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United States District Court
Northern District of California

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).

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

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

- 7 1) Diabetic Pack is an effective treatment for diabetes;
- 8 2) Diabetic Pack reduces or eliminates the need for insulin and other diabetes medications;
- 9 3) Scientific studies prove that Diabetic Pack is an effective treatment for diabetes; and
- 10 4) Diabetic Pack is clinically proven to cause an average drop in blood glucose levels of
 11 31.9%.
- 12 5) Insulin Resistance Pack reverses insulin resistance;
- 13 6) Insulin Resistance Pack manages insulin resistance;
- 14 7) Insulin Resistance Pack prevents diabetes;
- 15 8) Scientific studies prove that Insulin Resistance Pack is an effective treatment for insulin
 16 resistance; and
- 17 9) Insulin Resistance Pack is clinically proven to cause an average drop in blood glucose
 18 levels of 31.9%.

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

22 **B. Opening Expert Report of Dr. Charles**

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

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

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

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

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

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

3
4 In many of the human trials of various substances, e.g. vitamins,
5 minerals, trace elements and plant extracts, both positive and
6 negative studies are published; but it must be emphasized that it is
7 exceedingly difficult to prove a negative. Thus the properly
8 conducted, positive studies take precedence, and negative studies
9 often list the potential weaknesses of these studies to be improved
10 upon during future studies.

11 *Id.*

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

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

23 **LEVEL 1:** Strongly supporting usefulness for prediabetes or
24 diabetes using human randomized, blinded and/or controlled clinical
25 trials published in peer-reviewed journals. This level of scientific
26 rigor is substantially less than that required by the FDA for drug
27 approvals in which large scale, multicenter, prospective,
28 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.

1 *Id.*

2 Next, Dr. Charles describes his “results” for certain substances in each level. The Level 1
3 substances addressed in his report are Chromium, Magnesium, Zinc, white kidney bean extract,
4 Pitika root extract, Indian kino extract, Gymnema extract, Biotin and Vitamin D. *Id.* at 7-9. For
5 each of these substances, Dr. Charles cites to one or more blind, randomized or controlled study
6 that has found that the substance has a positive effect in the treatment of diabetes. *Id.* The Level 2
7 substances addressed in the report are Banaba leaf extract and Vanadium. *Id.* at 9. As to Banaba
8 leaf extract, Dr. Charles pointed to an “uncontrolled study” showing its beneficial effects for the
9 treatment of diabetes; as to Vanadium, he pointed to two controlled studies that were performed
10 with a small number of subjects. *Id.* Dr. Charles classified Vitamin A and Molybdenum as Level
11 3 substances. *Id.* at 9-10. As to these substances, he cites results of animal studies showing that
12 they prevent the onset of type 1 diabetes and improve wound healing (Vitamin A) and lower blood
13 sugar (Molybdenum). *Id.* Dr. Charles does not provide a review of the literature as to any of
14 these substances; nor does he address in any detail why he concludes the findings of the studies
15 he cites are valid. Finally, he does not discuss any studies that have found that these substances
16 are ineffective in treating diabetes.

17 In his Conclusions, Dr. Charles states as follows:

18
19 Given that pre-diabetes and diabetes represent diagnoses along a
20 dysglycemic continuum, rather than dichotomous categories; and
21 that most diabetic complications follow a similar continuum, it
22 appears that the Diabetic Pack and the Insulin-resistance Pack both
23 can be used to improve prediabetes and diabetes. The main
24 ingredients in both Packs reside in the Glucose Support Formula,
25 and this Formula is useful for both pre-diabetes and diabetes. Nine
26 of the thirteen ingredients of this formula have been shown to be
27 useful for pre-diabetes and/or diabetes using the strictest criteria –
28 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.

1 *Id.* at 10.

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

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

22 **D. FTC's Motion to Exclude**

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

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

18 The FTC argues Dr. Charles’s opinions are unreliable because he has not shown how he
19 reached his conclusions or pointed to any source that shows that he has followed the scientific
20 method “as it is practiced by (at least) a recognized minority of the scientists in their field.” *Id.* at
21 8 (quoting *Carnegie Mellon Univ. v. Hoffman-LaRoche*, 55 F. Supp. 2d 1024, 1034 (N.D. Cal.
22 1999) (citing *Daubert II*, 43 F.3d at 1318-19). The FTC makes two arguments in support of its
23 contention that Dr. Charles’s opinions are unreliable. First, it argues that his conclusions are
24 based on his own legal opinions regarding the FDA regulation of medical foods. *Id.* at 9-10.
25 Specifically, the FTC asserts Dr. Charles created his own system of classifying the ingredients in
26 WSN’s products, and drew conclusions about the strength of the evidence showing they are
27 effective in treating diabetes, based on his understanding that a less rigorous standard is applied to
28 medical foods than is applied to drugs by the FDA. *Id.* at 9. Even if Dr. Charles were qualified to

1 express legal opinions, the FTC asserts, this legal conclusion is not relevant to the issues in the
2 case because the claims asserted herein are brought under the FTC Act, not under FDA law. *Id.* at
3 9 (citing *Bristol-Meyers Co. v. FTC*, 738 F.2d 554 (2d Cir. 1984)). As a result, the FTC asserts,
4 Dr. Charles’s opinions are not based on medicine or the scientific method but instead on “legal
5 matters about which he has no expertise.” *Id.* at 10.

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

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

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

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

15 WSN rejects the FTC’s reliance on the *Bristol Meyers* case for the proposition that FDA
16 regulations are not relevant to claims brought under the FTC Act, arguing that that case “involves
17 a different type of product, a different procedural posture and a different type of advertising.” *Id.*
18 at 13 (citing *Bristol Meyers Co. v. FTC*, 738 F.2d 554 (2d Cir. 1984)). In particular, WSN asserts
19 that the *Bristol Meyers* case stands only for the proposition that with respect to over-the-counter
20 drugs, the FDA is not interested in questions of *comparative* safety but only *absolute* and therefore
21 the FDA regulatory scheme was not relevant to the FTC Act claims under the facts of that case.
22 *Id.* at 14. In contrast, WSN asserts, the FDA has made clear that it is interested in much more than
23 only the absolute safety of medical foods, which are at issue in this case, to the extent it has made
24 “overt efforts to regulate and develop standards for medical food claims.” *Id.* On the other hand,
25 WSN argues, the FTC “has never said a word about medical foods, and it appears that this case is
26 its very first attempt at regulating them.” *Id.* at 15. Thus, unlike the case of *Bristol Meyers*, WSN
27

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

1 contends, this is not a case where the FDA has “ceded its jurisdiction” of the claims at issue. *Id.*
2 Rather, the Court should strike a balance between the guidance offered by the FDA as to medical
3 foods and the statutory scheme under the FTC Act. *Id.* (citing *Pom Wonderful LLC v. Coca Cola,*
4 679 F.3d 1170, 1176 (9th Cir. 2012)).

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

13 Finally, WSN argues that Dr. Charles’s opinions are not unreliable simply because he did
14 not address the studies showing that the ingredients of WSN’s products have no effect. *Id.* An
15 expert is not required to “exclude every possible alternative in evaluating a given issue,” WSN
16 contends. *Id.* (citing *Bitler v. AO Smith Corp.*, 391 F.3d 1114, 1124-1125 n. 6 (10th Cir. 2004)).
17 At most, Dr. Charles’s failure to address alternatives goes to the weight of his opinion, not its
18 admissibility, according to WSN. *Id.* (citing *Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1230-
19 1231 (9th Cir. 1998)). Further, WSN asserts, Dr. Charles did adequately address the alternatives,
20 weighing the 160 positive studies and also taking into account the “numerous studies that show the
21 ingredients have no effect,” as well as the FDA’s standards governing medical foods, to conclude
22 that WSN’s products would be “useful as one star among a ‘constellation’ of a diabetic’s medical
23 regime.” *Id.* at 17. Thus, WSN asserts, there is no bias in Dr. Charles’s opinions as to the
24 efficacy of the substances contained in WSN’s products and Dr. Charles’s opinions are “perfectly
25 reliable.” *Id.* at 18.

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

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

18 The FTC also contends WSN’s argument that Dr. Charles’s opinion is relevant to issues in
19 the case even though he has not addressed the specific claims that are alleged by the FTC to be
20 false or misleading has no merit. *Id.* at 6-8. According to the FTC, WSN has not identified any
21 other issues in the case to which Dr. Charles’s opinions are relevant. *Id.* at 6. Further, WSN’s
22 reliance on the fact that the FTC is trying to hold the individual defendants liable has no bearing
23 on this question, the FTC contends, because it is undisputed that the individual defendants had
24 authority to control or actively participated in the deceptive activities, which is sufficient to hold
25 an individual liable for injunctive relief. *Id.* at 6-7 (citing *FTC v. Stefanichik*, 559 F.3d 924, 931
26 (9th Cir. 2009)). Even as to the award of monetary damages against individual defendants, which
27 requires knowledge or reckless disregard of the deceptive conduct, the FTC contends Dr. Charles
28 has “no role in establishing the individual defendants’ level of knowledge.” *Id.* at 7. The FTC

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

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

15 **E. The FTC's Supplemental Brief**

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

27
 28 23. Does FDA consider type 1 or type 2 DM to be conditions for
 which a medical food could be labeled and marketed?

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

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

15 Defendants assert in response that the Court should not consider a document that did not
16 exist at the time Dr. Charles prepared his expert report. Defendants' Response to Plaintiff's
17 Supplemental Brief in Support of its Motion to Exclude Expert Testimony of Dr. M. Arthur
18 Charles ("Defendants' Supp. Brief") at 1. Defendants further assert that the Court should not rely
19 on the updated guidance because the FDA's "categorical elimination of diabetes from the universe
20 of indications appropriate to be managed by medical foods constitutes an unlawful rulemaking in
21 violation of the [Administrative Procedures Act ("APA")." *Id.* (citing *Catholic Health Initiatives*
22 *v. Sebelius*, 617 F.3d 490 (D.C. Cir. 2010)). WSN further asserts the Court should not rely on the
23 new guidance because it is "totally inconsistent with the manner by which the FDA has regulated
24 medical foods for decades." *Id.* at 2. In light of the fact that there is a long history of permitting
25 medical foods to be marketed for diabetes, WSN contends, "it was perfectly reasonable for Dr.
26 Charles to opine that [WSN's] medical foods were appropriate for people with diabetes." *Id.*
27 Finally, WSN contends that if the Court considers the new guidance, the Court should reopen
28 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.*

1 **III. ANALYSIS**

2 **A. Legal Standard**

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

5
6 If scientific, technical, or other specialized knowledge will assist the
7 trier of fact to understand the evidence or to determine a fact in
8 issue, a witness qualified as an expert by knowledge, skill,
9 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.

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

13
14 Faced with a proffer of expert scientific testimony, then, the trial
15 judge must determine . . . whether the expert is proposing to testify
16 to (1) scientific knowledge that (2) will assist the trier of fact to
17 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.

18 509 U.S. 579, 590 (1993).

19 With respect to the first requirement, that an expert must testify to “scientific knowledge,”
20 the Court explained that “[t]he adjective ‘scientific’ implies a grounding in the methods and
21 procedures of science . . . [while] the word ‘knowledge’ connotes more than subjective belief or
22 unsupported speculation . . . [and] ‘applies to any body of known facts or to any body of ideas
23 inferred from such facts or accepted as truths on good grounds.’” *Id.* at 590 (quoting Webster’s
24 Third New International Dictionary 1252 (1986)). The Court declined to set forth a definitive test,
25 but offered some “general observations” about the types of factors that might be considered in
26 determining whether this requirements is met. *Id.* at 593. These include: 1) whether the
27 methodology can be or has been tested; 2) whether the theory and technique has been subjected to
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1 peer review; 3) if a “particular scientific technique” is involved, the known or potential rate of
2 error; and 4) the degree of acceptance in the relevant scientific community. *Id.* at 592-94.

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

12 The second requirement under Rule 702, that expert testimony must “assist the trier of fact
13 to understand the evidence or to determine a fact in issue,” “goes primarily to relevance.” *Id.* at
14 591. This is a question of “fit,” and “is not always obvious.” *Daubert*, 509 U.S. at 591. The
15 Court cautioned that “scientific validity for one purpose is not necessarily scientific validity for
16 other, unrelated purposes.” *Id.* To meet this requirement there must be “a valid scientific
17 connection to the pertinent inquiry.” *Id.* In other words, the expert testimony must “logically
18 advance[] a material aspect of the proposing party’s case.” *Daubert II*, 43 F.3d at 1315. This
19 requirement is more stringent than the relevancy requirement of Rule 402 of the Federal Rules of
20 Evidence, “reflecting the special dangers inherent in scientific expert testimony.” *Jones v. U.S.*,
21 933 F.Supp. 894, 900 (N.D.Cal., 1996) (citing *Daubert*, 509 U.S. at 591; *Daubert II*, 43 F.3d at
22 1321 n. 17). In particular, expert testimony ““can be both powerful and quite misleading because
23 of the difficulty in evaluating it.”” *Id.* (quoting *Daubert*, 509 U.S. at 595 (citation omitted)).
24 “Therefore, a federal judge should exclude scientific expert testimony under the second prong of
25 the *Daubert* standard unless he is ‘convinced that it speaks clearly and directly to an issue in
26 dispute in the case.’” *Id.* (quoting *Daubert II*, 43 F.3d at 1321 n. 17).

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

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

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

5 WSN has offered Dr. Charles's opinions to show that use its products "can be used to
6 improve prediabetes and diabetes" because each ingredient has been "shown to have some merit or
7 potential usefulness." Snow Motion Decl., Ex. C. (Charles Expert Report) at 10. The main issue
8 that the Court must resolve, however, is whether the *particular claims* that WSN is alleged to have
9 made about its products are false or lack substantiation. Dr. Charles's expert report does not
10 "speak clearly and directly" to that issue. To the contrary, although Dr. Charles concluded his
11 report by stating that "the claims made by Wellness Support Network are truthful and
12 substantiated," *id.*, he does not identify the "claims" to which he is referring. Further, in his
13 deposition, when he was asked, "what claims are you talking about?" Dr. Charles was unable to
14 provide a clear answer. *See* Snow Motion Decl., Ex. D (Charles Dep.) at 175-181. At one point
15 he stated that the "claims" included a "testimonial" that could be accessed through WSN's
16 websites, while at another he stated that the "claims" he was talking about were "virtually all
17 these references [cited by Dr. Charles] in both the rebuttal and the expert report." *Id.* at 179.
18 Because Dr. Charles did not make clear what claims he was addressing in his report, his opinions
19 are neither clear nor direct and are not likely to be helpful to the trier of fact. Therefore, the Court
20 finds Dr. Charles's opinions should be excluded for failure to meet the "fit" requirement of Rule
21 702 and *Daubert*.

22 **2. Whether Dr. Charles's opinions are reliable**

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

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

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

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

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

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

4 **IV. CONCLUSION**

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

8 **IT IS SO ORDERED.**

9 Dated: October 4, 2013

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13 JOSEPH C. SPERO
14 United States Magistrate Judge
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United States District Court
Northern District of California