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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

WELLNESS SUPPORT NETWORK, INC., a corporation,

ROBERT HELD, individually and as an officer of Wellness Support Network, Inc., and

ROBYN HELD, individually and as an officer of Wellness Support Network, Inc.,

Defendants.

CASE NO. 3:10-CV-04879-JCS

FEDERAL TRADE COMMISSION'S MOTION TO EXCLUDE EXPERT TESTIMONY OF DR. M. ARTHUR CHARLES

Date: August 9, 2013
Time: 9:30 a.m.
Courtroom: G, 15th Floor

ORAL ARGUMENT REQUESTED

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NOTICE OF MOTION TO EXCLUDE EXPERT TESTIMONY

On August 9, 2013, at 9:30 a.m., pursuant to Civil Local Rule 7-2, the Federal Trade Commission ("Plaintiff," "FTC," or the "Commission") will and hereby does move this Court to exclude the opinions of Dr. M. Arthur Charles ("Dr. Charles") in support of Wellness Support Network, Inc., Robert Held, and Robyn Held (collectively, "WSN") under *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579 (1993).

For the reasons set forth below, the Court should exclude Dr. Charles' expert reports, and bar Dr. Charles from testifying in this matter.

I. INTRODUCTION

In this case, the FTC alleges that WSN's advertisements marketing pills made of vitamins, minerals, and plant extracts are deceptive and misleading to consumers. In its complaint, the FTC identifies nine misleading claims (the "challenged claims")[1] made by WSN's ads, including that the pills will treat diabetes, treat and manage insulin resistance, and significantly reduce blood glucose. Because there is no competent and reliable scientific evidence substantiating these claims, WSN's advertisements are deceptive and misleading. Individuals who purchase WSN's products do so at the risk of wasting their money on pills that are unlikely to help them. Some of WSN's customers may even forego other treatments, relying on WSN's promises of treatment and amelioration of their disease.

The three key issues for the Court to resolve in this matter are: 1) whether WSN's ads make the challenged claims; 2) whether the challenged claims are false or lack adequate

[1] The FTC alleges that WSN's advertisements for its products make 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%.

First Amended Complaint, Dkt. No. 27 at ¶¶ 24, 26.

substantiation; and 3) whether the challenged claims are material to prospective consumers. *See FTC v. Pantron I, Corp.*, 33 F.3d 1088, 1095 (9th Cir. 1994). Dr. Charles has no relevant expertise with respect to whether the ads convey the challenged claims or whether the challenged claims are material. The expert report, rebuttal report, and deposition testimony of WSN's diabetes expert, Dr. Charles, must therefore be directed towards the substantiation of the challenged claims. Dr. Charles' reports and opinions, however, fail to meet the requirements of *Daubert* for the following three reasons:

First, Dr. Charles fails to consider and offer an opinion on the single issue within the scope of his expertise: whether the challenged claims are truthful and substantiated. Instead, Dr. Charles' reports offer opinions *only* as to the truth and substantiation of 1) various testimonials on WSN's website; and 2) the particular article references cited in Dr. Charles' reports. Dr. Charles' opinions are not relevant. *Daubert* requires more.

Second, Dr. Charles bases his opinions on a legal opinion formed as a result of his review of irrelevant FDA-related documents. In particular, Dr. Charles concludes that, under FDA regulations, clinical testing of a food "automatically" classifies that food as a drug. His legal opinion is plainly inadmissible: only the Court may rule on the law. His report and deposition, however, make clear that his legal opinion constitutes a necessary element of his opinions regarding the effectiveness of certain ingredients of WSN's products. Because a critical step in Dr. Charles' analysis is unscientific and unreliable, Dr. Charles' reports must be excluded.

Third, Dr. Charles asserts that studies indicating some positive result for diabetic patients should "take precedence" over studies showing detrimental or statistically insignificant results. Without authority to demonstrate that this preference has a basis in science—which Dr. Charles does not provide—this assertion is plain and simple bias in favor of WSN. Dr. Charles has made clear that he applied this preference throughout the analysis in his report, and his report is inadmissibly unreliable as a result.

II. FACTUAL AND PROCEDURAL BACKGROUND

The FTC's lawsuit alleges that Defendants' advertising for diabetes and insulin-resistance products is deceptive and violates the Federal Trade Commission Act. Dkt. No. 27. The two

products at issue—WSN's Diabetic Pack and WSN's Insulin Resistance Pack—are pills comprised of a selection of vitamin, mineral, and plant-extract ingredients. The Diabetic Pack and Insulin-Resistance Pack have different names and labels, but they are the same product: the ingredients and the dosages for the Diabetic Pack and the Insulin-Resistance Pack are identical. Snow Decl. Ex. A, List of Ingredients In Diabetic and Insulin-Resistance Packs; Snow Decl. Ex. B, Transcript of Deposition of Robyn Held, 72:1-4 ("Q. Was there is difference between the product that Wellness Support Network called the Diabetic Pack and the Insulin Resistance Pack? A. No. Only in name.").

Fact and expert discovery are now complete. The parties' motions for summary judgment are due on August 30, 2013.[2] Dkt. No. 111. Argument for the summary judgment motions is set for November 8, 2013. Dkt. No. 116. Both parties have identified a single expert witness and both have served opening and rebuttal expert reports by their respective experts. Each party has also taken their expert deposition, most recently with the FTC taking the deposition of Dr. Charles on June 27, 2013.

WSN served Dr. Charles' opening report on April 11, 2013. Dr. Charles began his report with a brief discussion regarding the physiology and treatment of pre-diabetes and diabetes. Declaration of Jacob A. Snow In Support of Motion To Exclude Expert Testimony ("Snow Decl."), Ex. C, Opening Expert Report of Dr. M. Arthur Charles, 2-4 ("Charles Report"). In the next section, titled "Methodology," Dr. Charles identified a number of "concepts for evaluation of the Wellness Support Network's products." *Id.* at 6-7. At issue in this motion are two of those concepts: 1) Dr. Charles' notion that "positive" studies "take precedence" over "negative" studies, discussed below in section IV(B)(2); and 2) Dr. Charles' description of three "clinical effectiveness categories," which, in his view require a level of effectiveness less rigorous than that set by the FDA for drugs. *See id.* Dr. Charles' categories are discussed below in section IV(B)(1).

[2] Resolution of the present motion before the parties present their motions for summary judgment on August 30, 2013 will narrow the case and simplify the Court's analysis in considering the dispositive motions.

In the next section, titled "Results," Dr. Charles assigned certain WSN ingredients to his "clinical effectiveness categories." *Id*. at 8-10. Noticeably absent from Dr. Charles' report is any discussion of how he knows that the WSN products provide any of the benefits they claim since there are no studies or tests of WSN's products. Dr. Charles cited to articles ostensibly supporting his conclusions, but did not offer any review of the existing literature for any ingredient. Nor did Dr. Charles discuss the details of any study or compare studies with each other. Dr. Charles concluded his report with the statement that "[i]t is also my opinion that the claims made by [WSN] are truthful and substantiated." *Id.* at 10. But Dr. Charles did not explain what "claims made by WSN" he was referring to. *Id.*

III. RELIABILITY AND RELEVANCE OF EXPERT TESTIMONY

Federal Rule of Evidence 702 permits experts qualified by "knowledge, experience, skill, expertise, training, or education" to testify "in the form of an opinion or otherwise" based on "scientific, technical, or other specialized knowledge," but only if that knowledge will "assist the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. Under *Daubert*, this Court must rule on the admissibility of expert scientific testimony through a two-part analysis: first, this Court must determine whether an expert's testimony reflects "scientific knowledge," whether the findings are "derived by the scientific method," and whether the work product is "good science." *Daubert*, 509 U.S. at 590, 593. And second, this Court must determine whether the expert's testimony is "relevant to the task at hand." *Id.* at 597.

Under the first prong of this analysis, an expert's methodology may not be reliable if the expert "fail[s] to address and exclude alternative explanations for the data on which he bases his findings" or "reject[s] studies reporting contrary empirical findings." *Carnegie Mellon Univ. v. Hoffmann–LaRoche, Inc.*, 55 F. Supp. 2d 1024, 1034-35 (N.D. Cal. 1999). In addition, a court may exclude expert testimony on the ground that an expert's purported methodology fails to explain his final conclusion. *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). In other words, neither "*Daubert* [nor] the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court

may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Id.*

The Court should also "*make certain* that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999) (emphasis added). The court should consider whether an expert prepared his methodology for purposes of litigation, or articulated the methodology before litigation and without any incentive to reach a particular outcome. *See Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir.1995) ("Daubert II").

Under the second prong, the relevancy or "fit" analysis, the Court must "ensure that the proposed expert testimony . . . logically advance[s] a material aspect of the proposing party's case." *Redfoot v. B.F. Ascher & Co.*, No. 05-cv-2045-PJH, 2007 WL 1593239, at *4 (N.D. Cal. June 1, 2007) (citing *Daubert II*, 43 F.3d at 1315). The standard for fit is higher than bare relevance. *Id.* (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994)); *see also Daubert II*, 43 F.3d at 1317, n.17 (explaining that Rule 702's "relevance" requirement is not "merely a reiteration of the general relevancy requirement of Rule 402"). As a result, the Court "should exclude the scientific expert testimony under the second prong of the *Daubert* standard unless [the court] is convinced that it speaks clearly and directly to an issue in dispute in the case." *Jones v. United States*, 933 F. Supp. 894, 900 (N.D. Cal. 1996) (internal quotations omitted).

Courts should resolve expert challenges early because the admissibility of an expert's testimony is a designated "preliminary question" under Federal Rule of Evidence 104(a). *Lukov v. Schindler Elevator Corp.*, No. 11-cv-00201-EJD, 2012 WL 2428251, at *1 (N.D. Cal. June 26, 2012). Finally, it is WSN's burden to show that its expert testimony is admissible. *Joiner*, 522 U.S. at 144. Because WSN cannot meet its burden here, Dr. Charles' expert reports and testimony must be excluded.

IV. ARGUMENT

A. Dr. Charles' Opinions Are Irrelevant.

In his expert reports, Dr. Charles never mentions the claims challenged by the FTC, nor does he provide any analysis of whether those claims exists are truthful or adequately substantiated. And at his deposition Dr. Charles made clear that the "claims" he was referring to were not the challenged claims, but certain testimonials offered by WSN and the articles referenced in his reports. Snow Decl., Ex. D, Transcript of Deposition of Dr. M. Arthur Charles, 178:25-180:2 ("Charles Dep."). In other words, Dr. Charles assessed the existence of substantiation for "claims" that *are not at issue* in this lawsuit. His opinions are therefore of no help to the Court in determining whether the claims challenged by the FTC are truthful and substantiated.

1. The Elements of Deceptive Advertising Focus on the Nine Challenged Claims in the FTC's Complaint.

In its complaint, the FTC challenges nine claims made by WSN's ads. *Supra* note 1. The determination of whether WSN's advertisements violate the FTC Act requires a three-part inquiry, with each part focusing on the claims made by WSN in the relevant advertisements, as alleged by the FTC in its First Amended Complaint (i.e., the "challenged claims"). First, the Court must determine whether WSN disseminated advertisements conveying *the challenged claims*. Second, the Court must assess whether *the challenged claims* were false or misleading. Third, the Court must determine whether *the challenged claims* are material to prospective consumers. *Pantron*, 33 F.3d at 1095; *Kraft, Inc. v. FTC*, 970 F.2d 311, 314 (7th Cir. 1992); *FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285, 297 (D. Mass. 2008), *aff'd*, 684 F.3d 1 (1st Cir. 2010).

Only the second prong—whether the challenged claims are false or misleading—is relevant to the present motion. Under the second prong, the FTC can make the necessary showing in two ways (both at issue in this case). First, the FTC can show that the challenged claims are false. *Pantron*, 33 F.3d at 1096. And second, the FTC can show that the advertiser lacked a "reasonable basis" in making the challenged claims. *Id.* The advertisements lack a

reasonable basis, and are therefore deceptive, when the advertiser lacks adequate substantiation for the challenged claims. *Id.*

Dr. Charles is not qualified to assess whether the advertisements convey the challenged claims (the first part of the inquiry), nor whether those claims would be material (the third part of the inquiry). *See* Charles Dep. 38:24-39:1 (testifying that he is not an expert in advertising); 39:2-9 (testifying that he is not an expert in marketing); 39:10-13 (testifying that he is not an expert in human psychology); 40:20-24 (testifying that he is not an expert in how consumers understand advertisements); 41:1-3 (testifying that he does not have training in how consumers perceive advertising). Thus, the only issue for which Dr. Charles has relevant expertise is whether the challenged claims are truthful or sufficiently supported by competent and reliable scientific evidence.

2. Dr. Charles' Does Not Opine on Whether The Challenged Claims Are Truthful or Substantiated.

Dr. Charles' two reports never mention the claims challenged by the FTC. *See generally*, Charles Report and Snow Decl. Ex. F, Rebuttal Expert Report of Dr. M. Arthur Charles, 4 ("Charles Rebuttal Report"). Nor does Dr. Charles provide any analysis corresponding to the challenged claims. *Id.* Instead, he states without explanation that "the claims made by Wellness Support Network are truthful and substantiated." Charles Report at 10. Dr. Charles' reports never specify what "claims" he was referring to.

At his deposition, Dr. Charles provided the puzzling explanation that by "claims," he meant "some of the testimonials we've reviewed and the scientific studies that I've referenced. The more clinical evaluations." Charles Dep. 175:23-176:9. When asked what "testimonials" he was referring to, he mentioned the testimonials on WSN's website. Dr. Charles also referred to an article from *Life Extension Magazine* as a "testimonial."[3] Charles Dep. 176:23-178:2. Dr. Charles identified the lists of articles and studies he cites in his report as constituting "claims" as he used the term in his report. Charles Dep. 178:25-180:2. Apart from the "testimonials" and

[3] Snow Decl. Ex. E,*A Natural Approach to Lowering Blood Sugar*, Life Extension Magazine, (September 2000). The article cited by Dr. Charles does not name the author.

the cited articles, Dr. Charles did not identify anything else he considered a "claim" made by WSN that, in his opinion, was truthful and substantiated.[4]

Of central concern to Federal Rule of Evidence 702 is whether the expert's testimony "will help the trier of fact to understand the evidence or determine a fact in issue." Fed. R. Evid. 702(a). Because Dr. Charles' reports do not consider or analyze the challenged claims, they are not helpful to the Court in determining the central issue in this case: whether the challenged claims are truthful and substantiated. Dr. Charles' reports and testimony is therefore inadmissible and should be excluded.

B. Dr. Charles' Opinions Are Unreliable.

When an expert's testimony does not grow out of pre-litigation research and is not peer reviewed, the expert must (1) "explain precisely how they went about reaching their conclusions" and (2) "point 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 the scientists in their field." *Carnegie Mellon Univ.* 55 F. Supp. 2d at 1034 (N.D. Cal. 1999) (citing *Daubert II*, 43 F.3d at 1318-19).

Dr. Charles' opinions fail to meet this standard for two reasons: First, Dr. Charles has based his opinions relating to effectiveness on a plainly unscientific legal opinion far outside his expertise, formed through review of irrelevant FDA-related documents. Second, Dr. Charles — without explanation—gives precedence to studies that purportedly confirm the efficacy of particular ingredients of WSN's products while explicitly disregarding those studies showing negative or statistically insignificant results.

[4] Under Federal Rule of Civil Procedure 26(a)(2)(B)(i), Dr. Charles' reports must provide a complete statement of all of his opinions. Having expressed no opinion regarding the challenged claims in his reports or his deposition, he may not do so now.

1. Dr. Charles' Opinion Improperly Relies on a Legal Conclusion That High Quality Testing "Automatically" Classifies a Substance as a Drug Under FDA Law.

Dr. Charles' reports are unreliable and inadmissible because Dr. Charles improperly relies on his own legal opinion regarding the regulation of medical foods by the Food and Drug Administration ("FDA"). But critically, the particular point of law he relies upon—whether medical foods are "automatically" classified as drugs if substantial clinical tests are performed—is irrelevant to the merits of this case. The *FTC Act* is at issue here; neither Dr. Charles' nor anyone else's parsing of *FDA* law is relevant. As the Second Circuit wrote in *Bristol-Meyers Co. v. FTC*, 738 F.2d 554 (2d Cir. 1984), "[i]nsofar as FDA requirements and regulations are concerned, they simply do not govern this case. Not only is a different regulatory scheme involved, but generally speaking the FDA is concerned only with evaluating absolute safety and efficacy . . . ." 738 F.2d at 559. The FTC, by contrast, is concerned with the truth and substantiation of claims conveyed in particular advertisements. Dr. Charles' reliance on FDA law renders his opinions inadmissible, but his misadventures' larger lesson is that the FDA's detailed statute and regulations have no place in this matter. The proper focus of the Court's inquiry is whether WSN's advertisements were deceptive under Section 5 and Section 12 of the FTC Act. 15 U.S.C. §§ 45, 52.

The core of Dr. Charles' analysis is his assignment of certain ingredients to three "clinical effectiveness categories," which he calls "Level 1," "Level 2," and "Level 3." Charles Report at 7. According to Dr. Charles, Level 1 status is assigned to substances where evidence "strongly supports" usefulness of the substance for pre-diabetic or diabetic individuals. *Id.* Level 2, similarly, corresponds to substances where evidence "support[s]" usefulness. *Id.* And Level 3 substances, in Dr. Charles' rubric, have evidence "possibly supporting" usefulness. *Id.*

This hierarchy is, by Dr. Charles' admission, "substantially less than that required by the FDA for drug approvals in which large scale, multicenter, prospective, randomized, double-blinded and controlled trials are the norm." *Id.* Dr. Charles explains that the less rigorous standard is justified because "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." *Id.* In other words, as Dr. Charles explained during his deposition, his conclusion was that "if you do [clinical tests] anywhere near what the FDA requires for a drug, *then you're automatically classified as a drug*." Charles Dep. 169:9-11 (emphasis added). Dr. Charles even acknowledged that WSN's products have "never been studied," but explained that "the reason for that, as I described before, is because there's language in the FDA documents saying *you shouldn't study it or it will turn into a drug . . . .*" Charles Dep. 181:14-17 (emphasis added). Dr. Charles concluded that, because testing a medical food would turn it into a drug, such high-quality tests cannot be performed. Charles Dep. 221:9-13.

In his rebuttal report, Dr. Charles explains further that "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 and even if the substance is a component of a commonly consumed food with known beneficial effects." Charles Rebuttal Report at 4. "It follows," Dr. Charles wrote, "that the scientific rigor for approval of prescription drugs by the FDA would be higher than those used for dietary supplements or medical foods." *Id.*

Dr. Charles' understanding of how the FDA regulates medical foods is, as he explained in his deposition, the sole reason he created his three-level categorization scheme. *See* Charles Dep. 220:17-221:13. Dr. Charles testified that he reviewed FDA regulations and formed an opinion with respect to their implications for the testing of drugs and medical foods as those substances are defined in FDA law. *Id.* Dr. Charles' understanding of those regulations is a legal conclusion and an inappropriate subject for expert testimony. *United States v. Caputo*, 517 F.3d 935, 942 (7th Cir. 2008) (excluding an expert from testifying regarding the meaning of the FDA statute and regulations).

Dr. Charles based his entire rubric of "clinical effectiveness categories" on his understanding of the law. *See* Charles Report at 7; Charles Rebuttal Report at 4; Charles Dep. 220:17-221:13; 125:12-126:13. A critical step of his reasoning, then, is based not in medicine or the scientific method as *Daubert* requires, but in legal matters about which he has no expertise.

See Charles Dep. 43:18-21 (testifying that he is not a lawyer); 43:22-44:5 (testifying that he has no formal training relating to FDA regulation of medical foods); 45:15-24 (testifying that before this case he has never reviewed any FDA documents relating to medical foods). His entire analysis, therefore, is unreliable and inadmissible. *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994) ("[A]ny step that renders the analysis unreliable . . . renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology.").

2. Dr. Charles Never Explains How His Preference For Positive Studies Is Grounded In Science.

Dr. Charles' reports fails to provide any sound scientific basis for his effectiveness opinions. While he cites studies that purportedly show the efficacy of ingredients in WSN's products, Dr. Charles fails to analyze the numerous studies that show that the ingredients have no effect. His only justification for this approach is that "positive clinical studies often take precedence over negative studies." Charles Report at 6. His report's entire explanation for this concept is 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.

Charles Report at 6. Dr. Charles cited no authority explaining the scientific basis for this concept. Nor did he elaborate in his report on what he meant by "positive," or "negative" studies. And in listing his ingredient-related conclusions, Dr. Charles never explained how the principle had been applied to give particular studies "precedence" over others. Dr. Charles has written bias into his methodology.

When asked about this subject at his deposition, Dr. Charles clarified that there was also a third category, "neutral" studies, which he had omitted from his report:

> Q All right. What do you mean by positive studies?
> A Studies that would show a change in whatever you're -- agent that you're trying to use to create a change.

> Q Okay. So what –
> A So a change in the direction that you would expect it to be changing. So for in diabetes you would expect it to say lower the blood sugar, lower the A1C.
> Q Okay so a positive study would do that?
> A Yes. There's actually three kind of studies and I should have put that in here. There should be a positive study, a neutral study and a negative study. I shouldn't use negative, because I may have seen one negative study where there was actually the detriment sugars in all the studies I reviewed, but most of the studies are either positive or neutral, not negative. So neutral would be no statistical change . . . .

Charles Dep. 182:8-183:1. As clarified by Dr. Charles in his deposition, "positive" studies are those showing a benefit to diabetes patients. "Negative" studies are those showing a detriment to diabetes patients. And "neutral" studies are those showing no statistically significant change at all. In preparing his report, Dr. Charles cited only to positive studies. Charles Dep. 189:22-25 ("Q. . . . You talked about the positive studies? A. Yeah I didn't really talk about the neutral studies."). Ultimately, Dr. Charles' preference for "positive" over "negative" and "neutral" studies appears to be nothing more than a preference for studies that demonstrate efficacy—and thereby support WSN—over those that do not.

To comply with *Daubert*, Dr. Charles must explain *precisely* how he went about reaching his conclusions *and* he must point to some *objective source* to show that he followed the scientific method. *Carnegie Mellon Univ.*, 55 F. Supp. 2d at 1034 (citing *Daubert II*, 43 F.3d at 1318-19). Dr. Charles has done neither. Instead, he has invented a rule that allows him to disregard studies that report contrary empirical findings. Dr. Charles has not cited to any authority—much less any "objective source"—to demonstrate the scientific validity of his extraordinary rule preferring positive over negative and neutral studies.

Dr. Charles' reports must also include "a *complete statement* of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B)(i) (emphasis added). But those reports do not breathe a word about the numerous neutral studies refuting those positive studies Dr. Charles elects to cite.[5] Dr. Garvey also identifies numerous contrary

[5] Some of the articles Dr. Charles cites point to significant studies that show the ingredients have no statistically significant effect. *See* Snow Decl. Ex. G, William T. Cefalu & Frank. B. Hu, *Role of Chromium in Human Health and in Diabetes*, 27 DIABETES CARE 2741, 2741-2742 (2004) (noting that "significant controversy still exists regarding the effect of chromium supplementation on parameters assessing human health" and that "[results] from other studies

(in Charles' terms, "neutral") studies as well, but again, Dr. Charles does not mention them.[6] Nor does Dr. Charles ever address alternative explanations for the purportedly positive studies, as he must. *See Carnegie Mellon Univ.*, 55 F. Supp. 2d 1024 at 1034 (excluding an expert who "fail[s] to address and exclude alternative explanations for the data on which he bases his findings"). Dr. Charles must explain why he discounts contrary empirical studies *and* he must rule out alternative explanations for studies he relies on in support his opinions. The Court is not permitted under *Daubert* to simply take an expert at his word.

These omissions are a textbook violation of *Daubert* and Federal Rule of Evidence 702. *See Carnegie Mellon Univ.*, 55 F. Supp. 2d at 1034; *Daubert II*, 43 F.3d at 1318-19 (affirming exclusion of experts where "the experts neither explain the methodology [they] followed to reach their conclusions nor point to any external source to validate that methodology.").

(27-32) have indicated little or no benefit of chromium on any of these variables"); Snow Decl. Ex. H, D.M. Smith, et al., *A Systematic Review of Vanadium Oral Supplements for Glycemic Control in Type 2 Diabetes Mellitus*, 101 QUART. J. MED. 351 (2008) ("There is *no rigorous evidence* that oral vanadium supplementation improves glyceamic control in type 2 diabetes. *The routine use of vanadium for this purpose cannot be recommended*.") (emphasis added). Dr. Charles never explains why he discredits the neutral results in the studies he cites.

[6] Snow Decl. Ex. I, Opening Expert Report of Dr. W. Timothy Garvey ("Garvey Report") at 33-64. For example, Dr. Garvey identifies several studies of Dr. Charles' "Level 1" or "strongly supporting" ingredients, including vitamin D, biotin, magnesium, and chromium, which found "no effects" or "no significant effects" of these ingredients on treating, managing, or preventing diabetes. *See e.g.*, Garvey Report at 40 (study finding no effect of vitamin D on fasting glucose, fasting insulin, A1C, and other indicators of glycemic control); 43 (study finding no significant effect on biotin on fasting glucose or fasting insulin); 46 (reports finding magnesium had no effect on parameters of glucose control); 53 (studies finding that chromium had no effect on glucose tolerance, fasting insulin, fasting glucous or insulin). Dr. Charles never explains why those studies are not valid.

V. CONCLUSION

For the reasons stated above, Dr. Charles' report is not relevant, complete, or reliable. The Court should exclude Dr. Charles' testimony as inadmissible under *Daubert v. Merrell Pharmaceuticals*.

Respectfully Submitted,

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