UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

FEDERAL TRADE COMMISSION, Plaintiff, v. WELLNESS SUPPORT NETWORK, INC., et al., Defendants.	Case No. 10-cv-04879-JCS **ORDER GRANTING FEDERAL TRADE COMMISSION'S MOTION TO EXCLUDE EXPERT TESTIMONY OF DR. M. ARTHUR CHARLES** Re: Dkt. No. 119

I. INTRODUCTION

The Federal Trade Commission ("FTC") brings this action under Section 13(b) of the Federal Trade Commission Act ("FTC Act") seeking an injunction and other equitable relief based on what it alleges are deceptive claims made by Defendant Wellness Support Network, Inc. ("WSN") in its advertising of two of its products, the Diabetic Pack and the Insulin Resistance Pack. Presently before the Court is the FTC's Motion to Exclude Expert Testimony of Dr. M. Arthur Charles ("Motion"). A hearing on the Motion was held on Friday, September 27, 2013. For the reasons stated below, the Motion is GRANTED.[1]

II. BACKGROUND

A. First Amended Complaint

According to the First Amended Complaint ("FAC"), WSN is a closely held California corporation with its principal place of business in Glendale, California. FAC ¶ 6. The FTC alleges that WSN "advertised, marketed, distributed, or sold a variety of dietary supplements, including the Diabetic Pack and Insulin Resistance Pack to consumers throughout the United

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

States." *Id*. It further alleges that Defendants Robert and Robyn Held are owners and Directors of WSN and that Robert Held is the President of WSN, while Robyn Held is its Secretary and Chief Financial Officer. *Id*. ¶¶ 7-8. According to the FTC, Robert and Robyn Held together developed WSN's advertising and marketing, as well as the website where they display their advertising. *Id*.

The FTC alleges that WSN's advertising of the Diabetic Pack and the Insulin Resistance Pack makes the following claims:

1) Diabetic Pack is an effective treatment for diabetes;

2) Diabetic Pack reduces or eliminates the need for insulin and other diabetes medications;

3) Scientific studies prove that Diabetic Pack is an effective treatment for diabetes; and

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

5) Insulin Resistance Pack reverses insulin resistance;

6) Insulin Resistance Pack manages insulin resistance;

7) Insulin Resistance Pack prevents diabetes;

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

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

Id. at ¶¶ 24, 26. According to the FTC, these claims are false or were not substantiated at the time they were made and therefore violate Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52. *Id*. ¶¶ 25, 27.

B. Opening Expert Report of Dr. Charles

Dr. Charles is Clinical Professor of Medicine with extensive experience in the study and treatment of diabetes. *See* Declaration of Jacob A. Snow in Support of Federal Trade Commission's Motion to Exclude Expert Testimony of Dr. M. Arthur Charles ("Snow Motion Decl."), Ex. C, Attachment 1 (Curriculum Vitae of Dr. Arthur Charles, M.D., Ph.D.). His expert report consists of the following main sections: 1) a section entitled "Relevant Insights into Pre-Diabetes and Type 2 Diabetes" ("Insights section"); 2) a "Methodology" section; 3) a section

summarizing Dr. Charles's "Results"; and 4) "Conclusions." *Id.*, Ex. C (Charles Opening Expert Report).

In the Insights section, Dr. Charles discusses the causes of pre-diabetes and type 2 diabetes and the many complicating factors that make treatment for these diseases difficult. *Id.* at 2-3. For example, "[b]oth pre-diabetes and diabetes are associated with a group of independent cardiovascular death risk factors" that must also be treated. *Id.* at 3. According to Dr. Charles, the current care of type 2 diabetes in the United States is "at the fair to poor level despite appropriate diet, exercise and medication plans, which have been readily available for several decades." *Id.* Consequently, he opines, "ancillary care using FDA approved drugs, dietary supplements and medical foods all appear important." *Id.* at 3-4.

In the Methology section, Dr. Charles begins with two "general concepts for type 2 treatment evaluations relevant to medical foods." *Id.* at 4. The first "General concept" is that a number of oral drugs that were initially approved by the FDA for treatment of diabetes have been taken off the market. *Id.* at 5. According to Dr. Charles, this shows that "large, double-blinded, randomized and controlled clinical trials of oral drugs do not necessarily prove efficacy for type 2 diabetes." *Id.* The second "General concept" is that "FDA approved drugs are often only useful in a subset of diabetic patients." *Id.* For example, Dr. Charles opines, "[t]he commonly used drug, metformin, has been shown to be extremely effective in large, long-term, double-blinded, randomized and controlled trials, and yet this drug is not useful for many patients who have type 2 diabetes" because the drug primarily improves insulin resistance and therefore is only effective for patients who have adequate insulin secretion. *Id.* According to Dr. Charles, "[t]hese two concepts are extremely important in the evaluation of any agents, including medical foods used for type 2 diabetes." *Id.* at 6.

Next, Dr. Charles lays out "[s]pecific concepts for evaluation of the Wellness Support Network's products." *Id.* The first specific concept offered by Dr. Charles is that the "[p]reponderance of clinical evidence can be used to treat patients." *Id.* In other words, "many commonly used drugs, orally ingested products and treatments are used for the care of human patients, sometimes based on the preponderance of clinical data or anecdotal evidence." *Id.*

Second, Dr. Charles opines that "[p]ositive clinical studies often take precedence over negative studies." *Id*. Specifically, Dr. Charles states as follows:

> In many of the human trials of various substances, e.g. vitamins, minerals, trace elements and plant extracts, both positive and negative studies are published; but it must be emphasized that it is exceedingly difficult to prove a negative. Thus the properly conducted, positive studies take precedence, and negative studies often list the potential weaknesses of these studies to be improved upon during future studies.

Id.

Third, Dr. Charles opines that the effectiveness of a substance for treatment depends on the "quantity and chemical form" ingested. *Id*. at 6. In particular, a substance that is absorbed in its macromolecular form in the gastrointestinal tract, as are the products in WSN's Diabetic Pack and Insulin Resistance Pack, is likely to be more effective in lowering blood glucose levels than it will be if it is administered in its elemental form. *Id*. Therefore, Dr. Charles opines, "comparisons of exact dosing quantities . . . are potentially invalid." *Id*. at 7.

Dr. Charles's fourth "specific concept" is the assignment of "clinical effectiveness categories to the Wellness products." *Id*. Dr. Charles explains that "[s]ince there are no federal guidelines to assess substances used as medical foods," he has "arbitrarily" grouped the ingredients used in the Diabetic Pack and the Insulin Resistance Pack into the following three levels:

> **LEVEL 1**: Strongly supporting usefulness for prediabetes or diabetes using human randomized, blinded and/or controlled clinical trials published in peer-reviewed journals. This level of scientific rigor is substantially less than that required by the FDA for drug approvals in which large scale, multicenter, prospective, randomized, doubleblinded and controlled trials are the norm. Studies of similar design and rigor to the FDA requirements would potentially require a product to be classified as a drug, and thus require FDA approval prior to marketing and sales. This regulation and associated costs make equally rigorous studies of medical foods unlikely.
>
> **LEVEL** 2: Supporting usefulness for pre-diabetes or diabetes using uncontrolled, open label studies in normal, pre-diabetic or diabetic humans.
>
> **LEVEL 3**: Possibly supporting usefulness for human pre-diabetes or diabetes using preliminary human anecdotal or animal studies.

Id.

Next, Dr. Charles describes his "results" for certain substances in each level. The Level 1 substances addressed in his report are Chromium, Magnesium, Zinc, white kidney bean extract, Pitika root extract, Indian kino extract, Gymnema extract, Biotin and Vitamin D. *Id.* at 7-9. For each of these substances, Dr. Charles cites to one or more blind, randomized or controlled study that has found that the substance has a positive effect in the treatment of diabetes. *Id*. The Level 2 substances addressed in the report are Banaba leaf extract and Vanadium. *Id*. at 9. As to Banaba leaf extract, Dr. Charles pointed to an "uncontrolled study" showing its beneficial effects for the treatment of diabetes; as to Vanadium, he pointed to two controlled studies that were performed with a small number of subjects. *Id*. Dr. Charles classified Vitamin A and Molybdenum as Level 3 substances. *Id*. at 9-10. As to these substances, he cites results of animal studies showing that they prevent the onset of type 1 diabetes and improve wound healing (Vitamin A) and lower blood sugar (Molybdenum). *Id*. Dr. Charles does not provide a review of the literature as to any of these substances; nor does he address in any detail why he concludes the findings of the studies he cites are valid. Finally, he does not discuss any studies that have found that these substances are ineffective in treating diabetes.

In his Conclusions, Dr. Charles states as follows:

> Given that pre-diabetes and diabetes represent diagnoses along a dysglycemic continuum, rather than dichotomous categories; and that most diabetic complications follow a similar continuum, it appears that the Diabetic Pack and the Insulin-resistance Pack both can be used to improve prediabetes and diabetes. The main ingredients in both Packs reside in the Glucose Support Formula, and this Formula is useful for both pre-diabetes and diabetes. Nine of the thirteen ingredients of this formula have been shown to be useful for pre-diabetes and/or diabetes using the strictest criteria – Level 1. Each ingredient of this Formula has been shown to have some merit or potential usefulness. Since many of these substances have different mechanisms of action, their use should also be at least additive, i.e., when adding one substance with another, one observes a result which is the sum of the two substances, rather than a lesser result, which may explain some of the testimonials. Thus, it is my opinion that Wellness Support Network's two Packs are justified, and perhaps even needed, as a medical food supplement to be used with the full knowledge of patients' physicians for use in pre-diabetes and diabetes. It is also my opinion that the claims made by Wellness Support Network are truthful and substantiated.

Id. at 10.

C. Rebuttal Expert Report and Deposition Testimony of Dr. Charles

In his May 24, 2013 Rebuttal Expert Report, Dr. Charles responds to the FTC's expert, Professor Garvey. *See* Snow Motion Decl., Ex. F. Dr. Charles criticizes Professor Garvey's opinion because he does not address the implications of the fact that WSN's products are, in his opinion, medical foods. *Id*. Rather, Dr. Charles contends, the FTC's expert seems to assume that WSN's products are subject to the requirements promulgated by the Food and Drug Administration ("FDA") for the testing of drugs. *Id*. According to Dr. Charles, medical foods are not subject to these strict requirements and indeed, companies that seek to market medical foods must avoid conducting rigorous tests because "FDA has stated that if an article has been substantially studied as a new drug, it cannot later be marketed for another purpose, such as a food or dietary supplement, regardless of whether it was approved as a new drug or even if the substance is a component of a commonly consumed food with known beneficial effects." *Id*. at 4; *see also* Snow Motion Decl., Ex. D (Charles Dep.) at 169, 220-221 (testifying that the opinions expressed in his report are based on the understanding that under FDA guidelines, when medical foods are subjected to high quality clinical trials, they become drugs and therefore these types of tests can't be performed on medical foods). Dr. Charles further opined in his deposition that there are no guidelines for how to evaluate the efficacy of medical foods or the type of tests that need to be conducted. *Id*. at 125-126. He noted that "there's a constellation of things that you can use to describe the validity of a study" and that he chose in his report to rely, in part, on whether the tests involved human randomized trials. *Id*. at 126.

D. FTC's Motion to Exclude

In the Motion, the FTC asserts that Dr. Charles's opinions are offered only to address the question of whether the claims WSN is alleged to have made about its products are false or lack adequate substantiation. Motion at 1-2 (citing *FTC v. Pantron I, Corp*., 33 F.3d 1088, 1095 (9th Cir. 1994)). On this question, the FTC asserts, Dr. Charles's opinions are neither relevant nor reliable and therefore they are inadmissible under Rule 702 of the Federal Rules of Evidence and *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579 (1993). *Id*. at 2.

On the question of relevance, the FTC contends the standard under *Daubert* and Rule 702 is higher than the general relevance requirement under Rule 402 of the Federal Rules of Evidence, requiring that the evidence "logically advance a material aspect of the proposing party's case," or "speak[ ] clearly and directly to an issue in dispute in the case." *Id*. at 5 (quoting *Redfoot v. B.F. Ascher & Co*., 2007 WL 1593239, at *4 (N.D. Cal. June 1, 2007) (citing *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 43 F.3d 1311, 1315 (9th Cir. 1995) ("*Daubert II*"); *Jones v. United States*, 933 F. Supp. 894, 900 (N.D. Cal. 1996)). This standard is not met by Dr. Charles's opinions, the FTC contends. *Id*. at 6-8. In particular, although Dr. Charles concludes in his report that "the claims made by Wellness Support Network are truthful and substantiated," he does not identify in his report the claims he finds are "truthful or substantiated." *Id*. Nor does he mention any of the nine specific claims the FTC alleges in its FAC were made by WSN in its advertising. *Id*. at 7. Further, the FTC points to Dr. Charles's testimony in his deposition that when he said WSN's claims were substantiated, the "claims" he was referring to were statements made in a testimonial that was quoted on the website and the articles referenced in his own reports, not the claims alleged by the FTC to have been made by WSN that are at issue in this case. *Id*. at 6 (citing Snow Motion Decl., Ex. D (Charles Dep.) at 178:25-180:2; *see also* Snow Motion Decl., Ex. E (article referred to as a testimonial by Dr. Charles).

The FTC argues Dr. Charles's opinions are unreliable because he has not shown how he reached his conclusions or pointed to any source that shows that he has followed the scientific method "as it is practiced by (at least) a recognized minority of the scientists in their field." *Id*. at 8 (quoting *Carnegie Mellon Univ. v. Hoffman-LaRoche*, 55 F. Supp. 2d 1024, 1034 (N.D. Cal. 1999) (citing *Daubert II*, 43 F.3d at 1318-19). The FTC makes two arguments in support of its contention that Dr. Charles's opinions are unreliable. First, it argues that his conclusions are based on his own legal opinions regarding the FDA regulation of medical foods. *Id*. at 9-10. Specifically, the FTC asserts Dr. Charles created his own system of classifying the ingredients in WSN's products, and drew conclusions about the strength of the evidence showing they are effective in treating diabetes, based on his understanding that a less rigorous standard is applied to medical foods than is applied to drugs by the FDA. *Id*. at 9. Even if Dr. Charles were qualified to

express legal opinions, the FTC asserts, this legal conclusion is not relevant to the issues in the case because the claims asserted herein are brought under the FTC Act, not under FDA law. *Id*. at 9 (citing *Bristol-Meyers Co. v. FTC*, 738 F.2d 554 (2d Cir. 1984)). As a result, the FTC asserts, Dr. Charles's opinions are not based on medicine or the scientific method but instead on "legal matters about which he has no expertise." *Id*. at 10.

Second, the FTC argues that Dr. Charles's opinion is not reliable because he does not offer any sound scientific basis for his opinion that "positive clinical studies often take precedence over negative studies." *Id*. at 11 (citing Snow Motion Decl., Ex. C (Charles Report) at 6). According to the FTC, Dr. Charles has never explained how this principle "had been applied to give particular studies 'precedence over others.'" *Id*. at 11. Further, in his deposition Dr. Charles clarified that in addition to "positive" and "negative" studies there are "neutral studies," which are those that show no statistically significant change as a result of ingesting the substance. *Id*. at 12. According to the FTC, Dr. Charles conceded that in his report, he did "not really talk about the neutral studies." *Id*. at 12. The FTC contends Dr. Charles failed to point to any scientific source showing that in relying only on positive studies he was following the scientific method. *Id*. It also points out that Dr. Charles was required to include *all* of his opinions in his report and yet he never addressed the "neutral" studies showing that the substances in WSN's products are *not* effective for treating diabetes, even though many of these studies were cited in the report by the FTC's expert, Professor Garvey. *Id*. at 12-13.

In its Opposition brief, WSN argues that Dr. Charles's claims are both relevant and reliable. As to relevance, WSN argues Dr. Charles need not limit his testimony to the claims that the FTC alleges were made by WSN in order to establish relevance. *Id*. at 4. Rather, it asserts, even if Dr. Charles did not address the specific claims alleged in the complaint – which WSN denies – Dr. Charles's opinions are relevant to broader issues in the case, such as whether the individual defendants "hoodwinked" their customers. *Id*. (citing *FTC v. Swish Marketing*, 2010 U.S. Dist. LEXIS 15016, at *9 (N.D. Cal. Feb. 22, 2010)). Further, WSN asserts, the opinions offered by Dr. Charles are "complex because Diabetes is a complex condition." *Id*. at 5-7. Thus, his opinions are not "as rote as the FTC would have preferred" but they will "shed[] an invaluable

light on a variety of issues which would greatly benefit the Court in ruling in this case." *Id*. at 7. WSN rejects the FTC's reliance on Dr. Charles's deposition testimony about how he used the word "claims," pointing out that Dr. Charles acknowledged that he was confused about how the word "claim" was defined. *Id*. at 7-8. WSN also argues that Dr. Charles's testimony is relevant because it is in line with federal law governing medical foods. *Id*. at 8-11.

WSN further asserts that Dr. Charles's opinions are reliable. With respect to Dr. Charles's reliance on the FDA regulation of medical foods, WSN contends that there is no rule that an expert witness may not refer to the law in expressing an opinion. *Id*. at 11-15. Rather, WSN asserts, an "expert's testimony is proper under Rule 702 if the expert does not attempt to define the legal parameters within which the jury must exercise its fact-finding functions." *Id*. at 12 (quoting *Specht v. Jensen*, 853 F.2d 805, 809 (10th Cir. 1988)).[2] Further, WSN asserts, even though experts do not generally testify about the law, the court may permit such testimony in cases such as this one involving "highly complex and technical matters." *Id*. (citing *Flores v. Arizona*, 516 F.3d 1140, 1166 (9th Cir. 2008), *rev'd on other grounds*, *Horne v. Flores*, 557 U.S. 433 (2009)).

WSN rejects the FTC's reliance on the *Bristol Meyers* case for the proposition that FDA regulations are not relevant to claims brought under the FTC Act, arguing that that case "involves a different type of product, a different procedural posture and a different type of advertising." *Id*. at 13 (citing *Bristol Meyers Co. v. FTC*, 738 F.2d 554 (2d Cir. 1984)). In particular, WSN asserts that the *Bristol Meyers* case stands only for the proposition that with respect to over-the-counter drugs, the FDA is not interested in questions of *comparative* safety but only *absolute* and therefore the FDA regulatory scheme was not relevant to the FTC Act claims under the facts of that case. *Id*. at 14. In contrast, WSN asserts, the FDA has made clear that it is interested in much more than only the absolute safety of medical foods, which are at issue in this case, to the extent it has made "overt efforts to regulate and develop standards for medical food claims." *Id*. On the other hand, WSN argues, the FTC "has never said a word about medical foods, and it appears that this case is its very first attempt at regulating them." *Id*. at 15. Thus, unlike the case of *Bristol Meyers*, WSN

[2] WSN erroneously cites *Specht* as a decision by the Ninth Circuit.

contends, this is not a case where the FDA has "ceded its jurisdiction" of the claims at issue. *Id*. Rather, the Court should strike a balance between the guidance offered by the FDA as to medical foods and the statutory scheme under the FTC Act. *Id*. (citing *Pom Wonderful LLC v. Coca Cola*, 679 F.3d 1170, 1176 (9th Cir. 2012)).

WSN also argues that Dr. Charles's understanding of the law, particularly that the level of substantiation required for a claim about medical food is less than what is required for a claim about a drug, is accurate. *Id*. This is because subjecting a substance to extensive testing would result in it being classified as a drug rather than a medical food, WSN asserts. *Id*. at 15-16 (citing Declaration of Leslie Holmes in Support of Defendants' Opposition to Plaintiff's Motion to Exclude Expert Testimony of Dr. M. Arthur Charles ("Holmes Opposition Decl."), Ex. L (FDA, *Draft Guidance for Industry: Dietary Supplements New Dietary Ingredient Notifications and Related Issue,* July 2011; *id*., Ex. I (61 Fed. Reg. 60669)).

Finally, WSN argues that Dr. Charles's opinions are not unreliable simply because he did not address the studies showing that the ingredients of WSN's products have no effect. *Id*. An expert is not required to "exclude every possible alternative in evaluating a given issue," WSN contends. *Id*. (citing *Bitler v. AO Smith Corp*., 391 F.3d 1114, 1124-1125 n. 6 (10th Cir. 2004)). At most, Dr. Charles's failure to address alternatives goes to the weight of his opinion, not its admissibility, according to WSN. *Id*. (citing *Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1230-1231 (9th Cir. 1998)). Further, WSN asserts, Dr. Charles did adequately address the alternatives, weighing the 160 positive studies and also taking into account the "numerous studies that show the ingredients have no effect," as well as the FDA's standards governing medical foods, to conclude that WSN's products would be "useful as one star among a 'constellation' of a diabetic's medical regime." *Id*. at 17. Thus, WSN asserts, there is no bias in Dr. Charles's opinions as to the efficacy of the substances contained in WSN's products and Dr. Charles's opinions are "perfectly reliable." *Id*. at 18.

In its Reply brief, the FTC rejects WSN's suggestion that the FTC's involvement in a case involving medical foods (at least, according to WSN) is somehow inappropriate, noting that the FTC Act confers broad power on the FTC to challenge misleading advertising "for products of

every stripe." Reply at 2. Further, the FTC asserts, the FDA and FTC involve different regulatory schemes and *Bristol Meyers*, as well as other cases cited by WSN, support the conclusion that "the FTC's action should proceed unencumbered by inferences about what the FDA would (or would not) do if it pursued a similar action." *Id.* at 3 (citing *Thompson Med. Co. v. FTC*, 791 F.2d 189 (D.C. Cir. 1986)). The FTC rejects WSN's assertion that it should not trespass on the FDA's "supposed exclusive 'jurisdiction' over medical foods," arguing that "the FTC and the FDA have, for over four decades, operated under a 'Memorandum of Understanding' which governs the division of responsibilities between the two agencies." *Id.* at 4 (citing *Working Agreement Between FTC and FDA* ("Memorandum of Understanding"), 36 Fed. Reg. 18539 (1971)); *see also* Declaration of Jacob A. Snow in Support of Federal Trade Commission's Reply to WSN's Opposition to Federal Trade Commission's Motion to Exclude Expert Testimony of Dr. M. Arthur Charles ("Snow Reply Decl."), Ex. A (Memorandum of Understanding). In any event, the FTC contends, WSN has not established that its products are medical foods. *Id.* at 5. To the contrary, it asserts, "the only relevant pronouncements have been from the FDA, which stated in a warning letter on September 27, 2005 that 'the therapeutic claims on [WSN's] web site establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease." *Id.* (citing Snow Reply Decl., Ex. D) (September 27, 2005 letter).

The FTC also contends WSN's argument that Dr. Charles's opinion is relevant to issues in the case even though he has not addressed the specific claims that are alleged by the FTC to be false or misleading has no merit. *Id.* at 6-8. According to the FTC, WSN has not identified any other issues in the case to which Dr. Charles's opinions are relevant. Id. at 6. Further, WSN's reliance on the fact that the FTC is trying to hold the individual defendants liable has no bearing on this question, the FTC contends, because it is undisputed that the individual defendants had authority to control or actively participated in the deceptive activities, which is sufficient to hold an individual liable for injunctive relief. *Id.* at 6-7 (citing *FTC v. Stefanchik*, 559 F.3d 924, 931 (9th Cir. 2009)). Even as to the award of monetary damages against individual defendants, which requires knowledge or reckless disregard of the deceptive conduct, the FTC contends Dr. Charles has "no role in establishing the individual defendants' level of knowledge." *Id.* at 7. The FTC

also argues that to the extent Dr. Charles denies that WSN actually made the claims alleged by the FTC in its advertising and addresses *other* claims that he finds were made by WSN, his opinions as to those opinions are not relevant. The FTC asserts that those opinions at best establish that WSN made some *other* claims on its website that were not misleading. The truth of these other claims is not relevant, however, to whether the claims alleged in the FAC are false or lack substantiation, the FTC asserts. *Id*. (citing *National Comm'n on Egg Nutrition v. F.T.C.*, 570 F.2d 157, 161 (7th Cir. 1977)).

As to the reliability of Dr. Charles's opinions, the FTC reiterates its argument that by making his understanding of FDA regulations of medical foods the "cornerstone" of his analysis, Dr. Charles has rendered his analysis flawed and unreliable. *Id*. at 8. Dr. Charles is not qualified to provide legal opinions, the FTC asserts, and these opinions should be excluded. *Id*. at 9-12. The FTC also reiterates its position that Dr. Charles has not pointed to an objective source showing that he followed an acceptable scientific method when he addressed only "positive" studies. *Id*. at 11-12.

E. The FTC's Supplemental Brief

After briefing on the FTC's Motion was complete, the FDA issued new guidance on medical foods, namely, an updated edition of the FDA guidance that was cited by WSN in its opposition brief. *See* Federal Trade Commission's Supplementary Brief in Support of its Motion to Exclude Expert Testimony of Dr. M. Arthur Charles ("FTC Supp. Brief"); Declaration of Jacob A. Snow in Support of Federal Trade Commission's Supplementary Brief in Support of its Motion to Exclude Expert Testimony of Dr. M. Arthur Charles ("Snow Supp. Brief Decl."), Ex. A (*Draft Guidance for Industry: Frequently Asked Questions About Medical Foods, Second Edition*). Like the previous edition, this draft guidance is nonbinding and states that it being distributed "for comment purposes only" and not for implementation. Snow Supp. Brief Reply Decl., Ex. A at 1. It contains the following discussion of whether products used to address diabetes can be labeled and marketed as medical foods:

> 23. Does FDA consider type 1 or type 2 DM to be conditions for which a medical food could be labeled and marketed?

> No. Diet therapy is the mainstay of diabetes management. A regular diet can be modified to meet the needs of an individual affected by either type of DM (along with appropriate drug therapy if necessary). Under 21 CFR 101.9(j)(8)(ii), a medical food must be intended for a patient who has a limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone. Therefore, FDA generally would not consider a product labeled and marketed for DM to meet the regulatory criteria for a medical food.

Id. at 12. While the FTC continues to take the position that the question of whether or not WSN's products would be classified by the FDA as medical foods is not relevant to this case, it offers this recent guidance in order to "finally put the 'medical food' issue to rest." FTC Supp. Brief at 3.

Defendants assert in response that the Court should not consider a document that did not exist at the time Dr. Charles prepared his expert report. Defendants' Response to Plaintiff's Supplemental Brief in Support of its Motion to Exclude Expert Testimony of Dr. M. Arthur Charles ("Defendants' Supp. Brief") at 1. Defendants further assert that the Court should not rely on the updated guidance because the FDA's "categorical elimination of diabetes from the universe of indications appropriate to be managed by medical foods constitutes an unlawful rulemaking in violation of the [Administrative Procedures Act ("APA")]." *Id*. (citing *Catholic Health Initiatives v. Sebelius*, 617 F.3d 490 (D.C. Cir. 2010)). WSN further asserts the Court should not rely on the new guidance because it is "totally inconsistent with the manner by which the FDA has regulated medical foods for decades." *Id*. at 2. In light of the fact that there is a long history of permitting medical foods to be marketed for diabetes, WSN contends, "it was perfectly reasonable for Dr. Charles to opine that [WSN's] medical foods were appropriate for people with diabetes." *Id*. Finally, WSN contends that if the Court considers the new guidance, the Court should reopen discovery. *Id*. In particular, WSN asserts that "FTC has repeatedly interjected itself in FDA's regulation of [WSN's] products and impacted the result" and therefore, it should be permitted to take discovery on communications between the FDA and the FTC which led to the FDA's issuance of the new guidance. *Id*.

III. ANALYSIS

A. 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).

With respect to the first requirement, that an expert must testify to "scientific knowledge," the Court explained that "[t]he adjective 'scientific' implies a grounding in the methods and procedures of science . . . [while] the word 'knowledge' connotes more than subjective belief or unsupported speculation . . . [and] 'applies to any body of known facts or to any body of ideas inferred from such facts or accepted as truths on good grounds.'" *Id*. at 590 (quoting Webster's Third New International Dictionary 1252 (1986)). The Court declined to set forth a definitive test, but offered some "general observations" about the types of factors that might be considered in determining whether this requirements is met. *Id*. at 593. These include: 1) whether the methodology can be or has been tested; 2) whether the theory and technique has been subjected to

peer review; 3) if a "particular scientific technique" is involved, the known or potential rate of error; and 4) the degree of acceptance in the relevant scientific community. *Id*. at 592-94.

The Ninth Circuit has noted that the "scientific knowledge" requirement is usually met by "[e]stablishing that an expert's proffered testimony grows out of pre-litigation research or that the expert's research has been subjected to peer review." *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 43 F.3d 1311, 1318 (9th Cir. 1995) ("*Daubert II"*). However, when such evidence is not available, the proponent's experts may satisfy this requirement by "explain[ing] precisely how they went about reaching their conclusions and point[ing] to some objective source – a learned treatise, the policy statement of a professional association, a published article in a reputable scientific journal or the like – to show that they have followed the scientific method, as it is practiced by (at least) a recognized minority of scientists in their field." *Id*. at 1319.

The second requirement under Rule 702, that expert testimony must "assist the trier of fact to understand the evidence or to determine a fact in issue," "goes primarily to relevance." *Id*. at 591. This is a question of "fit," and "is not always obvious." *Daubert*, 509 U.S. at 591. The Court cautioned that "scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes." *Id*. To meet this requirement there must be "a valid scientific connection to the pertinent inquiry." *Id*. In other words, the expert testimony must "logically advance[ ] a material aspect of the proposing party's case." *Daubert II*, 43 F.3d at 1315. This requirement is more stringent than the relevancy requirement of Rule 402 of the Federal Rules of Evidence, "reflecting the special dangers inherent in scientific expert testimony." *Jones v. U.S.*, 933 F.Supp. 894, 900 (N.D.Cal., 1996) (citing *Daubert*, 509 U.S. at 591; *Daubert II*, 43 F.3d at 1321 n. 17). In particular, expert testimony "'can be both powerful and quite misleading because of the difficulty in evaluating it.'" *Id*. (quoting *Daubert*, 509 U.S. at 595 (citation omitted)). "Therefore, a federal judge should exclude scientific expert testimony under the second prong of the *Daubert* standard unless he is 'convinced that it speaks clearly and directly to an issue in dispute in the case.'" *Id*. (quoting *Daubert II*, 43 F.3d at 1321 n. 17).

B. Whether the Expert Opinion of Dr. Charles Satisfies the Requirements of *Daubert*

1. Whether Dr. Charles's opinions are relevant to the issues in the Case

The FTC contends Dr. Charles' expert opinions do not meet the relevance requirement *Daubert* and Rule 702 and the Court agrees.

WSN has offered Dr. Charles's opinions to show that use its products "can be used to improve prediabetes and diabetes" because each ingredient has been "shown to have some merit or potential usefulness." Snow Motion Decl., Ex. C. (Charles Expert Report) at 10. The main issue that the Court must resolve, however, is whether the *particular claims* that WSN is alleged to have made about its products are false or lack substantiation. Dr. Charles's expert report does not "speak clearly and directly" to that issue. To the contrary, although Dr. Charles concluded his report by stating that "the claims made by Wellness Support Network are truthful and substantiated," *id*., he does not identify the "claims" to which he is referring. Further, in his deposition, when he was asked, "what claims are you talking about?" Dr. Charles was unable to provide a clear answer. *See* Snow Motion Decl., Ex. D (Charles Dep.) at 175-181. At one point he stated that the "claims" included a "testimonial" that could be accessed through WSN's websites, while at another he stated that the "claims'" he was talking about were "virtually all these references [cited by Dr. Charles] in both the rebuttal and the expert report." *Id*. at 179. Because Dr. Charles did not make clear what claims he was addressing in his report, his opinions are neither clear nor direct and are not likely to be helpful to the trier of fact. Therefore, the Court finds Dr. Charles's opinions should be excluded for failure to meet the "fit" requirement of Rule 702 and *Daubert*.

2. Whether Dr. Charles's opinions are reliable

Even if the Court were to find that Dr. Charles's opinions were sufficiently relevant to the issues of this case, it would exclude Dr. Charles's opinions on the ground that he has not established that he has used a scientific method that complies with *Daubert* in his analysis.

As discussed above, Dr. Charles has "arbitrarily" created a hierarchy to describe the level of "clinical effectiveness" of the ingredients used in WSN's products. According to his hierarchy, the Level 1 substances ("strongly supporting usefulness") are those in which there are "human

randomized and/or controlled clinical trials published in peer-reviewed journals"; Level 2 substances ("supporting usefulness") are those in which there have been "uncontrolled, open label studies in normal, pre-diabetic or diabetic humans; and Level 3 substances ("possibly supporting usefulness") are those where there is "preliminary human anecdotal or animal studies"). Dr. Charles does not point to any object source showing that his classifications follow "the scientific method, as it is practiced by (at least) a recognized minority of scientists" in his field.

Further, in classifying the various substances in these categories, he has, by his own admission, only addressed "positive clinical studies"; his only basis for failing to address studies that have found that these substances are *not* useful for treating diabetes is his unsupported assertion that "the properly conducted, positive studies take precedence." Again, however, he points to no objective source showing that in taking this approach he has followed an accepted scientific method. Indeed, *Daubert* requires that Dr. Charles address alternative explanations for the purportedly positive studies, that is, the he explain why he chose to rely on the studies that found the various substances to be beneficial instead of the studies that found that they had no effect. *See Carnegie Mellon University v. Hoffmann-LaRoche, Inc.*, 55 F.Supp.2d 1024, 1034 (N.D.Cal., 1999).

Dr. Charles's apparent reliance on FDA regulations governing medical foods in support of his system of classification further highlights the fact that his methodology is not grounded in scientific principles; rather, he appears to have created his hierarchy on the basis of his understanding of FDA regulations governing medical foods and in particular, the fact that under FDA regulations, a substance may be classified as a drug rather than a medical food if it is subjected to rigorous tests. Even assuming WSN's products were considered medical foods by the FDA –a question the Court need not reach – the degree of regulation they would be subjected to by the FDA simply is not relevant to the issues of this case. *See Bristol-Myers Co. v. F.T.C.*, 738 F.2d 554, 559 (2d Cir. 1984) (holding that FDA regulations were not relevant in case brought under FTC Act because "[n]ot only is a different regulatory scheme involved, but generally speaking the FDA is concerned only with evaluating absolute safety and efficacy, and not with the questions of comparative safety and efficacy that arise in OTC drug advertising"). Dr. Charles's

reliance on the regulatory scheme under the FDA, as opposed to scientific principles, to support his analysis does not satisfy *Daubert*'s requirement that an expert must offer "scientific knowledge."

IV. CONCLUSION

For the reasons stated above, the Court finds that Dr. Charles's Expert Report does not satisfy Rule 702 of the Federal Rules of Evidence and *Daubert*. Therefore, the testimony of Dr. Charles shall be excluded. Accordingly, the Motion is GRANTED.

IT IS SO ORDERED.

Dated: October 4, 2013

JOSEPH C. SPERO
United States Magistrate Judge

United States District Court
Northern District of California