UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

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| FEDERAL TRADE COMMISSION,<br>Plaintiff,<br>v.<br>WELLNESS SUPPORT NETWORK, INC., et al.,<br>Defendants. | Case No. 10-cv-04879-JCS<br><br>**ORDER RE SUMMARY JUDGMENT MOTIONS**<br><br>Re: Dkt. Nos. 163, 169 |

United States District Court
Northern District of California

## I. INTRODUCTION

Plaintiff Federal Trade Commission ("FTC") asserts that Defendants Wellness Support Network, Inc. ("WSN"), Robert Held and Robyn Held have engaged in false advertising and deceptive practices in connection with the sale of their products Diabetic Pack and Insulin Resistance Pack, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) & 52. The FTC now brings a Motion for Summary Judgment ("the FTC Motion") seeking entry of summary judgment against all three Defendants as to all of the issues in the case, including liability, entry of a permanent injunction and an award of restitution. Defendants, in turn, bring a Motion for Summary Judgment ("Defendants' Motion") asking the Court to hold, as a matter of law, that: 1) the FTC's causes of action fail because Defendants' products are medical foods and as such, the standard the FTC seeks to apply is inapplicable; and 2) Robert and Robyn Held may not be held individually liable on FTC's claims as to any award of restitution. A hearing on the Motions was held on February 14, 2014 at 9:30 a.m. For the reasons stated below, the FTC Motion is GRANTED. Defendants' Motion is DENIED.[1]

[1] The parties have consented to the jurisdiction of the undersigned magistrate judge pursuant to 28 U.S.C. § 636(c).

## II. BACKGROUND

### A. Factual Background[2]

#### 1. Parties

Defendant WSN is a closely held California corporation co-owned by individual defendants Robert and Robyn Held. Joint Statement of Undisputed Material Facts ("JSUF") ¶¶ 2, 4, 9. Robert Held co-founded WSN and has served over the years as its president and a director. JSUF ¶¶ 4, 17. Robyn Held co-owns WSN with Robert Held, and has served as director, CFO, Secretary, and COO. *Id*. ¶¶ 9, 63. As of January 2013, Robert and Robyn Held are the only two officers of WSN. *Id*. ¶ 19.

#### 2. Diabetes and Insulin Resistance

Diabetes mellitus is a group of disorders (hereinafter, referred to collectively as "diabetes") characterized by abnormal glucose metabolism. Declaration of W. Timothy Garvey, M.D. Pursuant to 28 U.S.C. § 1746 ("Garvey Decl."), Ex. 1 (Expert Report of W. Timothy Garvey) ("Garvey Report") at 9. Diabetes affects over 10% of the adult population in the United States. *Id.* Diabetes is characterized by abnormal glucose metabolism, in particular "hyperglycemia," which refers to high levels of glucose (or sugar) in the blood. *Id*. 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. *Id*. 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. *Id*. Over time, high levels of blood glucose can damage many parts of the body. *Id.* Long-term complications of diabetes include heart disease and stroke, peripheral artery disease, high blood pressure, blindness, kidney disease, neuropathy, hearing loss and skin disorders. *Id*. Diabetes is the leading cause of kidney failure, new cases of blindness and nontraumatic lower-limb amputations in the United States. The overall goal in treatment of diabetes and prediabetes is to maintain the blood sugar level in a range that will minimize damage

[2]In its factual background section the Court relies on the facts set forth in the parties Joint Statement of Undisputed Material Facts. In addition, the Court relies on facts that it finds to be undisputed, based on the parties' briefs and supporting evidence, even where the parties have not expressly stipulated to those facts.

to the body. *Id*. at 17.

**3. WSN's Products**

This case involves two products WSN began selling in 2004, the Diabetic Pack and the Insulin Resistance Pack (collectively, "the Products"). *See* JSUF ¶¶ 93-94, 99-100. The Diabetic Pack and the Insulin Resistance Pack are the same products and have always contained identical ingredients. *Id*. ¶¶ 24, 60. WSN advertised the Products as containing vitamins, minerals, and botanical extracts, formulated into three components: the Glucose Support Formula, the Vitamin-Mineral Formula, and the Calcium-Magnesium Formula. *Id*. ¶¶ 93, 95. The company advertised and sold the Products until at least 2011. Declaration of FTC Investigator Kelly Ortiz in Support of Federal Trade Commission's Motion for Summary Judgment ("Ortiz Decl."), Ex. 1 (Robert Held Depo.) at 25:14-26:12. Although in 2011 WSN stopped marketing the Products under the names "Diabetic Pack" and "Insulin Resistance Pack," it continues to sell products that are essentially the same under different names. *Id*.; *see also* JSUF ¶¶ 25, 26, 56, 79. While the Glucose Support Formula ("GSF") component retains that name, the Calcium-Magnesium Formula and Vitamin and Mineral Formula have been combined into the "Life Support Formula" ("LSF"). JSUF ¶¶ 56, 79. GSF and LSF are sold separately. *Id*. ¶ 56. Although WSN no longer advertises a "Diabetic Pack," the Diabetic Pack is still available for purchase and WSN continues to sell and advertise the individual components of the Diabetic Pack, including GSF. *Id*. ¶ 67; *see also* Second Declaration of David Gonzalez in Support of Federal Trade Commission's Motion for Summary Judgment ("Second Gonzalez Decl."), Ex. 2.

The Products were originally developed by Robert Held, who formulated them on the basis of scientific studies he found on the Internet. JSUF ¶¶ 29-30. Defendants claim that the Products assist in the dietary or nutritional management of diabetes by providing nutrients which typical diabetics lack. *Id*., ¶ 47.

The majority of Defendants' customers find WSN on the Internet. JSUF ¶ 70. Customers have purchased the Products on the WSN website, Amazon.com, eBay.com, and over the phone. JSUF ¶ 71; Ortiz Decl., Ex. 4 (Robyn Held Dep.) at 32:17-33:9. After subtracting money returned to customers, WSN's sales revenue for the Products between 2004 and 2012 totaled

$2,198,612.12. Declaration of David Gonzalez in Support of Federal Trade Commission's Motion for Summary Judgment ("Gonzalez Decl.") ¶ 5 and Ex. A at 4.

**4. WSN's Advertising**

Robyn and Robert Held develop all advertising and marketing for WSN products, including the Diabetic Pack and the Insulin Resistance Pack. JSUF ¶ 6. They also created together the website through which WSN advertises the Diabetic Pack and the Insulin Resistance Pack, www.realfoodnutrients.com. *Id*. ¶ 7. However Robyn Held did not do anything to verify the accuracy of claims made in WSN's advertising, testifying that this was Robert Held's job. Ortiz Decl., Ex. 5 (Robyn Held Depo.) at 191. According to Robyn Held, Robert Held made determinations about the accuracy of the claims in the advertising based on "whatever research and study he's done." *Id*.

Since January 2004, to increase the prominence of its website in search engines, WSN has used keywords and metatag data as well as Google Adword Campaigns, which are "pay-per-click"("PPC") campaigns. Ortiz Decl., Ex. 15 (Defendants' Response to Plaintiff's First Set of Interrogatories ("First Interrogatory Resp."), #1 at 4; *id*., Ex. 4 (Robyn Held Depo.) at 107 ("Google Ad-Words Campaign is a PPC campaign"). Keywords that have been used by WSN to advertise the Products include "alternative diabetes," "diabetes control," "cure diabetes," "cure for diabetes," "diabetic cure," "remedies diabetes," "natural diabetes cure," and "diabetes treatment." Ortiz Decl., Ex. 4 (Robyn Held Depo.) at 127-128.

WSN has advertised its Diabetic Pack and Insulin Resistance Pack primarily through online PPC campaigns. JSUF ¶¶ 102-103. The PPC marketing campaign for the Diabetic Pack and Insulin Resistance Pack was designed by Robert Held. Ortiz Decl., Ex. 15 (First Interrogatory Resp.), #1 at 5. Although outside contractors managed the campaigns,[3] the keyword and adword phrases that were the focus of the campaign were developed by Robert Held. *Id*. at 5-6. Some of WSN's more successful PPC ads read as follows:

New Diabetes Breakthrough

[3] The outside contractors were Telic Ionic Media and Gilleard Marketing. Ortiz Decl., Ex. 15 (First Interrogatory Resp.), #3 at 6; JSUF ¶¶ 105, 108..

Clinically Proven Natural Solution
Have Normal Blood Sugar Levels

Control Blood Sugar Level
Clinically Proven Natural Solution
To Diabetes With A 90% Success Rate

Can't Lower Your Blood Sugar?
Clinically Proven Drug Free
Solution That Lowers Blood Sugar

A Diabetes Breakthrough
Reverse the Effects of Diabetes
Money Back Guarantee

Ortiz Decl., Ex. 9 (Document entitled "RealFoodNutrients Diabetes campaign setup" listing WSN's "successful past ads"); *id*., Ex. 6 (Deborah Gilleard Depo.) at 134:7-18. Consumers clicking on WSN's PPC ads would land on WSN's website. Ortiz Decl., Ex. 15 (First Interrogatory Resp.), #1-3 at 4-6.

Defendants' website contained numerous pages advertising the Products. *See* Ortiz Decl., Exs. 17- 48 (printouts of some of Defendants' webpages); *id*., Ex. 49 (CD-ROM containing corresponding HTML files, provided by WSN during discovery); *see also* Second Gonzalez Decl., Exs. 1-2; First Amended Complaint ("FAC") (Dkt. 27, Exs. A-C). The advertising consistently highlighted the Products' ability to lower blood sugar levels and reduce dependency on medication and emphasized the existence of scientific proof demonstrating these benefits. For example, between 2007 and 2010 and in 2012, Defendants' website included a page for Diabetic Pack with a picture of the product next to a large headline announcing a "Diabetes Breakthrough." FAC, Ex. A at 2 (2009); Ortiz Decl., Exs. 42-46 at 1 (2007-2010). Under the headline, the website stated that the product is "a medical food specifically formulated for the dietary management of diabetes," and went on to state: "Lower your blood sugar, safely and effectively with absolutely NO SIDE EFFECTS!! GUARANTEED!!" *Id*. These claims were followed by a checklists of "breakthrough benefits" including "lower blood glucose levels" and "less dependency on medications." *Id*.

The website also contained testimonials, including one from customer "Barbara Culver" stating as follows:

> 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!

Ortiz Decl., Ex. 42 (2007) at 2-3; *id*., Ex. 43 (2008) at 2-3; *id.*, Ex. 44 at 2-3 (2009); *id*., Ex. 45 at 2-3 (2010); *id*., Ex.46 at 2-3 (2012). Another testimonial, from "James Marshall," stated: "[m]y blood sugar went from 230 to 117 in just 21 days." Ortiz Decl., Exs. 42-46 at 1 (2007-2010). Another testimonial was from "Jeff Rice," who stated that his use of Diabetic Pack had resulted in a "transformation of [his] sugar's running in the 300 to 250 range to 120 and lower." Ortiz Decl., Ex. 47 (2009); *id*., Ex. 48 (2010). The testimonial states further:

> The first doctor put me on Glucotrol 10 mg. The second doctor put me on Glucophage 2000 mg along with the Glucotrol. Also Neurontin 300 mg, Tricor 160 mg, Lipitor 200 mg, Diovan 80 mg and vandia. 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 said no!!! That's when 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.

Ortiz Decl., Ex. 47 (2009) at 1-2, Ex. 48 (2010) at 1-2.

In addition to touting the reduction in blood sugar levels, most of the testimonials also referenced the low carb diet recommended as part of the Diabetic Pack regimen. The testimonial of "Mary Jane Burnett" states that "[t]he instructions for your program made sense and the diet is easy to follow" and that her blood sugar levels dropped after a few weeks of using the Diabetic Pack "and following the diet." Ortiz Decl., Ex. 47 at 2. "Joan Lynch" states, "[n]eedless to say, I am not going to take any medication since I am doing so well with the Diabetic Pack nutrients and diet." *Id*. at 2-3. "Stephen Houston" states, "you can . . . beat diabetes" by "1. Diet. Cut the carbs to below 100 grams a day maximum. 2. Take the Diabetic Pack. You will see the difference in a week or two [and] 3. Get serious about exercise. . ." *Id*. The testimonial of Gene and Mary Tayloe states that "the low carb diet seems to be working for her as well as me." *Id*. at 3-4. Gwen and Larry Taylor's testimonial states that "Larry has seen a great improvement in his sugar levels"

after taking WSN's products "according to your instructions, along with the information you gave me over the phone concerning the items I should pack for his breakfast and lunch." *Id*. at 4. "Edward Tisdale" states that his "blood sugar levels have fallen to the normal range" after he "stopped eating breads and cereals and other carbs" and started using the Diabetic Pack. *Id*. at 6. "Mike Corcoran" states that he "stuck to a low carb diet (no more than 4 grams a day) and took the nutrients faithfully every day." *Id*. at 8.

The website contained numerous references to science, including the headline, "Nobel Prize Winning Technology Validates WSN Diabetic Pack Ingredients." Ortiz Decl., Exs. 42-45 (2007-2010) at 1. A subsequent page included the heading (in smaller typeface than the previous headline) "Nobel Prize Validates Amazing Technology." Ortiz Decl., Exs. 42-44 (2007-2009), 46 (2012) at 2. Under this heading, the website contained the following explanation of how Diabetic Pack works:

> The reason the WSN® Diabetic Pack works is because it operates at the cellular level and addresses a key problem that every type 2 diabetic has. All type 2 diabetics have a deficiency of key nutrients the body needs to support healthy blood sugar levels. Your cells simply do not process blood sugar like they should. The WSN® Diabetic Pack helps your body metabolize blood sugar more efficiently.
>
> The WSN® Diabetic Pack provides these key nutrients as 100% Foodform® vitamins and minerals for maximum absorption, retention and utilization in the cells of the body. Nobel Prize winning science and over 60 independent American university studies confirm the superiority of Foodform® technology.
>
> The WSN® Diabetic Pack also contains important botanical extracts. A recent independent clinical trial was done on one of these 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% and average weight loss of 4.8 pounds in just 30 days.**

*Id*.

WSN's webpages for the Insulin Resistance Pack made similar claims to those made for the Diabetic Pack. *See* Ortiz Decl., Exs. 17-23 (2007-2011), 28 (2011), 30-41 (2007-2011). In particular, the list of "breakthrough benefits" included "Reduced Insulin Resistance," "Improved Utilization of Glucose," and "Helps Prevent Diabetes." Ortiz Decl., Exs. 17-23 (2007-2011), 30-35 (2007-2011), 38 (2010). The website promised "Reverse Insulin Resistance, safely and

effectively with absolutely NO SIDE EFFECTS !! GUARANTEED!!" Ortiz Decl., Exs. 17-23 (2007-2011) at 1; *id*, Exs. 30-41 (2007-2011) at 1. It also referred to the Insulin Resistance Pack as "specifically formulated for the dietary management of insulin resistance." Ortiz Decl., Exs. 19-22 (2007-2010), 30 (2007), 32-33 (2009-2010), 35 (2007), 38 (2010), 41 (2011) at 1. The WSN website claimed that the Insulin Resistance Pack, like the Diabetic Pack, is "the most technologically advanced product of its kind available anywhere and was validated by the 1999 Nobel Prize for physiology." Ortiz Decl., Exs. 17-19 (2007-2008, 2011) at 2; *id*., Ex. 20 (2008) at 3; *id*., Ex. 23 (2011) at 2; *id*., Exs. 30-31 (2007-2008); *id*., Ex. 32 (2009) at 3; *id*., Ex. 35 (2007) at 2. The Insulin Resistance Pack advertisements also contained the language quoted above relating to the "important botanical extracts" and the "recent independent clinical trial [that] was done on one of these herbal ingredients." Ortiz Decl., Ex. 17-21 (2007-2009, 2011), 23 (2011), 30-32 (2007-2009), 34-35 (2007, 2011) at 2; *see* also Ortiz Decl., Ex. 28 (2011) (containing similar language). Finally, some WSN webpages that advertised the Insulin Resistance Pack promised that "a new breakthrough can protect you from becoming diabetic and can help you reverse and eliminate your insulin resistance condition." Ortiz Decl., Ex. 17-18 (2008, 2011), 31 (2008) and 34 (2011) at 1.

WSN's advertising also included newsletters, which were written by Robert Held and were sent to customers and available on WSN's website. *See* JSUF ¶¶ 48-57.

As noted above, WSN hired third parties to assist with online marketing, including Gillead Marketing ("Gillead"). JSUF ¶¶ 105-108. In 2010, Gillead conducted a survey of individuals who landed on Defendants' website but did not purchase the products ("2010 Online Survey"). JSUF ¶ 109; Ortiz Decl., Ex. 6 (D. Gillead Depo.) at 112-115; *id*., Ex. 7 (2010 Online survey). The survey was completed by 96 individuals and indicated that the main reasons those individuals were searching on the Internet for information about the condition were to learn about natural remedies for diabetes and to get information about how to control their sugar levels. *Id.*

**5. Customer Feedback and Other Information Relating to the Effectiveness of WSN's Products**

It is undisputed that no scientific studies were ever conducted to establish the effectiveness

of WSN's Products. JSUF ¶ 31. Rather, Defendants' claims about the Products are based on research studies addressing the benefits of the individual ingredients contained in Diabetic Pack and Insulin Resistance Pack. *Id*., ¶ 31. In addition, Robert Held testified that he believed the products were effective because people told him the Products worked for them, but he conceded that he did not know how many people had told him the Products worked. Ortiz Decl., Ex. 1 (Robert Held Depo.) at 123-124. Similarly, when asked how many people WSN's products had *not* worked for, Mr. Held stated that he "[didn't] have clue." *Id*., Ex. 2 at 217. Between 2004 and 2007, WSN received approximately 384 consumer complaints about the Diabetic Pack. JSUF ¶ 91. Some individuals complained that the product was not working for them while others said their doctor did not support their use of the product. JSUF ¶ 92.

**6. FDA Warning Letters and FTC Investigation Demand**

In 2005, the Food and Drug Administration ("FDA") sent a letter to Robert Held warning that it considered WSN's Diabetic Pack to be a drug and that WSN's claims regarding diagnosis, mitigation, treatment and cure for diabetes did not comply with the Food, Drug and Cosmetic Act, 21 U.S.C. § 321(g)(1) ("FDCA") and associated FDA regulations. *See* Declaration of Craig Kauffman ("Kauffman Decl."), Ex. 1 (Sept. 27, 2005 Letter from FDA to Robert Held ). In 2006, the FDA sent another warning letter to Robert Held, again warning that WSN's claims violated the FDCA and FDA regulations. *Id*., Ex. 2 (Oct. 12, 2006 Letter from FDA to Robert Held).

In 2007, the FTC sent WSN, care of Robert Held as President, a Civil Investigation Demand requiring that WSN produce documents and respond to FTC interrogatories on the subject of whether WSN was making misleading statements about the safety or efficacy of its products. Declaration of FTC Investigator Kelly Ortiz (in Support of Federal Trade Commission's Opposition to Defendants' Motion for Summary Judgment) ("Ortiz Opposition Decl., Ex. 1 (Civil Investigation Demand"). According to the FTC, this demand marked the beginning of the investigation that culminated in the instant action. FTC Opposition at 6.

**B. First Amended Complaint**

In the First Amended Complaint ("FAC"), the FTC asserts two causes of action against

Defendants based on WSN's allegedly deceptive claims, one as to the Diabetic Pack and the other as to the Insulin Resistance Pack. Both causes of action are asserted under Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

In its first cause of action ("Count One"), the FTC asserts that Defendants' advertising of the Diabetic Pack made the following deceptive claims:

a. Diabetic Pack is an effective treatment for diabetes;

b. Diabetic Pack reduces or eliminates the need for insulin and other diabetes medications;

c. Scientific studies prove that Diabetic Pack is an effective treatment for diabetes; and

d. Diabetic Pack is clinically proven to cause an average drop in blood glucose levels of 31.9%.

FAC, ¶ 24. The FTC further alleges that these representations "are false or were not substantiated at the time they were made," and therefore, that the making of these representations constituted a deceptive act or practice and false advertising, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52. *Id*., ¶ 25.

In its second cause of action ("Count Two"), the FTC asserts that Defendants' advertising of the Insulin Resistance Pack made the following deceptive claims:

a. Insulin Resistance Pack reverses insulin resistance;

b. Insulin Resistance Pack manages insulin resistance;

c. Insulin Resistance Pack prevents diabetes;

d. Scientific studies prove that Insulin Resistance Pack is an effective treatment for insulin resistance; and

e. Insulin Resistance Pack is clinically proven to cause an average drop in blood glucose levels of 31.9%.

*Id*., ¶ 26. The FTC further alleges that these representations "are false or were not substantiated at the time they were made," and therefore, that the making of these representations constituted a deceptive act or practice and false advertising, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52. *Id*., ¶ 27.

The FTC alleges that "[c]onsumers have suffered and will continue to suffer substantial

injury as a result of Defendants' violations of the FTC Act" and that Defendants have been unjustly enriched as a result of the alleged conduct. *Id*., ¶ 28. The FTC requests a permanent injunction to prevent further violations of the FTC Act, as well as other relief "as the Court finds necessary to redress injury to consumers . . . including, but not limited to, rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies." *Id*., Prayer.

**C. The Motions**

In its summary judgment motion, the FTC contends the undisputed facts establish liability on both of its causes of action. FTC Motion at 3. In particular, according to the FTC, the undisputed facts demonstrate that all nine claims alleged in the FAC (listed above) were made by Defendants, that the claims were likely to mislead reasonable consumers because Defendants lacked a reasonable basis for making the claims, and that the representations were material. To establish that the claims were unsubstantiated, the FTC offers an expert report by Dr. W. Timothy Garvey. The FTC further contends that the undisputed facts establish that it is entitled to an award of consumer restitution in the amount of $2,198,612.12 and injunctive relief as set forth in its proposed order. It also asserts both Robert and Robyn Held should be held individually liable in this action as to the award of monetary damages.

In their Opposition brief, Defendants argue that their advertisements do not make any of the nine claims set forth in the FTC's complaint. Defendants further assert that the FTC is not entitled to summary judgment on liability because the determination of whether their advertising claims are likely to mislead must be made with reference to the distinctive substantiation requirements that the Food and Drug Administration ("FDA") applies to medical foods, which the FTC has not considered. Defendants also argue that Dr. Garvey's testimony relating to whether Defendants' claims are substantiated should be excluded as unreliable and lacking credibility. As to the consumer injury damages sought by the FTC, Defendants do not dispute the calculation of WSN's sales (in the amount of $2,198,612.12) but contend there is a genuine dispute of material fact as to whether this amount represents actual consumer injury. Defendants assert that if there is any consumer injury, the appropriate amount should be $468,568.56. Defendants also argue that

Robert and Robyn Held should not be held individually liable because they did not act in a knowingly dishonest way. Finally, they contend the provisions of the FTC's proposed injunction, which requires regular disclosures to the FTC of certain types of information for a period of twenty years, is unreasonable.

Defendants seek summary judgment on the FTC's causes of action for the same reason they oppose the FTC motion, namely, WSN's products are medical foods and therefore the FDA's substantiation requirements for medical foods must be taken into account. Defendants further assert that the claims made in their advertising were not misleading because they were "substantially qualified" and because Defendants advised their customers to use their products "as part of a constellation of modalities to improve their condition." Defendants also seek summary judgment on liability on the grounds that the FTC's standard: 1) violates the First Amendment of the United States Constitution; 2) circumvents the Administrative Procedures Act, 5 U.S.C. § 553 *et seq*. ("APA"); and 3) is an unlawful use of a guidance document. Defendants further seek summary judgment that Robert and Robyn Held are not individually liable as to any award of restitution. According to Defendants, individual liability as to money damages cannot be established because the evidence is not sufficient to show that either Robert or Robyn acted in a knowingly dishonest way. Defendants ask that the Court consider the testimony of their expert, Dr. Charles, on the question of individual liability even though the Court has held that Dr. Charles's testimony is inadmissible to establish that Defendants' claims about their products are not misleading.

The FTC argues in its response that there is sufficient evidence to establish individual liability on a restitution award as to both Robert and Robyn Held. It also rejects Defendants' assertion that its advertising was not misleading because it included disclaimers and instructions about how the product should be used. The FTC argues that Dr. Charles's testimony is inadmissible for all purposes under the Court's previous ruling. Finally, the FTC argues that the requirements of the FDA with respect to medical foods are irrelevant to its claims and that the application of the FTC's standard does not violate the First Amendment or circumvent the APA.

## III. ANALYSIS

### A. Fed. R. Civ. P. 56

Summary judgment on a claim or defense 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." Fed. R. Civ. P. 56(a). In order to prevail, a party moving for summary judgment must show the absence of a genuine issue of 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. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Once the movant has made this showing, the burden then shifts to the party opposing summary judgment to designate "specific facts showing there is a genuine issue for trial." *Id.* "[T]he inquiry involved in a ruling on a motion for summary judgment . . . implicates the substantive evidentiary standard of proof that would apply at the trial on the merits." *Anderson v. Liberty Lobby Inc*., 477 U.S. 242, 252 (1986). On summary judgment, the court draws all reasonable factual inferences in favor of the non-movant. *Id*. at 255.

### B. Admissibility of Expert Testimony

#### 1. Legal Standard

The admissibility of expert testimony is governed by Rule 702 of the Federal Rules of Evidence, which provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

F.R.Evid. 702. In determining whether expert testimony meets the requirements of Rule 702, courts follow the approach set forth in *Daubert v. Merrell Dow Pharms., Inc*., in which the Supreme Court described the relevant inquiry as follows:

> Faced with a proffer of expert scientific testimony, then, the trial judge must determine . . . whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to

> understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.

509 U.S. 579, 590 (1993).

**2. Dr. Garvey**

**a. Background**

The FTC submits the testimony of W. Timothy Garvey, M.D., to establish that WSN's claims about Diabetic Pack and Insulin Resistance Pack are false and/or unsubstantiated. Dr. Garvey has extensive qualifications in the field of diabetes and insulin resistance. Garvey Report at 1-4 & Att. A (curriculum vitae). Dr. Garvey's report begins with a summary of conclusions that tracks the nine claims in the FAC, finding that each claim is misleading. *Id*. at 8-9. He goes on to explain that to substantiate these claims, "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." *Id*. at 20. According to Dr. Garvey, such studies would need to be "controlled," "randomized" and "double-blind." *Id.* In addition, he opines, these studies would have to include enough subjects for the results to be statistically meaningful, and use the same dosages and formulations as are contained in Defendants' products. *Id*. at 24-25. Further, Dr. Garvey addresses the studies performed on each of the individual ingredients in the Products to show why the studies of these ingredients that have been conducted do not provide competent and reliable scientific evidence to support the therapeutic claims made by WSN about the Products. *Id*. at 33-64.

In his deposition, Dr. Garvey testified that he did not review Defendants' advertising or attempt to determine whether Defendants actually made the nine claims that are the basis of the FTC's causes of action. Declaration of Andrew S. Ittleman in Support of Defendants' Opposition to FTC's Motion for Summary Judgment ("Ittleman Opposition Decl."), Ex. A (Garvey Depo.) at 197, 257-258. Rather, he was instructed by the FTC only to evaluate the claims with reference to the scientific evidence. *Id*. at 264. Consequently, Dr. Garvey did not look at WSN's website in "any kind of comprehensive way." *Id*. at 258. Dr. Garvey also testified that his opinions about whether the claims were supported by scientific evidence were based on his experience "as a

scientist and as a physician" and that the standard applied by the FDA to medical foods was "immaterial to the way that [he] looked at [the question]." *Id*. at 199.

Defendants contend Dr. Garvey's opinions are not reliable (because he did not review the WSN website) and not credible (because he did not take into account the fact that Defendants' products are medical foods) and therefore, that his opinions should be excluded under Rule 702 of the Federal Rules of Evidence. WSN Opposition at 9-15. Defendants also cite *Sommerfield v. City of Chicago*, 254 F.R.D, 317, 320-321 (N.D. Ill. 2008), a civil rights case in which an expert's opinion about the quality of a police investigation was excluded because he did not review the actual evidence of the police investigation but instead relied on deposition summaries prepared by the plaintiff's counsel.

**b. Discussion**

Defendants' argument that Dr. Garvey should have considered the FDA's standards for medical foods in formulating his opinions is essentially the same as their argument on the merits as to whether Defendants' claims about the Products are misleading. For the reasons stated below, the Court rejects that argument and therefore declines to exclude Dr. Garvey's opinions on that basis. The Court also rejects Defendants' contention that Dr. Garvey's opinions lack a reliable foundation because he did not review WSN's website to see if Defendants made the claims that FTC attributes to them. Dr. Garvey is an expert in the science and treatment of insulin resistance and diabetes. His opinions about whether the scientific studies support the claims attributed to Defendants by the FTC are based on that expertise. Further, Dr. Garvey did not rely on summaries provided by counsel, in contrast to *Sommerfield*, but on actual scientific studies of the ingredients in Defendants' products. *See* Garvey Report at 29-32 & Attach. E. Thus, his opinions are supported by sufficient facts to be reliable. Accordingly, the Court finds that Dr. Garvey's opinions satisfy the requirements of Rule 702 and are not subject to exclusion.

**3. Dr. Charles**

**a. Background**

In its October 4, 2013 Order, the Court held that the opinions of Defendants' expert, Dr. Charles, did not satisfy the requirements of Rule 702 and *Daubert* because: 1) Dr. Charles did not

address the claims that are the subject of the FTC's causes of action and therefore, his opinions do not satisfy the relevance requirement; and 2) Dr. Charles did not use a methodology that satisfied the reliability requirement. Accordingly, the Court excluded Dr. Charles's testimony.

Defendants now ask the Court to consider Dr. Charles's opinions on the question of individual liability. Defendants' Motion at 7-8. According to Defendants, Dr. Charles's testimony is relevant to individual liability, namely, whether Robyn and Robert Held made statements about their products in order to "hoodwink" their customers. *Id*. at 8 Dr. Charles's testimony is relevant to this question, Defendants assert, because he testified that the Products were "indeed useful for diabetic patients, and that the best way of knowing whether they were having their desired effect was by monitoring the patient." *Id*. at 7.

**b. Discussion**

As the Court discussed in its October 4, 2013 Order, Dr. Charles's opinions – including his opinion that the Products are useful for diabetic patients – are not based on a reliable scientific methodology. As such, his opinions do not satisfy the requirements of Rule 702 even assuming they are relevant to the question of what Robert or Robyn Held knew or believed about the effectiveness of their Products. Accordingly, the Court rejects Defendants' request that it consider Dr. Charles's opinions on the question of individual liability.

**C. Summary Judgment on Liability**

**1. Legal Standard Governing FTC Act Claims**

Section 5(a) of the FTC Act declares unlawful "unfair or deceptive acts or practices in or affecting commerce." 15 U.S.C. § 45(a). Section 12 of the FTC Act prohibits the dissemination of "any false advertisement" in order to induce the purchase of "food, drugs, devices, or cosmetics." 15 U.S.C. § 52(a)(2). It also provides that the dissemination of any such false advertisement is an "unfair or deceptive act or practice in or affecting commerce" within the meaning of section 5. 15 U.S.C. § 52(b). To prevail on a claim under these sections, the FTC must show that 1) there is a representation, omission or practice that 2) is likely to mislead consumers acting reasonably under the circumstances, and 3) the representation, omission or practice was material. *FTC v. Pantron I Corp*., 33 F.3d 1088, 1095 (9th Cir. 1994) (citing *In re*

*Cliffdale Assocs., Inc*., 103 F.T.C. 110, 163-64 (1984)). Where an action is based on affirmative claims by the defendant, the FTC is not required to show that the claims were made with an intent to deceive; claims that are material and misleading violate Sections 5 and 12 of the FTC Act even if they were made in good faith. *F.T.C. v. World Travel Vacation Brokers, Inc.*, 861 F.2d 1020, 1029 (7th Cir. 1988) (citations omitted).

**2. Whether FDA Standard for Medical Foods Must be Considered**

Defendants contend the standard that applies to the FTC's claims must take into account the regulations promulgated by the FDA for medical foods. The Court has already rejected this argument, finding that the degree of regulation to which Defendants' advertising claims would be subject by the FDA is not relevant to the issues in this case. Docket No. 155 at 17. The Court declines to revisit that holding here.[4]

**3. Whether FTC Standard Violates the First Amendment**

Defendants assert the FTC's efforts to regulate the claims they have made about their Products violate their commercial speech rights under the First Amendment of the United States Constitution. The Court disagrees.

Defendants' position is based on a body of case law that addresses the Constitutional requirements that govern the FDA's regulation of dietary supplements. *See, e.g., Pearson v. Shalala*, 164 F.3d 650 (1999). In *Pearson*, the court held that the constitutionality of FDA regulations that required preapproval of claims made on product labels was governed by the three-part test articulated by the Supreme Court in *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980). In *Central Hudson*, in turn, the Supreme Court held that a government scheme to limit potentially misleading commercial speech by an electric utility violated the First Amendment because it was more extensive than necessary to advance the state's legitimate interests in energy. 447 U.S. at 566-571. *Central Hudson*'s three-part test requires

[4] The Court notes that Defendants' request for reconsideration of its ruling on this issue, *see* Defendants' Opposition at 7, does not comply with the requirements of Civil Local Rule 7-9. The Court also declines to rule on Defendants' request that it exclude the FDA's 2013 Draft Guidance, *see* Defendants' Motion at 10-13, because the Court does not rely on that document or make any finding as to whether Defendants' products qualify as medical foods.

courts to consider: 1) whether the asserted government interest is substantial; 2) whether the regulation directly advances the governmental interest asserted; and 3) whether the fit between the government's ends and the means chosen to accomplish those ends is reasonable. *Pearson*, 164 F.3d at 655-656. Applying this test, the *Pearson* court held that a regulation that required preauthorization of labeling claims made by dietary supplement manufacturers did not meet the "fit" requirement under *Central Hudson* because it did not require the FDA to take into account associated disclaimers that might ensure that the proposed labeling claims would not be misleading to consumers. *Id*. at 656-657.

Defendants' reliance on *Pearson* and *Central Hudson* is misplaced. Neither decision stands for the proposition that a manufacturer or seller of dietary supplements – or for that matter, any product – has a First Amendment right to make claims that are false or deceptive. Nor do these cases announce a requirement that the three-part test under *Central Hudson* should be applied to causes of action based on a defendant's allegedly false or misleading advertising. Rather, these cases address the Constitutional requirements that apply to regulations that limit or ban whole categories of speech. The FTC does not rely on such a regulation in this case. Further, it is well-established that deceptive commercial speech is entitled to no protection under the First Amendment. *Florida Bar v. Went For It, Inc*., 515 U.S. 618, 623-34 (1995) ("Under *Central Hudson*, the government may freely regulate commercial speech that concerns unlawful activity or is misleading") (citing *Central Hudson*, 447 U.S. at 557); *see also Zauderer v. Office of Disciplinary Counse*l, 471 U.S. 626, 638 (1985) (holding that it is "well settled" that "[t]he States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading."). Accordingly, the Court finds that the FTC's claims do not implicate Defendants' constitutional rights under the First Amendment.

**4. Whether FTC Standard Violates the APA**

Defendants contend the APA bars the FTC's claims because the FTC is seeking to make new rules through adjudication rather than complying with the procedures that govern rulemaking under the APA. Defendants are incorrect.

Under 15 U.S.C. § 57a(a), the FTC may prescribe "interpretive rules and general

statements of policy with respect to unfair or deceptive acts or practices in or affecting commerce . . . and . . . rules which define with specificity acts or practices which are unfair or deceptive acts or practices in or affecting commerce." In prescribing such rules, the FTC must adhere to certain procedural requirements, which include providing notice of the proposed rule and an opportunity for comment. 15 U.S.C. § 57a(b). In *Patel v. Immigration and Naturalization Service*, the Ninth Circuit held that "an administrative agency . . . 'is not precluded from announcing new principles in an adjudicative proceeding and that the choice between rulemaking and adjudication lies in the first instance within the (agency's) discretion.'" 638 F.2d 1199, 1203 (9th Cir. 1980) (quoting *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 294 (1974)). The Supreme Court has explained the reason for this discretion as follows:

> [P]roblems may arise in a case which the administrative agency could not reasonably foresee, problems which must be solved despite the absence of a relevant general rule. Or the agency may not have had sufficient experience with a particular problem to warrant rigidifying its tentative judgment into a hard and fast rule. Or the problem may be so specialized and varying in nature as to be impossible of capture within the boundaries of a general rule. In those situations, the agency must retain power to deal with the problems on a case-to-case basis if the administrative process is to be effective. There is thus a very definite place for the case-by-case evolution of statutory standards. And the choice made between proceeding by general rule or by individual, ad hoc litigation is one that lies primarily in the informed discretion of the administrative agency. *See Columbia Broadcasting System v. United States*, 316 U.S. 407, 421, 62 S.Ct. 1194, 1202, 86 L.Ed. 1563.

*Securities and Exchange Commission v. Chenery Corp*., 332 U.S. 194, 202-203 (1947). Nonetheless, an agency may abuse its discretion when it makes a "prospective pronouncement of a broad, generally applicable requirement [in an adjudication], without application of the requirement to the parties before the [agency]." *Patel*, 638 F.2d at 1203 (citing *NLRB v. Wyman-Gordon Co.*, 394 U.S. 759, 763 (1969)).

In this case, the FTC relies on well-established rules and legal theories in seeking to establish that Defendants' claims violate Sections 5 and 12 of the FTC Act because they are false and lack substantiation. The FTC is not attempting to announce through adjudication any broad new rule that would require that it follow the rule-making procedures set forth in 15 U.S.C. § 57a(b). Rather, the FTC's action falls well within the agency's discretion. Therefore, the Court

rejects Defendants' assertion that the FTC's causes of action run afoul of the APA.[5]

**5. Whether Claims Were Made**

To show that a claim has been made, the FTC must establish that either 1) the representation has been explicitly stated in the defendant's advertising, or 2) the defendant's advertising, when viewed from the perspective of a reasonable consumer, gives the "net impression" that such a claim has been made. *F.T.C. v. Stefanchik*, 559 F.3d 924, 928 (9th Cir., 2009); *see also F.T.C. v. Direct Marketing Concepts, Inc*., 569 F.Supp.2d 285, 298 (D.Mass., 2008) (citations omitted). The Court may determine whether a defendant's advertising gives the "net impression" that a particular claim was made. *F.T.C. v. US Sales Corp*., 785 F.Supp. 737, 745 (N.D.Ill., 1992) (citing *FTC v. Colgate-Palmolive Co*., 380 U.S. 374 (1965)). "Advertising capable of being interpreted in a misleading way should be construed against the advertiser." *Resort Car Rental System, Inc. v. F. T. C*., 518 F.2d 962, 964 (9th Cir. 1975).

**a. Diabetic Pack is an effective treatment for diabetes (claim 1)[6]**

The Court concludes that Defendants' advertising gives the net impression that Diabetic Pack is an effective treatment for diabetes. As described above, WSN's advertisements for Diabetic Pack repeatedly claimed that Diabetic Pack lowers blood sugar and even that it can take the place of diabetes medications. *See, e.g.*, Ortiz Decl., Ex. 9 (listing successful past PPC ads including "Clinically Proven Drug Free Solution That Lowers Blood Sugar" and "Natural Diabetes Medicine Lower Blood Sugar, No Side Effects"); *id*., Exs. 42-45 (webpages for 2008 through 2010 advertising the Diabetic Pack as a "Diabetes Breakthrough" that will "[l]ower your blood sugar, safely and effectively with absolutely NO SIDE EFFECTS!! GUARANTEED!!");

[5] Defendants also challenge the FTC's purported reliance on a guidance document issued by the FTC. Defendants' Motion at 17-18. In particular, the FTC cited an "FTC Policy Statement Regarding Advertising Substantiation" in its opposition to Defendants' first motion to dismiss. *See* Docket No. 18 at 9. The FTC also cited the Ninth Circuit's decision in *Pantron I*, however, to support the same proposition. *Id*. Further, while the FTC cited this guidance document, it did not rely on it to establish any legal standard that is not also contained in applicable Ninth Circuit and Supreme Court decisions. Accordingly, there is nothing improper in the FTC's citation of that document.

[6] To avoid confusion, the Court adheres to the numbering used by the FTC in its Motion. The Court notes that the order in which the FTC addresses the claims alleged in the FAC switches the order of FAC Count 1(b) (now claim 3) and Count 1(c) (now claim 2).

*id.*, Exs. 42-43 (advertisements on 2007-2008 webpages listing "Lower Blood Glucose Levels" as one of the "Breakthrough Benefits" of Diabetic Pack); *id*, Exs. 42-46 (2007-2010 webpages containing customer testimonials claiming that customers had lowered their blood sugar using Diabetic Pack, including one by "Barbara Culver" stating that her blood sugar had dropped to the "low 100s" due to Diabetic Pack and that she stopped taking insulin ). Considered in light of Dr. Garvey's opinion that "[t]he overall goal for treatment of diabetes or prediabetic conditions is to optimize control of blood glucose levels," Garvey Report at 17, these advertisements would give a reasonable consumer the impression that Diabetic Pack is an effective treatment for diabetes.

**b. Scientific studies prove that Diabetic Pack is an effective treatment for diabetes (claim 2)**

The Court further finds that Defendants' advertising claimed that *scientific studies prove* that Diabetic Pack is an effective treatment for diabetes. In particular, Defendants' PPC advertising referred to the Diabetic Pack as "clinically proven" and its website stated that its ingredients were "validate[d]" by Nobel Prize Winning technology." Ortiz Decl., Exs. 9, 42-45. It also stated that "Nobel Prize winning science and over 60 independent American university studies confirm the superiority of [the] Foodform® technology" used in Diabetic Pack. *Id.*, Exs. 42-45. The website also claimed that "[s]tudies show a 31.9% drop in blood sugar levels" and went on to state that "[a] recent independent clinical trial was done on one of the[] herbal ingredients from this amazing product " and that type 2 diabetics "reported an average drop of blood glucose levels of 31.9%." *Id*. at 1-2.

The Court rejects Defendants' contention that these claims related only to the ingredients in their Foodform® technology and not to Diabetic Pack. *See* Defendants' Opposition at 2-3. Any reasonable consumer reading the description on Defendants' website of how Diabetic Pack works would conclude that the scientific studies relating to the Foodform® ingredients also establish that Diabetic Pack is effective in treating diabetes. *See* Ortiz Decl., Exs. 42-44 at 2; *id*., Ex. 45 at 2-3.

**c. Diabetic Pack reduces or eliminates the need for insulin and other diabetes medications (claim 3)**

The Court further finds that a reasonable consumer would get the net impression from

Defendants' advertising that Diabetic Pack reduces or eliminates the need for insulin and other diabetes medicine, notwithstanding references to diet and exercise or disclaimers advising consumers that they should use the Diabetic Pack under medical supervision and should continue to take their prescribed medication.

WSN's PPC advertising expressly promised a "drug-free" "solution" to diabetes. Ortiz Decl., Ex. 9. Similarly, Defendants' website stated that one of Diabetic Pack's "breakthrough benefits" is "less dependency on medications." Ortiz Decl., Exs. 42-45 at 2. The webpage also suggested that Diabetic Pack would reduce the need for medication by addressing the underlying causes of diabetes, stating as follows:

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

Ortiz Decl., Exs. 42-45 at 2. This impression was further reinforced by testimonials. "Barbara Culver" described how she eliminated "50 units of insulin" while achieving lower blood sugar with Diabetic Pack." Ortiz Decl., Exs. 42-46 at 2-3. "Jeff Rice" stated that he "threw all the medicines out the window and went a month with no medicine and just the Diabetic Pack supplements [and] . . . leveled off in the 120 (blood glucose) range." Ortiz Decl., Ex. 47 at 1-2. While it is true that some of these testimonials referred to the use of diet and exercise along with the Diabetic Pack, the overall impression of the testimonials was that it was the use of Diabetic Pack rather than a change in diet or increase in exercise that constituted the "breakthrough." *See, e.g.*, Ortiz Decl., Ex. 47 at 12 (testimonial of Susan Strouss stating that "diet and exercise were not working" and that although she had lost 110 pounds her blood sugar level was not going down").

Nor do WSN's disclaimers warning consumers that they should continue to take their medications counteract the net impression given by its advertising that Diabetic Pack would reduce or eliminate the need for insulin. For example, Defendants point to the following statement on their FAQ webpage:

> 3. When starting on the WSN Insulin Resistance Pack can I stop

> using other medications I am taking for my insulin resistant condition?
>
> You should continue to take any medications that have been prescribed by your physician. As your symptoms begin to reverse ... you should inform your physician about what is happening and that you want to reduce the amount of medications you are taking accordingly. Working together with your physician, you can continue to reduce any medications you are taking, and in some cases, completely eliminate the use of all medications.

Defendants' Opposition at 4; Ortiz Decl., Ex. Ex. 39 (2011 webpage) at 1. While this disclaimer advises that people should keep taking their medications when they start on Diabetic Pack, it also gives the strong impression that their need for insulin or other diabetes medications will be reduced as a result of using the Diabetic Pack.

Based on the above, the Court finds that Defendants' advertising claimed that Diabetic Pack reduces or eliminates the need for insulin and other diabetes medications.

**d. Diabetic Pack is clinically proven to cause an average drop in blood glucose levels of 31.9% (claim 4)**

Defendants claimed on their website, "Nobel Prize winning technology validates WSN Diabetic Pack Ingredients! Studies show a 31.9% drop in blood sugar levels!" Ortiz Decl., Exs. 42-45 at 1. While the website later stated that the "studies" were an "independent clinical trial" conducted on only one of the ingredients in Diabetic Pack, a reasonable consumer would get the overall impression that the claim referred not just to that single ingredient but also to Diabetic Pack. Ortiz Decl., Exs. 42-45 at 2. Therefore, the Court finds, based on the undisputed facts, that Defendants claimed on their website that Diabetic Pack is clinically proven to cause an average drop in blood glucose levels of 31.9%.

**e. Insulin Resistance Pack reverses insulin resistance (claim 5)**

WSN expressly claimed on its website that Insulin Resistance Pack reverses insulin resistance. Ortiz Decl., Exs. 30-41 at 1 (stating that the Insulin Resistance Pack "[r]everses insulin resistance, safely and effectively with absolutely NO SIDE EFFECTS!! GUARANTEED!!"). In 2008 and 2011, Defendants' website also stated, "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!!" *Id*., Exs. 31 & 34 at 1. Defendants' assertion that their website never stated that their product *alone* reversed insulin resistance misses the mark. *See* Defendants' Opposition at 5. Any reasonable consumer would understand from the headings on Defendants' website that Defendants were claiming that use of the Insulin Resistance Pack achieved this result. No more is required to establish that Defendants made this claim.

**f. Insulin Resistance Pack manages insulin resistance (claim 6)**

Defendants' website consistently contained the headline, "Insulin Resistance Breakthrough," followed by the statement that Insulin Resistance Pack is "specifically formulated for the dietary management of insulin resistance." Ortiz Decl., Exs. 22, 30, 32, 33, 38 & 41 at 1. Defendants' website also stated that "[t]he WSN Insulin Resistance Pack is a medical food for the dietary management of insulin resistance." Ortiz Decl., Exs. 22, 38 at 1. Given these express statements, there is no genuine dispute that Defendants claimed that Insulin Resistance Pack manages insulin resistance.

**g. Insulin Resistance Pack prevents diabetes (claim 7)**

Defendants' website claimed in 2008 and 2011, "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!" Ortiz Decl., Exs. 17-18 at 1. Other versions of Defendants' website stated that one of the "breakthrough benefits" of Insulin Resistance Pack is that it "helps prevent diabetes." Ortiz Decl., Exs. 19-23 at 1; *see also id*., Exs. 17-23 at 1 (warning that insulin resistance gets worse and becomes type 2 diabetes if "effective action" is not taken and telling readers that there is "good news" because "cutting-edge science and nutrition have come together to create a truly monumental and natural breakthrough for people who are insulin resistant," thus giving the impression that Insulin Resistance Pack can prevent insulin resistance from turning into diabetes). These express statements establish, as a matter of law, that Defendants claimed that Insulin Resistance Pack prevents diabetes.

**h. Scientific studies prove that Insulin Resistance Pack is an effective treatment for insulin resistance (claim 8)**

The Insulin Resistance Pack webpage, like the Diabetic Pack webpage, consistently

represented that "Nobel Prize winning science and over 60 independent American university studies confirm the superiority of Foodform® technology." Ortiz Decl., Ex. 17 & 18 at 2; *id.*, Ex. 19 at 1-2; *id*., Ex. 20-21 at 2; *id*., Ex. 23 at 1. Defendants also linked the "independent clinical trial" conducted on one of the Foodform® ingredients to the effectiveness of the Insulin Resistance Pack, just as they did in their Diabetic Pack advertising. *Id*. Therefore the Court concludes that there is no genuine dispute that Defendants claimed that scientific studies prove that Insulin Resistance Pack is an effective treatment for insulin resistance.

**i. Insulin Resistance Pack is clinically proven to cause an average drop in blood glucose levels of 31.9% (claim 9)**

WSN's Insulin Resistance Pack webpage contained the following statement:

> 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% and average weight loss of 4.8 pounds in just 30 days!

Ortiz Decl., Exs. 24-27 at 3-4; *id*., Ex. 28 at 4; *id*., Ex. 29 at 3-4. As discussed above, Defendants' advertising linked this study to the Insulin Resistance Pack in its description of how its product worked, namely using Foodform® technology. A reasonable consumer would get the net impression, based on Defendants' advertising, that Insulin Resistance Pack is clinically proven to cause an average drop in blood glucose levels of 31.9% and therefore there is no dispute of material fact that Defendants made this claim.

**6. Whether Claims Were Misleading**

**a. Legal Standard**

The FTC can prove that a representation is likely to mislead consumers – the second requirement to establish a violation of Sections 5 and 12 of the FTC Act – by establishing either 1) actual falsity of express or implied claims or 2) that the advertiser lacked a reasonable basis ("reasonable basis theory") for asserting that the message was true. *FTC v. Pantron I Corp*., 33 F.3d 1088, 1096 (9th Cir. 1994) (citations omitted). In *Pantron I*, the court explained that "[i]n determining whether an advertiser has satisfied the reasonable basis requirement, the . . . court must first determine what level of substantiation the advertiser is required to have for his

advertising claims. Then, the adjudicator must determine whether the advertiser possessed that level of substantiation." *Id*. The FTC has the burden of establishing that the advertiser's claims lack adequate substantiation. *Id*. The FTC is not required, however, to "conduct or present clinical studies showing that the product does not work as claimed." *F.T.C. v. QT, Inc*., 448 F.Supp.2d 908, 959 (N.D.Ill., 2006).

The reasonable basis theory distinguishes between two types of advertising claims – those that contain express representations about the level of support for the claim ("establishment claims") and those that simply claim that the product is effective without indicating any particular basis for the claim ("non-establishment claims"). *Removatron Intern. Corp. v. F.T.C.*, 884 F.2d 1489, 1492 n. 3 (1989). Where an establishment claim includes a particular level of substantiation (for example, a claim that scientific studies support the claim), the advertiser must show that the claim is supported by that level of substantiation. *Id*. The court must determine the appropriate level of substantiation for non-establishment claims. *F.T.C. v. QT, Inc*., 448 .Supp.2d at 959. To determine the appropriate level of substantiation for non-establishment claims, courts can look to a number of factors, including "1) the type of claim; (2) the product; (3) the consequences of a false claim; (4) the benefits of a truthful claim; (5) the cost of developing substantiation for the claim; and (6) the amount of substantiation experts in the field believe is reasonable." *Id.* (citing FTC Policy Statement Regarding Advertising Substantiation (appended to *In re Thompson Med. Co*., 104 F.T.C. 648, 839 (1984))).

**b. Discussion**

The claims discussed above include both establishment claims, *ie*., claims that are purportedly based on scientific studies (claims 2, 4, 8 and 9) and non-establishment claims (claims 1, 3, 5, 6 and 7). The FTC contends all of the claims are misleading because they lack a reasonable basis and that in addition, the establishment claims are actually false. The Court agrees.

As a preliminary matter, the Court addresses the level of substantiation required as to WSN's claims. As discussed above, for establishment claims advertisers must have the level of substantiation referenced in the claim itself whereas for non-establishment claims the Court must

determine the appropriate level of substantiation. Dr. Garvey applies the same standard to both establishment claims and non-establishment claims, opining that to support Defendants' claims, "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." Garvey Report at 20. He explains that a high level of support is required of claims such as the ones made by Defendants in this case because they are disease-specific treatment or prevention claims. *Id*. (citing standards used by United States Preventive Services Task Force to evaluate the quality of a scientific study regarding preventive services). The Court finds that this standard is appropriate as to both types of claims. As to the establishment claims, Defendants' claims reference clinical and scientific studies and thus, the opinion of diabetes experts as to what would support these claims provides an appropriate level of substantiation. The Court further finds that the standard is appropriate for the non-establishment claims, based on the factors listed above, because Defendants have made claims about treatment of a serious health condition where the consequences of adopting a particular course of treatment may be significant. In particular, the benefits of a truthful claim about a product that purports to be effective in the treatment of diabetes would be high; conversely, the consequences of a false claim – which in this case could include encouraging consumers with diabetes to stop using insulin or other medication to treat their condition – is also high.

Applying this standard, Dr. Garvey has offered detailed reasons for concluding that all nine of Defendants' claims lack adequate substantiation and, as to the establishment claims, are actually false. According to Dr. Garvey, well-designed human clinical studies to substantiate WSN's claims would need to be controlled, randomized, double-blind and statistically meaningful. *Id*. at 21, 25. In addition, the dosages and formulations studied should be the same as those sold by WSN because "physiological responses to drugs, vitamins, and minerals vary depending on dose[;] and . . . there may be interactions between the ingredients that affect their physiological actions." *Id*. at 25. Dr. Garvey concluded that no studies that adhere to these requirements exist for the challenged Products. *Id*. at 26 ("I conclude that none of the WSN claims… are supported by competent and reliable scientific evidence."). Defendants admit as

much. JSUF ¶ 31.

Dr. Garvey further opined that the studies cited by Defendants as to the individual ingredients in their Products are flawed in numerous respects beyond the fact that they do not test Defendants' Products. First, Dr. Garvey found that many of the studies cited by WSN were conducted in vitro or on animals and therefore cannot substantiate that the tested ingredients work in humans. *Id*. at 23-24. Second, Dr. Garvey identified numerous shortcomings in the single-ingredient studies that make them inapplicable to WSN's products, including insufficient size, lack of placebo or other controls, and testing of much larger doses than are found in WSN's products. *Id*. at 26-64. Third, Dr. Garvey found 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. *Id*. at 34 (calcium), 43-47 (magnesium), and 50-55 (chromium).

Defendants offer no admissible evidence sufficient to show a dispute of fact as to the actual falsity of the establishment claims or lack of a reasonable basis as to all of the claims. Although they cite a "wide array of studies regarding the individual ingredients" that purportedly show the beneficial effect of these ingredients, Opposition at 15, this opinion amounts to nothing more than argument by counsel as Defendants have offered no expert testimony to show that any of these studies support their claims. Further, the Court rejects Defendants' assertion that the claims are adequately substantiated because their Products are medical foods, as discussed above. Accordingly, the Court finds based on the undisputed facts that the FTC has demonstrated that all of Defendants' claims are misleading.

**7. Whether Claims Were Material**

Finally, the FTC must establish that the claims at issue are material, that is, that they "involve[ ] information that is important to consumers and, hence, likely to affect their choice of, or conduct regarding a product." *F.T.C. v. QT, Inc*., 448 F.Supp.2d at 960 (citations and quotations omitted). Express claims are presumed to be material. *FTC v. Pantron I Corp*., 33 F.3d at 1095-1906. Materiality is also presumed as to "claims that significantly involve health, safety, or other issues that would concern reasonable consumers." *F.T.C. v. QT, Inc*., 448

F.Supp.2d at 960. Because all of the claims in this case significantly involve the consumer's health, the materiality requirement is met.

**8. Conclusion**

The Court finds that the FTC is entitled to summary judgment that Defendants violated Sections 5 and 12 of the FTC Act based on the nine claims alleged in the FAC because the undisputed facts establish that: 1) Defendants' advertising made the nine claims; 2) the claims were misleading; and 3) the claims were material.

**9. Whether Robert and Robyn Held are Individually Liable**

Having found that Defendants' advertising violated the FTC Act, the Court now turns to the question of whether summary judgment is warranted as to the individual liability of Defendants Robert and Robyn Held. The Court concludes that the undisputed facts are sufficient to establish individual liability as to both Robert Held and Robyn Held.

An individual may be held liable for injunctive relief under the FTC Act on the basis of corporate acts or practices where: "1) . . . corporation committed misrepresentations or omissions of a kind usually relied on by a reasonably prudent person, resulting in consumer injury, and 2) . . .[the individual] participated directly in the acts or practices or had authority to control them." *FTC v. Publishing Clearing House*, 104 F.3d 1168, 1170 (9th Cir. 1997). To hold an individual liable for restitution on the basis of a violation of the FTC Act by the corporation, the FTC must also show that the individual had knowledge of the deception. *Id*. at 1171. To satisfy this requirement, the FTC must show that the individual "had actual knowledge of material misrepresentations, [was] recklessly indifferent to the truth or falsity of a misrepresentation, or had an awareness of a high probability of fraud along with an intentional avoidance of the truth." *Id.* (quoting *FTC v. American Standard Credit Systems, Inc*., 874 F. Supp. 1080, 1087 (C.D. Cal. 1994)). The FTC is not required to show, however, that an individual intended to defraud consumers in order to establish personal liability. *Id*.

Defendants do not dispute that Robert and Robyn Held participated in the advertising that is the subject of this action and had authority to control it. Rather, the only issue relating to individual liability is whether the undisputed facts establish that these Defendants satisfy the

knowledge requirement. The Court finds the Ninth Circuit's decision in *FTC v. Garvey*, 383 F.3d 891 (9th Cir. 2004), as well as a decision by this Court distinguishing *Garvey*, *FTC v. Medlab, Inc.*, 615 F. Supp. 2d 1068 (N.D. Cal. 2009), to be helpful in understanding the knowledge requirement. Both cases involve alleged violations of Sections 5 and 12 of the FTC Act based on claims about weight loss products that are similar to the claims in this action.

In *Garvey*, the FTC sought to impose individual liability on a spokesperson ("Garvey") who was hired to appear in infomercials about a weight loss product. 383 F.3d at 894-895. Garvey appeared in two infomercials and largely read from prepared scripts. *Id*. at 894. Three week before filming the first infomercial he and his wife were given samples of the product; prior to the filming of the first infomercial, Garvey lost eight pounds using the product. *Id*. Between the first and second infomercials, Garvey's wife lost 27 pounds using the product. *Id*. Garvey also received from the manufacturer two booklets with findings about the product sometime before the first infomercial. *Id*. After the infomercials, Garvey made several television and radio appearances to promote the product in which his statements were based on script points or guidelines provided by the manufacturer of the product. *Id*. at 895. Following a bench trial, the district court found that Garvey was not individually liable because he did not have actual knowledge of any material misrepresentation, he was not recklessly indifferent to the truth and he did not intentionally avoid the truth despite being aware that fraud was highly probable. *Id*. at 896. On appeal, the FTC argued that the evidence was sufficient to show that Garvey was recklessly indifferent or was aware that fraud was highly probable and intentionally avoided the truth. *Id*. at 901. The Ninth Circuit disagreed, holding that Garvey did not have the requisite mental state to support individual liability. *Id*. at 902. In reaching this conclusion, the court relied on the experience of Garvey and his wife using the product and the booklets about the products provided to Garvey by the company, stating: "Garvey had first-hand anecdotal evidence of the efficacy of the [weight loss product] and had information that purported to present scientific bases for his claims." *Id*.

The court went on to state that this information "was sufficient – at least for someone in Garvey's position – to avoid participant liability." *Id*. In a footnote, the Ninth Circuit also noted

that the fact that an individual is "merely a [hired] spokesperson is relevant" in determining whether an individual recklessly disregarded the truth or avoided the truth where there was a high probability of fraud. *Id*. at 902 n. 12. The reckless indifference standard "implies that an individual's subjective understanding should be taken into account," the court continued. *Id*. In light of Garvey's position, the Court held, Garvey was "only required to examine the material from the perspective of a reasonable layperson." *Id*. The Court found this standard was met based, in part, on the fact that the booklets that Garvey had been given purported to point to findings that supported the effectiveness of the weight loss product. *Id*. at 902.

In *Medlab*, the court reached the opposite result where the individual defendant, Scott Holmes, ran all the Defendant companies alleged to have violated Sections 5 and 12 of the FTC Act and was responsible for writing and placing all the advertisements that were the subject of the action. 615 F. Supp. 2d at 1073. These advertisements included claims that the effectiveness of the product was shown by "clinical studies." *Id.* The defendants argued that Holmes could not be held personally liable because he had a good faith belief that the product worked. *Id*. at 1081. Like Garvey, Holmes claimed that he personally had used the product and had lost 18 pounds. *Id*. at 1082. Nonetheless, the court found the facts of the case to be "obviously distinguishable" from the facts in *Garvey*. *Id*. The court cited evidence that Holmes was "deeply involved in designing the composition of the products and composing the representations at issue" in the case. *Id*. It also cited the "lack of evidence that the representations in his advertisements are scientifically possible or supported by clinical studies." *Id*. In addition, the court pointed out that Holmes continued to place misleading ads even after the FTC initiated a "red flag" campaign warning of "bogus claims" in his advertisements. *Id*. Finally, the court found that Holmes's statement that he had lost weight using the product did not create a factual dispute because the statement did not address whether the weight loss was achieved without dieting or exercising (as claimed in the defendants' advertisements) and did not cite to any clinical studies showing this result could be expected in any user. *Id*. Thus, the court concluded, there was no genuine dispute of fact as to individual liability. *Id*.

Here, as in *MedLab*, there is extensive and undisputed evidence that Robert Held was at

least recklessly indifferent to the truth or falsity of the representations in WSN's advertising about Diabetic Pack and Insulin Resistance Pack. Like Holmes – and in contrast to Garvey – the undisputed facts show that Robert Held founded WSN and ran the company together with his daughter Robyn. Further, Robert Held designed the composition of the products himself, like Holmes. *See* JSUF ¶¶ 29-30, 61-62. It is undisputed that Mr. Held is not trained as a scientist or a doctor but rather, obtained the information upon which he based the composition of the Products from research he conducted on the Internet. JSUF ¶ 29. It is also undisputed that Robert and Robyn Held developed all of WSN's advertising together and Robert Held drafted newsletters that were sent to WSN's customers and available on the website. JSUF ¶ 6. Given that this advertising contained statements about the effectiveness of the Products, including statements that indicated that scientific studies supported these claims, the undisputed facts in this case, as in *Medlab*, establish that Robert Held had the knowledge required to support individual liability.[7]

Similarly, while Robyn Held argues that she justifiably relied on Robert regarding the claims made, no reasonable fact finder could conclude that she was anything but reckless. It is undisputed that Robyn Held has never been involved in the formulation of the Products. The FTC also does not offer any evidence that controverts the testimony of Robyn Held that she was not responsible for determining the accuracy of the claims made in WSN's advertising but rather, that this was Robert Held's responsibility. However, Robyn Held (in contrast to Garvey) is a co-owner of WSN, plays a significant role in running the company, and was extensively involved in the creation of the advertising that is the subject of this action, including drafting and editing website content, and helping with the selection of testimonials and key-words. Nor is it disputed that Robyn Held was aware that the composition of the Products was based on Robert's research on the Internet, that Robert had no formal medical or scientific training that qualified him as an

[7] The Court notes that it does not rely on the FDA warning letters in support of this conclusion, which are cited by the FTC to establish individual liability. *See* FTC Opposition at 7 (Robert Held) and 14 (Robyn Held). As discussed above, the Court finds that the question of whether WSN's advertising complied with FDA requirements is not relevant to the claims in this case. Consequently, letters warning WSN that its advertising did not comply with those requirements has little bearing on the question of whether the Helds knew that WSN's advertising did not comply with the FTC Act.

expert on the treatment of diabetes, and that the Products were never scientifically tested. The Court concludes that in light of this knowledge, Robyn Held's conduct in relying on Robert Held's judgment as to the scientific validity of the claims made by WSN about the Products reflects reckless indifference to the truth or falsity of those statements.[8]

Therefore, both Robert and Robyn Held are personally liable for WSN's violations of the FTC Act.

**D. Summary Judgment on Remedy**

Under Section 13(b) of the FTC Act, "the Commission may seek, and after proper proof, the court may issue, a permanent injunction." 15 U.S.C. § 53(b). The Ninth Circuit has held that this provision gives the federal courts broad authority in determining appropriate remedies for violations of the FTC Act. *FTC v. Pantron I Corp*., 33 F.3d at 1102. In *Pantron I*, the court held that "the authority granted by section 13(b) is not limited to the power to issue an injunction; rather, it includes the authority to grant any ancillary relief necessary to accomplish complete justice.'" *Id*. (quoting *F.T.C. v. H.N. Singer, Inc*., 668 F.2d 1107, 1113 (9th Cir.1982)). Thus, the district court has broad discretion to order restitution and/or a permanent injunction where a violation of the FTC Act has been established. *Id*.

**1. Whether there is a Genuine Dispute of Fact as to Amount of Consumer Injury**

"[B]ecause the FTC Act is designed to protect consumers from economic injuries, courts have often awarded the full amount lost by consumers rather than limiting damages to a defendant's profits." *FTC v. Stefanchik*, 559 F.3d 924, 931 (9th Cir. 2009). Thus, in *Stefanchik*, the court awarded, on summary judgment, the full amount of the defendant's net sales where the evidence offered by the FTC – a statement by the president of the defendant company and an accounting report listing the amount of the defendant's net sales – was uncontroverted. *Id*. Here, the Court finds that the FTC is entitled to an award of restitution in the amount of $2,198,612 on summary judgment.

[8] At oral argument, the parties stipulated that while a party's state of mind is generally a fact question, there are no disputes as to the facts in this case regarding the state of mind of Robyn Held. Thus, the determination of whether she may be held individually liable is one of law and may be decided on summary judgment.

The FTC has introduced the Declaration of David Gonzalez in Support of Federal Trade Commission's Motion for Summary Judgment ("Gonzalez Decl.") to establish the amount of WSN's net sales of Diabetic Pack and Insulin Resistance Pack between 2004 and 2012. Gonzalez based his calculation on Microsoft Excel spreadsheets produced by WSN and offered a summary of the calculation as an attachment. Gonzalez Decl., Ex. A. Defendants do not dispute the accuracy of the calculation but contend the FTC has improperly included items from the Excel spreadsheets with result codes that do not represent consumer injury, namely, credits (CRE), errors (ERR), out-of-country sales (OCC) and reorders (REO, ASB and AUT). *See* Ittleman Opposition Decl., Ex. K (Declaration of Robyn Held in Support of Defendants' Opposition to Plaintiff's Motion for Summary Judgment) ("Robyn Held Decl."). According to Robyn Held, when these amounts are deducted, the total sales amount to $468,568.56. *Id*.

With respect to the CRE, ERR and OCC codes, Defendants' position fails because it is clear from the Gonzalez Declaration and attached summary that the revenue for transactions with these codes was considered to be 0. *See* Gonzalez Decl., Ex. A. The Court also rejects Defendants' assertion that the reorders should be excluded from the restitution award. Defendants contend reorders reflect purchases by satisfied customers and as such, do not establish consumer injury. WSN Opposition at 17. The Court disagrees. "A presumption of actual reliance arises once the Commission has proved that the defendant made material misrepresentations, that they were widely disseminated, and that consumers purchased the defendant's product." *F.T.C. v. Figgie Intern., Inc*., 994 F.2d 595, 605-606 (9th Cir. 1993). At least one court has held that this presumption is not rebutted merely because a customer reorders the product, reasoning as follows:

> While it may be logical to infer that the customers who reordered the defendants' products relied to some degree upon their experience with the products, the fact that the customers' experiences played a role in their purchasing decisions does not mean or even imply that the customers did not also rely upon the representations in the advertisements when making their subsequent purchases. . . . The FTC has demonstrated that the defendants made material representations, that the misrepresentations were widely disseminated, and that consumers purchased the defendants' products; thus, the court may presume that the consumers actually relied upon the advertisements, even when making subsequent purchases. *See Figgie International*, 994 F.2d at 605–06. To rebut this presumption, the defendants must introduce evidence

> demonstrating that the repeat customers did not rely on the advertisements. *Id.* at 606. The defendants have presented nothing more than mere speculation in this regard and, thus, have failed to meet their burden. Accordingly, the court will not reduce the defendants' monetary liability by the amount of the sales to consumers who reordered the products.

*F.T.C. v. National Urological Group, Inc*., 645 F.Supp.2d 1167, 1213 (N.D.Ga., 2008). This Court agrees with the reasoning of the court in *National Urological Group* and therefore reaches the same result, namely, that in the absence of affirmative evidence that customers who reordered did not rely, at least in part, on WSN's advertising, the amount of restitution for consumer injury should include sales even if they were reorders. The Court finds that there is no dispute of material fact and awards restitution in the amount of $2,198,612. 12.

**2. Whether the Requested Injunction is Unreasonable**

Defendants object to the reporting requirements contained in Section VIII(B) of the FTC's proposed order based on both their length and breadth. *See* Docket No. 163-1 ([Proposed] Final Judgment and Order for Permanent Injunction and Other Equitable Relief ("Proposed Order")). Section VIII(B) provides as follows:

> For 20 years after entry of this Order, each Defendant must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:
>
> > 1. Each Defendant must report any change in: (a) any designated point of contact; or (b) the structure of the Corporate Defendant or any entity that Defendant has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.
> >
> > 2. Additionally, each Individual Defendant must report any change in: (a) name, including aliases or fictitious name, or residence address; or (b) title or role in any business activity, including any business for which such Defendant performs services whether as an employee or otherwise and any entity in which such Defendant has any ownership interest, and identify the name, physical address, and any Internet address of the business or entity.

Proposed Order, Section VIII(B). Defendants ask the Court to reduce the reporting period from 20 years to 10 years and limit the terms of the injunction to sales, advertising, and/or marketing

activities involving products covered by the proposed order.[9] Defendants contend these changes are warranted because none of the Defendants has any history of regulatory violations, citing *FTC v. John Beck Amazing Profits*, 888 F. Supp. 2d 1006, 1016 (C.D. Cal. 2012). The Court finds the proposed reporting requirements to be reasonable and therefore rejects Defendants' request.

"The Federal Trade Commission Act . . . authorizes imposition of comprehensive prophylactic injunctive relief." *John Beck*, 888 F. Supp. 2d at 101 (citation omitted). In *F.T.C. v. Mandel Brothers, Inc.*, the Supreme Court explained that the FTC "is not limited to prohibiting 'the illegal practice in the precise form' existing in the past." 359 U.S. 385, 392 (1959) (quoting *Federal Trade Comm. v. Ruberoid Co.*, 343 U.S. 470, 473 (1952)). Rather, the FTC may "fashion its relief to restrain other like or related unlawful acts." *Id*. (citation omitted). "These 'fencing in' provisions are needed to prevent similar and related violations from occurring in the future." *Trans World Accounts, Inc. v. F.T.C.*, 594 F.2d 212, 215 (9th Cir. 1979) (citing *F.T.C. v. Mandel*, 359 U.S. at 392 (noting that "[i]t depends on the facts of each case and a judgment as to the extent to which a particular violator should be fenced in")).

While the injunctive relief entered under the FTC Act may be broad, it must bear a reasonable relation to the unlawful practices found to have occurred. *Litton Industries, Inc. v. F.T.C.*, 676 F.2d 364, 370 (9th Cir. 1982) (citing *FTC v. Colgate-Palmolive Co*., 380 U.S. at 394-95 (1965)). To determine whether this requirement is met, courts consider "(1) the seriousness and deliberateness of the violation; (2) [the] ease with which the violative claim may be transferred to other products; and (3) whether the respondent has a history of prior violations." *John Beck*, 888 F. Supp. 2d at 1012 (citations omitted). The scope of an injunction based on violation of the FTC Act is always based on the specific facts of the case, "the purpose being to prevent violations, the threat of which in the future is indicated because of their similarity or relation to those unlawful acts. . . found to have been committed . . . in the past." *Id*. (citing *NLRB v. Express Publ'g Co*., 312 U.S. 426, 436–437 (1941)).

[9] The Proposed Order defines "Covered Products" as "Diabetic Pack, Insulin Resistance Pack, WSN Glucose Support Formula, or any other drug, food, or dietary supplement." Proposed Order, Definitions.

In *John Beck*, the court found that a product-specific injunction would not be sufficient to prevent further unlawful conduct on the part of two of the defendants who ran the entity that had engaged in the unlawful practice, pointing to those defendants' "long history of blatantly disregarding the law." *Id*. at 1013. The court also found that the scope of the injunction was justified because 1) the technique of deception could be easily transferred to another type of product; 2) the past violations were "serious, pervasive and continuous," and 3) these defendants had extensive personal involvement in the scheme. *Id*. at 1014-1015. The Court also upheld a 20-year reporting requirement as to these defendants. *Id*. at 1016. However, it reduced the reporting period to 10 years for other defendants who did "not have the same history." *Id*.

Here, the facts establish that both Defendants were personally involved in serious violations of the FTC Act over a period of many years. These facts are sufficient to warrant a 20-year reporting period. Further, the scope of the reporting requirement is not unreasonable in light of the facts of the case. While it is true that Defendants will be required to report any changes in title or role with respect to their business activities, that information is necessary in order for the FTC to monitor Defendants' compliance. The Court notes that actual conduct that is proscribed under the proposed injunction is limited to certain categories of representations that are related to the violations that have been established in this case. *See* Proposed Order, Sections I, II and III. Indeed, Defendants do not challenge the scope of those provisions. Therefore, the Court rejects Defendants' objections with respect to the scope of the injunctive relief requested by the FTC.

## IV. CONCLUSION

For the reasons stated above, the FTC Motion is GRANTED. Defendants' Motion is DENIED. The Court enters final judgment and awards restitution and injunctive relief as set forth in the FTC's proposed final judgment and order.

**IT IS SO ORDERED.**

Dated: February 19, 2014

JOSEPH C. SPERO
United States Magistrate Judge