintains" rather than "lowers" blood sugar levels, in the overall context of the ad this distinction is meaningless. Testimonials in the ads still touted lower blood sugar levels. *See* Ortiz Ex. 46 at 1-4 (2010 website); *see also* Ortiz Ex. 48 (2010). And since diabetes is marked by high blood sugar, the phrase "maintain normal blood sugar levels" conveys either that DP first *lowers* blood sugar, or that it prevents it from rising once stabilized. Either reading conveys that DP is an effective treatment for diabetes.

⁷² FAC Ex. A at Dkt. 27-1, p. 3 (2009 website); Ortiz Exs. 42-43 at 1 (2007-2008 websites); Exs. 44-45 at 2 (2009-2010).

⁷³ "My blood sugar went from 230 to 117 in just 21 days." ("James Marshall") FAC Ex. A, Dkt. 27-1, p. 2 (2009 website); Ortiz Ex. 42-46 at 1 (2007-2010 websites); *see also* Ex. 47 at 14-15 (2009); Ex. 48 at 14-15 (2010). "[B]efore [DP] my reading was 191, now after just a few weeks my readings range from 93 to 112." ("Joan Lynch") FAC Ex. A, Dkt. 27-2, pp. 2-3 (2009 website). *See also* Ortiz Exs. 42 at 4 (2007 website); Exs. 43-45 at 4-5 (2008-2010); Ex. 46 at 4 (2010) (substantially similar).

"50 units of insulin."⁷⁴ The website touted "less dependency on medications" while promising lower blood sugar levels. ⁷⁵ In addition, one of WSN's most successful PPC ads promoted a "Natural Diabetes Medicine" that "lower[s] blood sugar" – certainly an "effective treatment" claim. Another PPC ad promoted a diabetes "solution" with a "90% success rate."⁷⁷

In sum, there is no genuine dispute that WSN claimed that DP is an effective treatment for diabetes.

b. WSN Claimed That Scientific Studies Prove That DP Is An Effective Treatment For Diabetes

In addition to claiming that DP is an effective treatment for diabetes, WSN claimed that *scientific studies prove* DP's efficacy. For example, several of WSN's most successful PPC ads expressly touted a "clinically proven" diabetes "solution." WSN's website also made this claim. The website represented that "Nobel Prize winning science and over 60 independent American university studies confirm the superiority of Foodform technology" -- "Foodform technology" being the manufacturing process for DP. The 2009 website also prominently claimed that "studies show a 31.9% drop in blood sugar levels," and stated:

A recent independent clinical trial was done on one of the[] herbal ingredients from this amazing product. This study was done on type

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⁷⁴ FAC Ex. A at Dkt. 27-2, p. 1 (2009 website) ("Barbara Culver" stating her blood sugar "just kept going up" in spite of "50 units of insulin plus pills twice a day," and that since using DP her "sugar is down in the low 100s" and "I don't take insulin anymore!"); *see also* Ortiz Exs. 42-44 at 2-3 (2007-2009 websites); Ex. 45 at 3-4 (2010); Ex. 46 at 2-3 (2010) (substantially similar).

⁷⁵ FAC Ex. A., Dkt. 27-1, p. 3 (2009 website); Ortiz Exs. 42-45 at 2 (2007-2010 websites).

⁷⁶ Ortiz Ex. 9 at 2 ("RealFoodNutrients Diabetes campaign setup"); *see also* Ortiz Ex. 6 at 125:20-25, 134:7-18 (Gilleard Dep.).

⁷⁷ Ortiz Ex. 9 at 2 ("RealFoodNutrients Diabetes campaign setup"); *see also* Ortiz Ex. 6 at 125:20-25, 134:7-18 (Gilleard Dep.).

⁷⁸ Ortiz Ex. 9 at 2 ("RealFoodNutrients Diabetes campaign setup"); *see also* Ortiz Ex. 6 at 125:20-25, 134:7-18 (Gilleard Dep.). *See also* SOF 106.

⁷⁹ FAC Ex. A at Dkt. 27-1, p. 3 (2009 website); Ortiz Exs. 42-45 at 2 (2007-2010 websites); *see also* FAC Ex. B at Dkt. 27-3, p. 5 (2010 website); Ortiz Ex. 46 at 2 (2010 website) (citing Nobel Prize support for the superiority of Foodform *nutrients*).

⁸⁰ FAC Ex. A, Dkt. 27-1, p. 2 (2009 website); Ortiz Exs. 42-45 at 1 (2007-2010 websites).

2 diabetics (mildly insulin dependent) and reported **an average drop of blood glucose levels of 31.9%...** [emphasis in original]"81

Repeated references to the Nobel Prize served to bolster the "studies prove" claim. For example, the site consistently claimed that DP "is the most technologically advanced product of its kind available anywhere and was validated by the 1999 Nobel Prize for physiology," suggesting that physiological studies prove the efficacy of DP. The website also reprints studies relating to various DP ingredients. ⁸⁴

Given the above, there is no genuine dispute that WSN claimed that scientific studies prove that DP is an effective treatment for diabetes.

c. WSN Claimed That DP Reduces Or Eliminates The Need For Insulin And Other Diabetes Medications

WSN's ads claimed that DP reduces or eliminates the need for insulin and other diabetes medications. WSN's PPC ads expressly promised a "drug-free" "solution" to diabetes. Similarly, the WSN website expressly stated that one of DP's "breakthrough benefits" is "less dependency on medications." In addition, the webpage said:

Diabetes is a disease that if you don't take effective action against, it simply gets worse.

⁸¹ FAC Ex. A, Dkt. 27-1, p. 3 (2009 website); Ortiz Exs. 42-45 at 2 (2007-2010 websites).

⁸² FAC Ex. A, Dkt. 27-2, p. 1 (2009 website); Ortiz Exs. 42-45 at 3 (2007-2010 websites). Robert Held admits that the Nobel Prize-winning technology described on the WSN website has nothing to do with lowering blood sugar and is not the technology underlying DP. Ortiz Ex. 1 at 137:11-25, 138:1-4 (B. Held Dep.).

⁸³ SOF 139; see also SOF 37.

References to studies of "ingredients" or "Foodform" do not negate the overall impression that DP *itself* has been proven effective by scientific studies. WSN's ads emphasize the link between DP and the Foodform process, thus conveying that Foodform's "proven" benefits will accrue to a product made using that process. Similarly, consumers could reasonably expect that an advertiser who touts studies on a product's ingredients is claiming that those studies support the efficacy of the product as a whole. *See FTC v. Nat'l Urological Grp.*, 645 F. Supp. 2d 1167, 1194-95, 1197 n.17 (N.D. Ga. 2008) (holding that representation in ad related to effectiveness of the product itself, even though express language discussed only its components), *aff'd*, 356 Fed. Appx. 358 (11th Cir. 2009) (unpublished).

⁸⁵ Ortiz Ex. 9 at 2 ("RealFoodNutrients Diabetes campaign setup"); *see also* Ortiz Ex. 6 at 125:20-25, 134:7-18 (Gilleard Dep.).

⁸⁶ FAC Ex. A., Dkt. 27-1, p. 3 (2009 website); Ortiz Exs. 42-45 at 2 (2007-2010 websites).

Unfortunately medications only treat the symptoms and usually do nothing to address the underlying causes. The good news is that cutting-edge science and nutrition have come together to create a truly monumental and natural breakthrough for diabetics.⁸⁷

This passage conveys that—unlike medications—DP will address the "underlying causes" of diabetes, thus permitting consumers to eliminate or reduce their medications.

Testimonials hammered the claim home. "Barbara Culver" described how she eliminated "50 units of insulin" while achieving lower blood sugar with DP. Another testimonialist "threw all the medicines out the window and went a month with no medicine and just the Diabetic Pack supplements. I leveled off in the 120 (blood glucose) range..."

Based on the above, there is no genuine dispute of material fact that WSN claimed that DP reduces or eliminates the need for insulin and other diabetes medications.

d. WSN Claimed That DP Is Clinically Proven To Cause An Average Drop In Blood Glucose Levels Of 31.9%

WSN claimed that DP is clinically proven to cause an average drop in blood glucose levels of 31.9%. The 2009 website prominently stated: "Nobel Prize winning technology validates WSN Diabetic Pack Ingredients! Studies show a **31.9%** drop in blood sugar levels! [emphasis in original]." These "studies" are later clarified to be an "independent clinical trial." The 31.9% claim consistently appeared on the website in other years as well, in slightly

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⁸⁷ FAC Ex. A at Dkt. 27-1, p. 3 (2009 website); Ortiz Exs. 42-45 at 2 (2007-2010 websites); FAC Ex. B at Dkt. 27-3, pp. 4-5 (2010 website) (substantially similar); *see also* Ortiz Ex. 46 at 2 (2010 website).

⁸⁸ FAC Ex. A at Dkt 27-2, p. 1 (2009 website); FAC Ex. B Dkt. 27-3, p. 5 to Dkt. 27-4, p. 1 (2010 website); Ortiz Ex. 43 at 2-3 (2008 website) (substantially similar statements); *see also* Ortiz Exs. 42 at 2-3 (2007 website); Exs. 44-46 at 2-3 (2009-2010) (substantially similar statements).

⁸⁹ Ortiz Exs. 47-48 at 1-2 (2009-2010 websites) (Jeff Rice testimonial).

⁹⁰ FAC Ex. A at Dkt. 27-1, p. 2 (2010 website); Ortiz Exs. 42-45 at p. 1 (2007-2010 websites).

⁹¹ "A recent independent clinical trial was done on one of the[] herbal ingredients from this amazing product. This study was done on type 2 diabetics (mildly insulin dependent) and reported **an average drop of blood glucose levels of 31.9%...** [emphasis in original]" FAC Ex. A at Dkt. 27-1, p. 3 (2009 website); Ortiz Exs. 42-45 at 2 (2007-2010 websites).

different form. ⁹² In addition, the website contained studies and articles about studies, including some relating to the study that purportedly showed the 31.9% drop in blood sugar. ⁹³ Based on these facts, there is no genuine dispute that WSN made the 31.9% claim.

e. WSN Claimed That IRP Reverses Insulin Resistance

WSN expressly claimed that IRP reverses insulin resistance. Proclaiming an "insulin resistance breakthrough," WSN's website consistently claimed the product would "reverse insulin resistance, safely and effectively." In some years, the website also carried a large headline stating, "You Can Reverse Insulin Resistance! Yes, a new breakthrough can protect you from becoming diabetic and can help you reverse and eliminate your insulin-resistant condition! Reverse Insulin Resistance, safely and effectively with absolutely NO SIDE EFFECTS!! GUARANTEED!!" Given these express statements, there is no genuine dispute that WSN claimed that IRP reverses insulin resistance.

f. WSN Claimed That IRP Manages Insulin Resistance

WSN expressly claimed that IRP manages insulin resistance. The WSN website consistently contained the bold headline, "Insulin Resistance Breakthrough," followed by the statement that IRP is "specifically formulated for the dietary management of insulin resistance." WSN's website also stated that "[t]he WSN Insulin Resistance Pack is a medical food for the dietary management of insulin resistance." Given these express statements, there is no genuine dispute that WSN claimed that IRP manages insulin resistance.

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⁹² Ortiz Exs. 25-29 at 4 (2008-2012 websites).

⁹³ SOF 37, 139. As noted at Sec. IV.A.2., neither this study nor any other was conducted on WSN products.

⁹⁴ FAC Ex. C, Dkt. 27-5, p. 3 (2010 website); Ortiz Exs. 30-34 at 1 (2007-2011 websites).

⁹⁵ Ortiz Ex. 31 at 1 (2008 website); Ex. 34 at 1 (2011).

⁹⁶ FAC Ex. C at Dkt. 27-5, p. 3 (2010 website); Ortiz Ex. 22 at 1 (2010 website); Ex. 30 at 1 (2007); Ex. 32 at 1 (2009); Ex. 33 at 1 (2010); Ex. 38 at 1 (2010); Ex. 41 at 1 (2011).

⁹⁷ FAC Ex. C at Dkt. 27-6, p. 3 (2010 website); Ortiz Exs. 22, 38 at 1 (2010 website).

⁹⁸ See Nat'l Urological Grp., 645 F. Supp. 2d at 1199 (holding that where language of representation is express, "no further analysis is needed" to find the claims).

g. WSN Claimed That IRP Prevents Diabetes

Some versions of WSN's IRP webpage were headlined, "You Can Reverse Insulin Resistance," and stated: "Yes, a new breakthrough can protect you from becoming diabetic and can help you reverse and eliminate your insulin resistant condition!" A promise to "protect you from becoming diabetic" is an express prevention claim, while a promise to "reverse and eliminate your insulin-resistant condition" reasonably conveys that the product will "prevent" diabetes. Other iterations of WSN's website also conveyed the claim, stating that one of IRP's "breakthrough benefits" is that it "helps prevent diabetes." Lastly, the IRP webpage offers a syllogism. The page refers to IRP as an "Insulin Resistance Breakthrough" that allows users to "reverse insulin resistance, safely and effectively." The ad goes on to warn that "insulin resistance is a condition that if you don't take effective action against, it simply gets worse, and becomes type 2 diabetes." Readers are then told the "good news" -- that "cutting-edge science and nutrition have come together to create a truly monumental and natural breakthrough for people who are insulin resistant." The ad thus conveys that: (1) without "effective action," insulin resistance becomes diabetes; (2) effective action prevents diabetes; (3) IRP takes effective action against insulin resistance; therefore (4) IRP prevents diabetes.

h. WSN Claimed That Scientific Studies Prove That IRP Is An Effective Treatment For Insulin Resistance

WSN claimed that scientific studies prove that IRP is an effective treatment for insulin resistance. Like the DP webpage, the IRP webpage consistently represented that "Nobel Prize winning science and over 60 independent American university studies confirm the superiority of

⁹⁹ Ortiz Ex. 17 at 1 (2008 website); Ex. 18 at 1 (2011).

¹⁰⁰ FAC Ex. C at Dkt. 27-5, p. 3 (2010 website); Ortiz Exs. 19-23 at 1 (2007-2011 websites).

¹⁰¹ FAC Ex. C at Dkt. 27-5, p.3 (2010 website); Ortiz Ex. 30 at 1 (2007 website); Ex. 32-32 at 1 (2009-2010).

¹⁰² FAC Ex. C at Dkt. 27-5, p. 4 (2010 website); Ortiz Ex. 17 at 1 (2008); Ex. 18 at 1 (2011); Ex. 19 at 1 (2007); Ex. 20 at 1 (2008); Ex. 21 at 2 (2009); Ex. 23 at 1 (2011).

¹⁰³ FAC Ex. C at Dkt. 27-5, p. 4 (2010 website); Ortiz Ex. 17 at 1 (2008); Ex. 18 at 1 (2011); Ex. 19 at 1 (2007); Ex. 20 at 1 (2008); Ex. 21 at 2 (2009); Ex. 23 at 1 (2011).

1	Foodform technology" ¹⁰⁴ – the same technology underlying IRP. Like the DP webpage, the IRP
2	webpage referenced the study that purportedly lowered blood glucose levels by 31.9%. ¹⁰⁵ Taken
3	together, the website's efficacy claims ("reverse insulin resistance," "reduce insulin resistance")
4	and references to studies convey that scientific studies prove IRP's efficacy. 106 References to
5	"clinical trials" and other science bolster the claim. There is thus no genuine dispute that
6	WSN claimed that scientific studies prove that IRP is an effective treatment for insulin
7	resistance.
8	i. WSN Claimed That IRP Is Clinically Proven To Cause An
9	Average Drop In Blood Glucose Levels Of 31.9%
10	WSN claimed that IRP is clinically proven to cause an average drop in blood glucose
11	levels of 31.9%. In addition to the multiple references to scientific studies described above,
12	some versions of WSN's IRP webpage contained the following statement:
13	A recent independent clinical trial was done on one of the[] herbal ingredients from this amazing product. This study was done on type
14	2 diabetics (mildly insulin dependent) and reported an average drop
15	of blood glucose levels of 31.9% and average weight loss of 4.8 pounds in just 30 days!
16	There is no genuine dispute that WSN claimed that IRP is clinically proven to cause an
	average drop in blood glucose levels of 31.9%.
17	2. WSN's Advertising Claims Are Likely To Mislead
18	WSN's claims are likely to mislead if they are false or unsubstantiated. As noted above,
19	substantiation for health claims must consist of competent and reliable scientific evidence, while
20	establishment claims must be supported by the level of evidence claimed in the ad.

e ad.

To establish that WSN's claims about the Products are false and/or unsubstantiated, the

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Ex. 28 at 4 (2011); Ex. 29 at 3-4 (2012).

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¹⁰⁴ FAC Ex. C at Dkt. 27-5, p. 4 (2010 website); Ortiz Ex. 17 at 2 (2008 website); Ex. 18 at 2 (2011); Ex. 19 at 1-2 (2007); Ex. 20 at 2 (2008); Ex. 21 at p. 2 (2009), Ex. 23 at 1 (2011). ¹⁰⁵ Ortiz Exs. 24-27 at 3-4 (2007-2010 website); Ex. 28 at 4 (2011); Ex. 29 at 3-4 (2012). ¹⁰⁶ In Re Removatron Int'l Corp., 111 FTC 206, 298 (1985), aff'd, 884 F.2d 1489 (1st Cir. 1989). ¹⁰⁷ *Id*. ¹⁰⁸ FAC Ex. C at Dkt. 27-5, p. 4 (2010 website); see also Ortiz Exs. 24-27 at 3-4 (2007-2010);

FTC submits the testimony of W. Timothy Garvey, M.D., ¹⁰⁹ a leading expert in the field of diabetes and insulin resistance. ¹¹⁰ In summary, Dr. Garvey states that to substantiate the significant prevention and treatment claims challenged here, "diabetes experts would require consistent results from well-designed and well-conducted studies in representative human populations that directly assess the specific therapeutic effects at issue." ¹¹¹

Dr. Garvey's report comprehensively describes the features of studies that would support WSN's efficacy claims. 112 According to Dr. Garvey, well-designed human clinical studies to substantiate WSN's claims would possess the following characteristics. First, they must be *controlled*, i.e., "a placebo, sham, or existing therapy is administered to a sub-set of participants." 113 Next, they must be *randomized*, i.e., subjects are randomly assigned to receive either placebo or the treatment being studied. 114 Third, they must be *double-blind*, i.e., neither the subjects nor the investigators know whether the subjects are receiving control or experimental treatment. 115 Fourth, they should be *statistically meaningful*, i.e., they should "include enough subjects to ensure adequate statistical power and sensitivity." 116 Finally, the dosages and formulations studied should be *the same* as those sold by WSN for two reasons: "[F]irst, physiological responses to drugs, vitamins, and minerals vary depending on dose[;] and second, there may be interactions between the ingredients that affect their physiological actions." 117 Dr. Garvey's conclusions are grounded in the fact that the challenged claims are significant disease-specific treatment and prevention claims for which experts would require a

¹⁰⁹ Garvey Dec.; Ex. A to Garvey Dec. (Garvey Report); Ortiz Ex. 11 (Garvey Dep.).

²² || ¹¹⁰ See Garvey Report at 1-2; see also Garvey Report, Att. A (curriculum vitae).

^{|| 111} Garvey Report at 20.

¹¹² Garvey Report at 19-26 (describing criteria for high-quality diabetes study design).

¹¹³ Garvey Report at 21.

¹¹⁴ Garvey Report at 21.

¹¹⁵ Garvey Report at 21.

¹¹⁶ Garvey Report at 25.

¹¹⁷ Garvey Report at 25.

high level of scientific support. 118

Dr. Garvey concludes, and WSN has admitted, that no studies of the type described by Dr. Garvey exist for the challenged Products. ¹¹⁹ In fact, despite numerous references to scientific evidence in their advertisements, WSN has *no studies of its products whatsoever*. ¹²⁰ Rather than testing their own products, WSN admits they relied on studies and other materials relating to individual ingredients in the Products. ¹²¹ These materials were largely found on the Internet by Defendant Robert Held, who is neither a doctor nor a scientist. ¹²² WSN further admits that most of the studies relied on were performed on only one ingredient each out of over 40 ingredients in WSN's Products, ¹²³ which in Dr. Garvey's opinion renders the studies inadequate to determine the efficacy of those Products. ¹²⁴ Dr. Garvey concludes, therefore, that these studies fall far short of providing adequate substantiation for WSN's efficacy claims. ¹²⁵

Dr. Garvey's expert report further concludes that the studies offered by WSN suffer from many deficits in addition to the fact that they do not test the combination of ingredients in WSN's Products. First, many of the studies were conducted in vitro or on animals, and such tests cannot substantiate that the tested ingredients work in humans. Second, the single-

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¹¹⁸ Garvey Report at 20.

¹¹⁹ Garvey Report at 26 ("I conclude that none of the WSN claims... are supported by competent and reliable scientific evidence."); SOF 31; *see also* Ortiz Ex. 14-A at 3-62, 63-126 (2nd RFA Resp. #192-255, 260-323).

¹²⁰ SOF 31; see also Ortiz Ex. 14-A at 3-62, 63-126 (2nd RFA Resp. #192-255, 260-323).

¹²¹ SOF 31. None of these studies were performed by or for Defendants. *See also* Ortiz 14-A at 3-62, 63-126 (2nd RFA Resp. #192-255, 260-323).

¹²² SOF 29; Ortiz Ex. 1 at 32:22-33:7, 33:15-22, 33:23-24, 33:25-34:4 (B. Held Dep.).

¹²³ Ortiz Ex. 1 at 39:23-40:1 (B. Held Dep.); see also Ortiz Ex. 3 (ingredient list).

¹²⁴ See Garvey Report at 27-28; see also Garvey Report at 23, 24-25; see also FTC v. SlimAmerica, Inc., 77 F. Supp. 2d 1263, 1274 (S.D. Fl. 1999) (holding that single-ingredient studies were insufficient to substantiate claims for a combination product, and requiring double-blind study of the combination of ingredients in the product because "ingredients taken in combination may interact in ways which negate the benefits of the same ingredients taken alone."

¹²⁵ Garvey Report at 26-27.

¹²⁶ Garvey Report at 23, 24.

ingredient studies suffered from various flaws that make them inapplicable to WSN's products, such as insufficient size, lack of placebo or other controls, and testing of much larger doses than are found in WSN's products. Lastly, Dr. Garvey determined that even some well-designed studies showing positive results for individual ingredients were not conclusive because other well-designed studies produced inconclusive or negative results. Dr. Garvey's uncontroverted opinion establishes that there is no genuine dispute that WSN's claims about the efficacy of their Products (Claims 1, 3, 5, 6, and 7) are unsubstantiated.

In addition, because WSN does not possess the level of scientific evidence claimed in its advertising, its establishment claims (Claims 2, 4, 8, and 9 as listed at Section IV.A.1.) are both unsubstantiated and false. These claims all assert that clinical or other scientific studies prove the efficacy of WSN's products. As stated above, Dr. Garvey's uncontroverted expert opinion is that WSN's efficacy claims must be supported by human clinical trials on the Products themselves. As WSN admits, and Dr. Garvey confirmed, the Products have not been tested in this or any other manner. The establishment claims are thus inherently false and unsubstantiated, and therefore likely to mislead.

3. WSN's Claims Are Material

To prove deception, the FTC must lastly show that the claims made by WSN were material. As explained above, express claims, health claims, and claims about a core aspect of a product are presumptively material. All of the challenged claims are health claims and all concerned efficacy, an issue that would be important to prospective customers. In addition, many of the claims were express. There is thus no genuine dispute that the claims are material.

¹²⁸ See Garvey at 34 (analyzing the calcium literature), 43-47 (analyzing the magnesium literature), and 50-55 (analyzing the chromium literature and noting on page 54 that "the considerable number of well-designed clinical trials that have observed no effect of chromium supplementation on glucose homeostasis makes it unlikely that chromium has a clinically significant effect on serum glucose, serum insulin, insulin secretion, or insulin sensitivity.").

¹²⁷ See Garvey Report at 26-64, comprehensively analyzing the available literature on many of

the Products' active ingredients and explaining why those studies fail to adequately substantiate

129 Garvey Report at 8.

Defendants' claims.

B. Defendants Are Liable For Injunctive And Monetary Relief

This Court has the authority to order both the injunctive and the equitable monetary relief sought by the FTC. To obtain consumer restitution, the FTC must show that WSN made misrepresentations "of a kind usually relied on by reasonably prudent persons and that consumer injury resulted." Reliance and resulting injury are proven by showing that WSN made widely disseminated material representations and that consumers purchased the Defendants' products. As described above, these requirements are fully met. Therefore, the Court should order consumer restitution as a matter of law. The proper measure of recovery is the full amount lost by consumers. Which as stated in Section II.C. is \$2,198,612.12.

C. Robert And Robyn Held Are Individually Liable

An individual may be liable for injunctive relief under the FTC Act not only for his or her own conduct, but for a corporation's deceptive conduct if he or she (1) participated in the deceptive practices or (2) had authority to control them. The Helds are liable under both theories. Mr. Held co-founded Wellness Support Network, co-owns the company, and has served over the years as its president and a director. Mr. Held wrote ads for the Products, administered the company's "pay-per-click" advertising campaigns, and selected search term keywords used to drive consumers to WSN's website. Although he is not a doctor or

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¹³⁰ 15 U.S.C. §53(b); *FTC v. Stefanchik*, 559 F.3d 924, 931 (9th Cir. 2009) ("The district court has broad authority under the FTC Act to 'grant any ancillary relief necessary to accomplish complete justice,' including the power to order restitution."); *FTC v. H. N. Singer, Inc.*, 668 F.2d 1107, 1111 (9th Cir. 1982).

¹³¹ *Pantron I*, 33 F.3d at 1102.

¹³² See FTC v. Natural Solution, Inc., No. CV-06-6112JFW, 2007 U.S. Dist. LEXIS 60783, at *19 (C.D. Cal. 2007) (quoting FTC v. Figgie Int'l, 994 F.2d 595, 604 (9th Cir. 1993)).

¹³³ See Sections II.C.; II.D.; IV.A.1-3.

¹³⁴ Stefanchik, 559 F.3d at 931.

¹³⁵ FTC v. Publ'g Clearing House, Inc., 104 F.3d 1168, 1170 (9th Cir. 1997).

¹³⁶ SOF 4, 17; Ortiz Ex. 13.

¹³⁷ Ortiz Ex. 4 at 107:25-108:11 (R. Held Dep.); Ortiz Ex. 15 at 5-6 (1st Rog Response), #3, #5. *See also* Ortiz Ex. 1 at 149:2-22, 149:23-150:13 (B. Held Dep.); Ortiz Ex. 2-A (Ex. 23 to B. Held Dep.).

scientist, ¹³⁸ Mr. Held personally reformulated the Products over the years, ¹³⁹ based not on consultation with experts but on his own interpretation of studies and other materials he found on the Internet. ¹⁴⁰

Robyn Held co-owns Wellness Support Network, and has served as director, CFO, Secretary, and COO.¹⁴¹ Ms. Held runs the day-to-day operations of the company and supervises all departments.¹⁴² Ms. Held participated in the decision to sell DP and IRP.¹⁴³ She also designed and edited the WSN website, wrote content for the website, and chose or approved advertising keywords used to drive potential customers to the website.¹⁴⁴ It is beyond dispute that the Helds participated in the deceptive practices and controlled the deceptive acts of the corporate defendant.¹⁴⁵

The Helds are also liable for monetary relief. To obtain such relief from an individual for corporate misconduct, the FTC must show not only that the individual participated in or had the ability to control the corporation's unlawful acts, but that he or she had knowledge of the deception. "Knowledge" can be established through: (1) actual knowledge of material misrepresentations, (2) reckless indifference to the truth or falsity of the misrepresentations, or

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¹³⁸ Ortiz Ex. 4 at 132:22-33:7, 33:15-22, 33:23-24, 33:25-34 (B. Held Dep.).

¹³⁹ SOF 61, 62; Ortiz Ex. 2 at 201:1-3 (B. Held Dep.); Ortiz Ex. 1 at 37:12-22, 115:16-18 (B. Held Dep).

¹⁴⁰ SOF 29; Ortiz Ex. 1 at 37:12-22, 38:6-13 (B. Held Dep.).

¹⁴¹ SOF 9, 63; Ortiz Ex. 12 at 15 (1st RFP Resp.) #27; Ortiz Ex. 13.

¹⁴² SOF 20, 21, 66.

¹⁴³ SOF 26, 27.

¹⁴⁴ SOF 7, 12, 65; Ortiz Ex. 4 at 107:25-108:11 (R. Held Dep.); Ortiz Ex. 15 at 6 (1st Rog Resp.) #5. *See also* Amended Answer ("Answer") (Dkt. 52) ¶ 8; FAC (Dkt. 27) ¶ 8; Ortiz Ex. 1 at 149:2-22, 149:23-150:13 (B. Held Dep.); Ortiz Ex. 2-A (B. Held Depo Ex. 23).

¹⁴⁵ Answer (Dkt. 52) ¶¶ 7-8; *see also* FAC (Dkt. 27) ¶¶ 7-8; *see Publ'g Clearing House*, 104 F.3d at 1170-71 (An individual's status as an officer and authority to sign documents on behalf of the corporation are sufficient to demonstrate control.); *see also FTC v. Amy Travel Serv., Inc.*, 875 F.2d 564, 573 (7th Cir. 1989).

¹⁴⁶ Publ'g Clearing House, 104 F.3d at 1171.

(3) awareness of a high probability of fraud along with an intentional avoidance of the truth. 147 The FTC need not show that a defendant intended to defraud consumers to hold the defendant individually liable for monetary relief. 148

Having participated directly in creating and approving the ads for the Products, the Helds had actual knowledge of the misrepresentations. In addition, their extensive participation in the violative conduct alone is sufficient to establish the requisite knowledge for monetary relief. 149

The Helds also displayed reckless indifference to the truth or falsity of their claims, continuing to make their deceptive claims even after the FDA issued warning letters in 2005 and 2006. 150 In addition, although proof of actual deception is not required to establish liability. 151 WSN's surveys put them on notice that some consumers may have been deceived by their claims. 152 Yet WSN continues to make claims similar to those challenged in this lawsuit. 153 For all of these reasons, the Helds are personally liable for injunctive and monetary relief.

The Proposed Order¹⁵⁴ D.

Generally speaking, the proposed Order bars WSN from making disease-related claims for certain types of products unless those claims are non-misleading and supported by at least two properly designed and administered human trials of the product. Non-disease, health-related

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<sup>147</sup> Id.
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¹⁴⁸ *Id.* (citing *Amy Travel*, 875 F.2d at 574).

¹⁴⁹ FTC v. Affordable Media, LLC, 179 F.3d 1228, 1235 (9th Cir. 1999).

¹⁵⁰ Declaration of Craig Kauffman (Dkt. 35-1); see Publ'g Clearing House, 104 F.3d at 1171.

¹⁵¹ Cyberspace.com, 453 F.3d at 1200-01.

¹⁵² Question: "What did you read on our website that caused you to decide on getting the Diabetic Pack?" Representative answers: "That it could/would lower my blood sugar and get rid of the diabetes"; "Testimonials of people lowering their blood sugar levels, by taking the product." *Question*: "What particularly attracted you about the Diabetic Pack (the supplements you ordered)?" Representative answers: "Getting off my (4) prescribed diabetic pills"; "I needed to get my blood sugar under control. I did not want to lose my eyesight or my kidneys." Ortiz Ex. 8 ("WSN Diabetes Pack Purchaser Survey"); see Ortiz Ex. 6 at 119:18-21 (Gilleard Dep.); see also Ortiz Ex. 7 ("WSN Diabetes pack Non-Purchaser Survey").

¹⁵³ 2d Gonzalez Dec., Ex. 2.

¹⁵⁴ Submitted concurrently with this Motion.

claims must be non-misleading and supported by competent and reliable scientific evidence. 1 2 WSN is also barred from misrepresenting studies, or that product benefits are scientifically proven. Defendants must also pay \$2,198,612.12, the full amount of consumer injury. Lastly, 3 the proposed Order includes provisions to ensure enforceability. 4 The scope of the proposed Order is proper given WSN's propensity to ignore warnings 5 about their claims, and the likelihood that they will continue to advertise deceptively if not 6 enjoined. The proposed Order is also proper given the potential consequences of WSN's claims. 7 8 As stated above, WSN claimed DP could reduce or eliminate the need for insulin and other diabetes medications. Dr. Garvey warns that use of WSN products instead of established 9 diabetes therapy could lead to serious injury, even death. ¹⁵⁵ A strong order is needed to protect 10 11 consumers. V. 12 **CONCLUSION** As shown above, there is no genuine dispute as to any material fact in this case. The 13 FTC therefore respectfully requests that the Court grant its motion for summary judgment and 14 15 enter the proposed order and judgment requested. 16 Respectfully Submitted, 17 JONATHAN E. NUECHTERLEIN 18 General Counsel 19 20 Dated: __December 6, 2013_ /s/ Laura Fremont_ 21 LAURA FREMONT KENNETH H. ABBE 22 JACOB A. SNOW 23 AUSTIN A.B. OWNBEY Attorneys for Plaintiff 24 Federal Trade Commission 25 26 27 ¹⁵⁵ Ortiz Ex. 11 at 260:4-262:3, 264:15-23 (Garvey Dep.). 28

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