MOTION TO EXCLUDE EXPERT TESTIMONY OF DR. M. ARTHUR CHARLES CASE NO. 10-CV-4879 JCS

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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. Marthur Charles ("Dr. Charles") support of Wellness Support Network, Inc., Robert Held, and Robyn Held (collectively, "WSN") un **Deu**bert v. Merrell Dow Pharms., yn1993). and Rob

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1	substantiation; and 3) welther the challenged claims are mialleto prospective consumerSee	
2	FTC v. Pantron I, Corp.33 F.3d 1088, 1095 (9th Cir. 1994)r. Charles has no relevant	
3	expertise with respect to wheththe ads convey the challenged claims or whether the chall	enaed
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In the next section, titled "Relts," Dr. Charles assigned rtagin WSN ingredients to his "clinical effectiveness categories ld. at 8-10. Noticeably absemb Dr. Charles' report is any discussion of how he knows that the WSN products provide any both they claim since there are no studies or sess twsN's products. Dr. Charles cited to articles ostensibly supporting his conclusions, but did not offer any review of the existierature for any ingredient. Nor did Dr. Charles discuss the idsetaf any study or compare studies with each other. Dr. Charles concluded his report with stratement that "[i]t is also my opinion that the claims made by [WSN] are truthful and substantiated."at 10. But Dr. Charles did not explain what "claims made bWSN" he was referring told. III. MOTION TO EXCLUDE EXPERT TESTIMONY OF DR. M. ARTHUR CHARLES CASE NO. 10-CV-4879JCS

may conclude that there is sily poo great an analytical gapetween the data and the opinion proffered." Id.

The Court should alson"ake certain an expert . . . ephoys in the courtroom the same level of intellectual rigor that characterizesphactice of an expert the relevant field." Kumho Tire Co., Ltd. v. Carmichael 26 U.S. 137, 152 (1999) (emasis added). The court should consider whether an expert preparied methodology for purposes of litigation, or articulated the methodology before litigation arithout any incentive to reach a particular outcome. See Daubert v. Merrell Dow Pharms.,,IA8.F.3d 1311, 1317 (9th Cir.1995) ("Daubert II").

Under the second prong, the relevancy or "fit" analysis, **ther**Omust "ensure that the proposed expert testimony . oglcally advance[s] a materiatspect of the proposing party's case." Redfoot v. B.F. Ascher & CoNo. 05-cv-2045-PJH, 2007 WL 1593239, at *4 (N.D. Cal. June 1, 2007) (citinDaubert II, 43 F.3d at 1315). The standford fit is higher than bare relevance. Id(citing In re Paoli R.R. Yard PCB Litig35 F.3d 717, 745 (3d Cir. 1994); e also Daubert II, 43 F.3d at 1317, n.17 (explaining that RODe's "relevance" requirement is not "merely a reiteration of the generelevancy requirement of RuteD2"). As a result, the Court "should exclude the scientific expetestimony under the second prong of Dreubertstandard unless [the court] is convinced thit speaks clearly and directly an issue in dispute in the case." Jones v. United State333 F. Supp. 894, 900 (N.D. Cal. 1996) (internal quotations omitted).

Courts should resolve expert challenges **expery**ause the admissibility of an expert's testimony is a designated "preliminary questio

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IV. ARGUMENT

Α. Dr. Charles' Opinions Are Irrelevant.

In his expert reports, Dr. Charles never mentithe claims challenged by the FTC, nor does he provide any analysis of whether thousand exists are truthful or adequately substantiated. And at his deposit Dr. Charles made clear that "claims" he was referring to were not the challenged claimbut certain testimonials offered by WSN and the articles referenced in his reports. Snow Decl., Ex. DanEscript of Deposition dDr. M. Arthur Charles 178:25-180:2 ("Charles Dep."). In other word Dr. Charles assessed the existence of substantiation for "claims" that renot at issuen this lawsuit His opinions are therefore of no help to the Court in determining whether their schallenged by the FTC are truthful and

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the cited articles, Dr. Charles did not identifyything else he consided a "claim" made by WSN that, in his opinion, was truthful and substantiated.

Of central concern to Federal Rule of *Gence* 702 is whether the expert's testimony "will help the trier of fact to undetand the evidence or determine a fact in issue." Fed. R. Evid. 702(a). Because Dr. Charles' reports do not comside analyze the challenged claims, they are not helpful to the Court in determining the centr

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

Dr. Charles' reports are usitable and inadmissible because Dr. Charles improperly relies on his own legal opinion regarding togulation 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 gos if substantial clinical tests are performed—is irrelevant to the merits of this case. THEC Actis at issue here; neither Dr. Charles' nor anyone else's parsing 5DA law is relevant. As the Second Circuit wrot sinstol-Meyers Co. v. FTC, 738 F.2d 554 (2d Cir. 1984), "[i]nsofar EDA requirements and regulations are concerned, they simply do not govern this case only is a different regulatory scheme invoAct

1 SeeCharles Dep. 43:18-21 (testifyingathe is not a lawyer); 422-44:5 (testifying that he has 2 no formal training relating to FDA regulation of medical foods); 45:15-24 (testifyiat before 3 this case he has never reviewed any FDA decuter relating to medical foods). His entire 4 analysis, therefore, is unliable and inadmissibleSee In re Paoli R.R. Yard PCB Litig., 35 Fl3d 717, 745 (3d Cir. 1994) ("[A]ny step ath renders the analysis unrelia... renders the expert's 5 6 testimony inadmissible. This is true whether step completely changes a reliable methodology or merely misapplies that methodology."). 7 2. Dr. Charles Never Explains How His Preference For Positive 8 Studies Is Grounded In Science. 9 10 Dr. Charles' reports fails to provide asyund scientific basis for his effectiveness opinions. While he cites studies at purportedly show the efficy of ingredients in WSN's 11 products, Dr. Charles fails to analyze the numerous studies that showethrat redients have ho 12 effect. His only justification for this approach is that "positive clinical studies often take 13 precedence over negative studies." Charles Repôrt blis report's entire explanation for this 14 concept is as follows: 15 16 In many of the human trials of arious substances, e.g. vitamins,

in many of the numan trials or arous substances, e.g. Vitamins, minerals, trace elements and plant extracts, both positive and negative studies are published; burhitist 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 reportwhat he meant by "positive," or "negative"

studies. And in listing his ingdient-related conclusions, Dr. at es never explained how the

23 principle had been applied to give particular studies "precedence" over others. Dr. Charles has

24 written bias into his methodology.

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When asked about this subj**et**this deposition, Dr. Charlesetified that there was also

26 a third category, "neutral" studies, ich he had omitted from his report:

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All right. What do you mean by positive studies? Studies that would show a ch

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Case3:10-cv-04879-JCS Document119 Filed07/05/13 Page15 of 18 Okay. So what -Q 1 So a change in the direct it that you would expect it to be А changing. So for in diabetes you would expect it to say lower the 2 blood sugar, lower the A1C. Okay so a positive study would do that? Q 3 Yes. There's actually the kind of studies and I should have put that in here. There suld be a positive study, a neutral 4 study and a negative study. I shouldn't use negative, because I may have seen one negative sturdyere there was actually the 5 detriment sugars in all the stedil reviewed, but most of the studies are either positive oruteal, not negative. So neutral 6 would be no statistical change 7 Charles Dep. 182:8-183:1. As clarified by Dr.adles in his depositin, "positive" studies are those showing a benefit to diabetes patient segative" studies are these howing a detriment to 8 9 diabetes patients. And "neutral" studies are ended wing no statistically significant change at 10 all. In preparing his repord r. Charles cited only to positivatudies. Charles Dep. 189:22-25 11 ("Q.... You talked about the positive studies? Yeah I didn't really talk about the neutral studies."). Ultimately, Dr. Charles' preferent for "positive" over "negative" and "neutral" 12 13 studies appears to be nothing more than æperete for studies that demonstrate efficacy-and 14 thereby support WSN—ovehose that do not. 15 To comply with Daubert Dr. Charles must explain precisely whe went about reaching 16 his conclusion and he must point to some objective source how that he followed the 17 scientific method.Carnegie Mellon Univ.55 F. Supp. 2d at 1034 (citimaubert II, 43 F.3d at 18 1318-19). Dr. Charles has done heit Instead, he has inventedule that allows him to disregard studies that report contrary empirized ings. Dr. Charles as not cited to any 19 20 authority—much less any "objective source"—to demonstrate the entific validity of his 21 extraordinary rule prefeing positive over negative and neutral studies. 22 Dr. Charles' reports must also include tamplete 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 23 24 added). But those reports do not breathe a vabodut the numerous neutral studies refuting those positive studies DC harles elects to cife. Dr. Garvey also identifies numerous contrary 25 26 ⁵ Some of the articles Dr. Chasleites point to significant studies the ingredients have no statistically significant effectSeeSnow Decl. Ex. G, William T. Cefalu & Frank. B. Hu, 27 Role of Chromium in Human Health and in Diabetes, 27B Dres CARE 2741, 2741-2742 (2004) (noting that "significant controversy bekists regarding theffect of chromium 28 supplementation on parameters assessing hueralth hand that "[results] from other studies MOTION TO EXCLUDE EXPERT TESTIMONY OF DR. M. ARTHUR CHARLES CASE NO. 10-CV-4879JCS

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