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**II.**



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\$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.**

Robyn

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

7 The website contained numerous references to science, including the headline, “Nobel  
8 Prize Winning Technology Validates WSN Diabetic Pack Ingredients.” Ortiz Decl., Exs. 42-45  
9 (2007-2010) at 1. A subsequent page included the heading (in smaller typeface than the previous  
10 headline) “Nobel Prize Validates Amazing Technology.” Ortiz Decl., Exs. 42-44 (2007-2009), 46  
11 (2012) at 2. Under this heading, the website contained the following explanation of how Diabetic  
12 Pack works:

13 The reason the WSN<sup>®</sup> Diabetic Pack works is because it operates at  
14 the cellular level and addresses a key problem that every type 2  
15 diabetic has. All type 2 diabetics have a deficiency of key nutrients  
16 the body needs to support healthy blood sugar levels. Your cells  
17 simply do not process blood sugar like they should. The WSN<sup>®</sup>  
18 Diabetic Pack helps your body metabolize blood sugar more  
19 efficiently.

20 The WSN<sup>®</sup> Diabetic Pack provides these key nutrients as 100%  
21 Foodform<sup>®</sup> vitamins and minerals for maximum absorption,  
22 retention and utilization in the cells of the body. Nobel Prize  
23 winning science and over 60 independent American university  
24 studies confirm the superiority of Foodform<sup>®</sup> technology.

25 The WSN<sup>®</sup> Diabetic Pack also contains important botanical extracts.  
26 A recent independent clinical trial was done on one of these herbal  
27 ingredients from this amazing product. This study was done on type  
28 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.**

29 *Id.*

30 WSN s webpages for





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of WSN s Products. JSUF ¶





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

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

21 The FTC argues in its response that there is sufficient evidence to establish individual  
22 liability on a restitution award as to both Robert and Robyn Held. It also rejects Defendants  
23 assertion that its advertising was not misleading because it included disclaimers and instructions  
24 about how the product should be used. The  
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**III. ANALYSIS**

**A. Fed. R. Civ. P. 56**

Summary judgment on a claim or defense is appropriate “if the movant shows that there is

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

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

11 **b. Discussion**

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

25 **3. Dr. Charles**

26 **a. Background**

27 In its ~~10/11~~ Order 4, 2013 M  
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1 address the claims that are the subject of the FTC s causes of action and therefore, his opinions do  
2 not satisfy the relevance requirement; and 2) Dr. Charles did not use a methodology that satisfied  
3 the reliability requirement. Accordingly, the Court excluded Dr. Charles s testimony.

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

11 **b. Discussion**

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

18 **C. Summary Judgment on Liability**

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

20 Section 5(a) of the FTC Act declares unlawful “unfair or deceptive acts or practices in or  
21 affecting commerce.” 15 U.S.C. § 45(a). Section 12 of the FTC Act prohibits the dissemination  
22 of “any false advertisement” in order to induce the purchase of “food, drugs, devices, or  
23 cosmetics.” 15 U.S.C. § 52(a)(2). It also provides that the disJETBT/F1 12 Tf(dLA00)4(sf1 0 0 1 0030000







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*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

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United States District Court  
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1 much. JSUF ¶ 31.

2 Dr. Garvey further opined that the studies cited by Defendants as to the individual  
3 ingredients in their Products are flawed in numerous respects beyond the fact that they do not test  
4 Defendants Products. First, Dr. Garvey found that many of the studies cited by WSN were  
5 conducted in vitro or on animals and therefore cannot substantiate that the tested ingredients work  
6 in humans. *Id.* at 23-24. Second, Dr. Garvey identified numerous shortcomings in the single-  
7 ingredient studies that make them inapplicable to WSN s products, including insufficient size,  
8 lack of placebo or other controls, and testing of much larger doses than are found in WSN s  
9 products. *Id.* at 26-64. Third, Dr. Garvey found that even some well-designed studies showing  
10 positive results for individual ingredients were not conclusive because other well-designed studies  
11 produced inconclusive or negative results. *Id.* at 34 (calcium), 43-47 (magnesium), and 50-55  
12 (chromium).

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

22 **7. Whether Claims Were Material**

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

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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

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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

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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.