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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.: CV 10-4879-JCS DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION TO EXCLUDE EXPERT TESTIMONY OF DR. M. ARTHUR CHARLES; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF Date: September 27, 2013 Time: 9:30 a.m. Dept: G, 15th Floor Magistrate Judge: Hon. Joseph C. Spero

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MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

As explicitly stated on the Defendants' website and shown throughout the Exhibits attached to the FTC's First Amended Complaint, the products at issue in this case are medical foods; *see* Holmes Dec.¶¶ 2, 3 and 4, Ex. A., pp.1, 6, 7; Ex. B., pp.1, 7, 8; Ex. C, pp.1, 5. At 21 U.S.C. § 360ee(b)(3), a medical food is defined as a "food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." As described by the FDA,

> The term "medical foods" does not pertain to all foods fed to sick patients. Medical foods are foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in a natural state) for the patient who is seriously ill or who requires the product as a major treatment modality. In general, to be considered a medical food, a product must, at a minimum, meet the following criteria: the product must be a food for oral or tube feeding; the product must be labeled for the dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and the product must be intended to be used under medical supervision…

Guidance for Industry: Frequently Asked Questions About Medical Foods, May 2007;[1] *see also* 61 Fed.Reg. 60669 ("…a medical food is intended for use as the source of nutrients that are necessary in the medical management of a particular disease or condition.")

Because medical foods are designed to be consumed or administered under the supervision of a physician, medical foods have different labeling requirements than dietary supplements and conventional foods and are exempted from the nutrient content claims under the Nutrition Labeling and Education Act of 1990; *Id. citing* 21 U.S.C. § 343(q)(5)(A)(iv). While "medical foods are foods as defined in the Act and are subject to the general food safety and labeling requirements of the Act,"[2] medical foods do not have to undergo premarket review or approval by FDA and individual medical food products do not have to be registered with FDA. *Id.*; *see also* 61 Fed.Reg. 60662 (November 29,

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[1] http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/MedicalFoods/UCM054048#ftn1.

[2] FDA Center for Food Safety and Applied Nutrition, *Compliance Program Guidance Manuel CP 7321.002 Medical Foods - Import and Domestic*, (Aug. 24, 2006) *available at* http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/ComplianceEnforcement/UCM073339.pdf

1996) ("Medical foods are used under the supervision of a physician when such distinctive nutritional requirements cannot be met with a conventional diet. These characteristics have led the agency to exempt medical foods from many of the requirements that apply to conventional foods.")

FDA has also made clear that the level of substantiation required for making a claim regarding a medical food is higher than that required for a conventional food, but not as high as that required for a drug. *Id.* The FDA has nevertheless described this standard as a "strong" one. *Id.* In this case, even though FDA has taken it upon itself to regulate the claims made for medical foods, the FTC would supplant the FDA and create a standard which flies in the face of FDA's and without ever subjecting that standard to notice and comment rulemaking procedures.

When evaluating the Defendants' products, Dr. Charles addressed head-on the fact that the Defendants' products are medical foods as defined by federal law with unique substantiation requirements. The FTC now complains that analysis renders his opinion unreliable and irrelevant. The FTC's expert, Dr. Garvey, had never heard prior to his deposition that the Defendants' products were medical foods, did not know what a medical food was at the time of his deposition, had never looked at any documents prepared by FDA detailing what medical foods are or how their claims must be substantiated, and did not even "bother to ascertain" whether the claims alleged by FTC to be the subject of this lawsuit appeared on the Defendants' website. Holmes Dec ¶5., Ex. D, Garvey Depo, at 197, 202-203 (By Dr. Garvey: "Could you define 'medical food' for me? This is a term that you keep using.")

In response to the FTC's subpoena *duces tecum*, Dr. Charles produced in excess of 160 studies that he reviewed as part of his analysis of this case, all of which show that the ingredients in the Wellness products benefit the diabetic condition. Holmes Dec. ¶ 7, Charles' Expert Report, at 60. In order to group those studies when drafting his report, Dr. Charles created categories which, as he testified at his deposition, were consistent with the manner by which he evaluates information about products when treating patients; *see e.g.* Holmes, Dec ¶ 6, Ex. E, Charles Depo, at 192-193. Dr. Garvey proceeded differently, categorizing the studies based on standards promulgated by the United States Preventative Services Task Force (USPSTF), which Dr. Garvey admitted was not the "end-all-and-be-all" and not applicable to products designed to assist persons with diseases or disease conditions; Holmes Dec.¶ 5 Ex. D, at 153-155.

II. F.R.E. 702

We rely upon this Court's recent analysis of Rule 702 of the Federal Rules of Evidence to set forth the legal standard which this Court will follow in ruling on the FTC's motion:

> Rule 702 of the Federal Rules of Evidence permits expert testimony if it "will help the trier of fact to understand the evidence or to determine a fact in issue." Fed.R.Evid. 702. The expert may provide testimony if "(1) the testimony is based on sufficient facts or data; (2) the testimony is the product of reliable principles and methods; and (3) the expert has reliably applied the principles and methods to the facts of the case." *Id.* In *Daubert v. Merrell Dow Pharmaceuticals*, the Supreme Court held that the Rule 702 analysis "entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology can be applied to the facts in issue." 509 U.S. 579, 593-94 (1993). Thus, district courts "are charged with a 'gatekeeping role,' the objective of which is to ensure that expert testimony admitted into evidence is both reliable and relevant." *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1360 (Fed. Cir. 2008).
>
> In *Daubert*, the Court suggested four non-exhaustive guiding factors to make this determination: (1) whether the expert's methodology has been tested or is capable of being tested; (2) whether the technique has been subjected to peer review and publication; (3) the known and potential error rate of the methodology; and (4) whether the technique has been generally accepted in the proper scientific community. *Daubert*, 509 U.S. at 593-95. The Court also emphasized that the focus of this inquiry, "of course, must be solely on principles and methodology, not on the conclusions that they generate." *Id.* at 595. When an expert's principles and methodology are sound, and the evidence relied upon sufficiently related to the case at hand, disputes about the degree of relevancy or accuracy may go to the testimony's weight, not its admissibility. *Primiano v. Cook*, 598 F.3d 558, 564-65 (9th Cir.2010).

TV Interactive Data Corp. v. Sony, 2013 U.S. Dist. LEXIS 28559, 6 (N.D. Cal. 2013) (Spero, J.)

III. ARGUMENT

A. Dr. Charles's Opinions are Relevant and Should Not be Stricken.

1. Dr. Charles is competent to testify regarding all aspects of diabetes.

The Government argues in its motion that "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." Motion, at 7. Although we do not dispute that point, we note the following:

First, Dr. Charles does not purport to be anything other than what he is, i.e. one of the leading experts in the Northern District of California on the issues of diabetes and pre-diabetes, both in terms of the conditions themselves, the products used to treat and manage them, and the practice of medicine for

diabetic patients. That Dr. Charles is not a psychologist or marketing expert should have no bearing on his ability to serve as an expert in this case.

And second, the FTC's expert, Dr. Timothy Garvey, has no more expertise on the subject matters outlined on Page 7 of the FTC's motion than does Dr. Charles.

2. Dr. Charles did not need to mention the subject claims in order to testify that the Defendants' products do what they say.

In its Motion, at 7, FTC argues that Dr. Charles's testimony is irrelevant because his "two reports never mention the claims challenged by the FTC." Consequently, FTC argues, Dr. Charles's reports "are not helpful to the Court in determining the central issue in this case: whether the challenged claims are truthful and substantiated." Motion, at 8. The FTC's argument misses the forest for the trees.

a. Expert testimony in FTC litigation serves a much broader purpose than the FTC would lead this Court to believe.

According to FTC, the sole job of an expert witness in FTC litigation is to evaluate claims listed in a Complaint – regardless of whether the claims were ever actually made – and testify if they are true. But no case stands for this narrow proposition. In reality, because the FTC's complaint sounds in fraud – and *especially* because the FTC has named two individuals as defendants in this case – the expert's job is much more significant.

To be sure, as it relates to all three Defendants, the FTC's complaint alleges that the Defendants "hoodwinked" their customers; *FTC v. Swish Marketing*, 2010 U.S. Dist. LEXIS 15016, 9 (N.D. Cal. 2010) (Seeborg, J.); *see also* Amended Complaint, at ¶ 28 ("Consumers have suffered and will continue to suffer substantial injury as a result of Defendants' violations of the FTC Act. In addition, Defendants have been unjustly enriched as a result of their unlawful acts or practices.") As it relates to the individual Defendants, the FTC's complaint has an even sharper sting. In order to establish individual liability in a Title 5 case, the FTC must establish not only that the Defendant "hoodwinked" its customer, but that the individual "had knowledge of and authority to control whatever acts led to the corporate misconduct." *FTC v. Benning*, 2010 U.S. Dist. LEXIS 64030, 4 (N.D. Cal. 2010). As such, this case is about much more than whether the subject claims were made and whether they were truthful.

As the FTC's complaint makes clear, the Defendants advertise the products at issue in this case as "a medical food specifically formulated for the dietary management of diabetes." *See* Holmes Dec.¶ 2, Ex. A. As the FTC's complaint also makes clear, the Defendants advise their customers that the products were "[t]o be used under medical supervision as part of your on-going medical treatment." Holmes Dec. ¶2, Ex. A, p.6. The Defendants also make clear on their website that the FDA "has not evaluated these claims pertaining to these medical foods. These medical foods are intended for the dietary management of diabetes and not intended to 'diagnose, treat, cure or prevent any disease,' because only a drug can legally make such a claim." *Id.* at, p.7. Dr. Charles's testimony addresses these points head on.

In its Motion, the FTC complains that Dr. Charles does not directly address the claims listed in the FTC's motion, but as the Defendants' Answer makes clear, the Defendants deny that they ever made those claims; *see* Holmes Dec. ¶7, Ex. F, Amended Answer, DE 52, at ¶¶ 24, 26. The FTC also complains that Dr. Charles is not competent to testify regarding whether the claims were made in the first place because he is not an expert in advertising, marketing or psychology. Motion, at 10. However, where Dr. Charles has the greatest level of expertise is exactly where he directed his attention as an expert, i.e. the practice of medicine, the recommending and prescribing of diabetic products, and "the experiences of physicians with their patients." Holmes Dec. ¶6, Ex. E, at 174:9. As such, Dr. Charles's testimony was perfectly appropriate and should not be stricken.

b. Dr. Charles's testimony is complex because Diabetes is a complex condition.

Dr. Charles's testimony is admittedly not as simple as the "hit/caught"[3] analysis the FTC argues it should be. The complexity of the testimony is due in large part to the complexity of diabetes itself, which Dr. Charles describes as being poorly treated in the United States "despite appropriate diet, exercise and medication plans, which have been readily available for several decades." Holmes Dec., ¶8, Ex. G, Charles Report at 3-4. As Dr. Charles described during his deposition, "diabetes is a disease that can actually be defined by one's blood sugars, and those definitions vary around the world." Holmes

[3] MAJOR LEAGUE (Paramount Pictures 1989).

Dec. ¶6, Ex. E, at 29:2-4. However, one's blood sugar "is just a small component of the definition of diabetes." *Id.* at 29:22-23. In reality, the problems associated with diabetes leading to the highest morbidity and mortality rates are related to how the glucose interacts with the proteins in the body:

> So when one has diabetes, then part of that definition is that most of the organ systems and metabolic schemes are damaged or not under normal mechanisms because they've been glycated, which means the blood sugar has attached to the protein like with the hemoglobin A1c. So that's a process that goes on all over the body and then turns this disease into a rather significant entity…which leads to then major complications [which] come in two types, microvascular and macrovascular.

Id. at 30:10-20; *see also* Holmes Dec. ¶8, Ex. G, at 3 ("Both pre-diabetes and diabetes are associated with unusually high rates of cardiovascular disease, which leads to 80-90% of the deaths in diabetic patients.")

Adding to this complexity is that, for several reasons, most drugs fail to effectively treat or cure diabetes. First, numerous FDA-approved diabetes drugs have been removed from the marketplace for safety concerns, or approved with severe restrictions and warnings which greatly reduced their usefulness; *Id.* at 5 (describing Troglitazone, Pioglitazone and Rosiglitazone). Second, Dr. Charles describes that the drugs which are not removed from the market are not useful in the majority of diabetic patients; *Id.* (describing Metformin, which is not useful for patients with Type 2 diabetes because they lack adequate insulin secretion.) Third, Dr. Charles describes the extraordinary difficulties associated with conducting randomized trials with diabetes patients because the diabetic condition necessarily includes so many variables. Holmes Dec. ¶6, Ex. E, at 92:12 – 93:22.

It naturally follows that the manner by which Dr. Charles evaluates products and treats his patients is commensurate with the complexity he attributes to diabetes. During his deposition, Dr. Charles testified that treating a patient with diabetes should include a "constellation" of treatments: "So any diabetic who is under medical supervision, that medical supervision should include a broad array of risk factor control, not just the glycemia or not just the dyslipidemia and so forth." *Id.* at 78:19-22. According to Dr. Charles, the stars of this "constellation" should include recommending a Southern Mediterranean diet (*Id.* at 85-87), exercise (*Id.* at 87:25), FDA approved drugs, such as Metformin (*Id.* at 166:5-7), and dietary supplements and medical foods (*Id.* at 116:13-19); *see also* Holmes Dec ¶8., Ex. G, at 4 ("Because of relatively poor US results for type 2 diabetes treatment, complementary care, e.g.

dietary supplements and *medical foods*, in addition to usual medical care, is one component that may provide valuable assistance to patients who have pre-diabetes and type 2 diabetes.") Interestingly, Dr. Charles testified that doctors treating diabetics routinely recommend diet and exercise programs *even though they have never been proven to work*; *see e.g.* Holmes Dec.¶6, Ex. E, at 87:23-88:5.

Returning to the Wellness products, Dr. Charles paid close attention to the manner by which they are regulated because the applicable regulatory regime necessarily governs how the products must be substantiated and provided to patients. Again, the FDA (*the* federal agency charged with administering Title 21) has explicitly stated that the level of substantiation for medical foods falls somewhere above conventional foods but below drugs. 61 Fed.Reg. 60669. Additionally, the FTC's Complaint makes clear that the products at issue in this case are medical foods, and customers are specifically cautioned prior to checkout that the products are "[t]o be used under medical supervision as part of your ongoing medical treatment." This instruction is consistent with the statutory definition of medical food, which provides that they are "formulated to be consumed…under the supervision of a physician…" 21 U.S.C. § 360ee(b)(3). So, while Dr. Charles's testimony may not have been as rote as the FTC would have preferred, it nevertheless sheds an invaluable light on a variety of issues which should greatly benefit the Court in ruling in this case.

c. Dr. Charles's misunderstanding of how FTC interprets the term "claim" should not lead to his testimony being stricken.

In its Motion, at 7-8, the FTC writes that Dr. Charles's testimony was "puzzling" when he explained "that by 'claims' he meant 'some of the testimonials we've reviewed and the scientific studies that I've referenced. The more clinical evaluations." Motion, at 7. However, whether Dr. Charles knows the legal definition of a "claim" should not render his testimony any less valuable to the Court in deciding this case. First, what the FTC fails to mention in its motion is that Dr. Charles was admittedly confused by that term during his deposition: "I don't know the definition of claims and how you use it. Maybe – did you want to define that a little better or should we just stick with what I think it means? I'm not a lawyer." Holmes Dec.¶6, Ex. E, at 181:2-5. And second, as the FTC acknowledges in its Motion, Dr. Charles is not a lawyer, so whether he knows the legal definition of an ambiguous term is of no relevance in this case.

However, regardless of whether Dr. Charles's understanding of the term "claims" is consistent with FTC's, his testimony is still valuable:

> But I think what I meant by claims were what does this company come out with, and there's testimonials and then there's studies that I think are much, much stronger than testimonials and much less stringent than, say, an FDA drug. So that's what I'm using as a claim for the ingredients.

Id. at 181:6-11. Here, Dr. Charles is referencing the Wellness website (which, unlike Dr. Garvey, he reviewed in his expert analysis of this case) and specifically the page on the Wellness website which includes hyperlinks to a host of studies regarding the individual ingredients in the two products.[4] To the extent that Wellness was making claims regarding its products by referring purchasers to this specific page and the studies listed there, it was perfectly appropriate for Dr. Charles to testify that those were Wellness's claims.

d. Dr. Charles's testimony regarding the Wellness products is perfectly in line with federal law governing medical foods.

The FTC also complains that because Dr. Charles never identified the "challenged claims," he did not testify regarding substantiation and thus his testimony should be excluded. Motion, at 8. However, again, FTC misses the point of Dr. Charles's testimony.

First, we remind the Court that this case is not simply about whether the "subject claims" – which Wellness denies were even made – were substantiated. Rather, the FTC's complaint sounds in fraud, and alleges that the Defendants "hoodwinked" their customers and that the individual Defendants knew about it and had the power to stop it. *Swish Marketing*, 2010 U.S. Dist. LEXIS at 9. No Court has held that an expert in a FTC case must confine his testimony to claims which may or may not have ever been made.

Second, Dr. Charles's testimony regarding substantiation is both critical and perfectly in line with how medical foods are defined by statute and regulated by FDA. In short, there is simply no question that Dr. Charles testified regarding the substantiation of the claims that he perceived, i.e. the

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[4] *See*, http://www.realfoodnutrients.com/Diabetes/ClinicalStudies.htm.

claims which Wellness actually made on its website, and likewise opined that the diabetic benefit of the individual ingredients in the two products was adequately substantiated. Holmes Ex. G, at 7-10.

In order to evaluate whether the diabetic benefit of the individual ingredients in the two products was adequately substantiated, Dr. Charles reviewed more than 160 studies, and grouped the ingredients into three categories "based on the available clinical research into each." *Id.* at 7.[5] Although the FTC later complains in its Motion that this was "nothing more than a preference for studies that demonstrate efficacy," that is simply not the case. In actuality, Dr. Charles's testimony regarding the substantiation of the Wellness products, is perfectly consistent with the statutory definition of medical foods and how Dr. Charles cares for his diabetic patients.

During his deposition, Dr. Charles testified about the manner by which he would evaluate Wellness's products both as an investigator and as a clinician. Naturally, as Dr. Charles testified, both evaluations hinge on how the products are regulated. First, FTC Counsel asked Dr. Charles to testify as an investigator based on a hypothetical wherein a product manufacturer seeks advice from Dr. Charles regarding whether a treatment for diabetes actually works and the "kind of evidence" the manufacturer should have prior to marketing the product. Holmes Dec. ¶6, Ex. E, at 135:11-23. Furthermore, in this hypothetical, FTC Counsel asked Dr. Charles to assume that the manufacturer has *not* asked the FDA what the product is and, furthermore, that the manufacturer does not even know "anything about FDA." *Id.* at 136:10-18. Following this hypothetical, FTC counsel asked Dr. Charles as follows: "What kind of evidence would you either want to see or have performed?" *Id.*

From the perspective of an investigator, Dr. Charles testified that due to the lack of guidelines governing the level of substantiation required for medical foods, it was impossible to answer FTC Counsel's question:

> [U]nfortunately, as the investigator, I'm like really at a loss because I don't have any guidelines which I could tell the subject -- yeah, but these were in response to this particular product and I could use these but it would be really nice if there were guidelines like everything else that we do. So usually as a physician you have, you know, guidelines to help you do stuff and keep, you know, within some kind of semblance of what might be considered reasonable. That's why I think the FDA sent out that questionnaire asking for guidance on how to deal with medical foods from

[5] In Part B2 of its Motion, FTC also challenges this grouping process as being unreliable, and we will address that portion of its argument in turn.

> a regulatory point of view and what kind of studies should be done to make sure that their products are good.[6] But then they never responded to that, so it kind of left a void.

Id. at 144:25-145:13. Faced with this void of FDA guidelines governing the substantiation required for medical foods, Dr. Charles testified that, as an investigator, he would advise the manufacturer that a "reasonable" level of confidence regarding the effectiveness of the product would be appropriate. *Id.* at 144:19-25.

From the perspective of a treating physician, Dr. Charles testified that the best way of knowing whether a product is working is by monitoring the patient, which is exactly consistent with the statutory definition of "medical food;" *see* 21 U.S.C. § 360ee(b)(3) (a medical food "…is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements…are established by medical evaluation.") First, when asked by FTC Counsel whether his patients always follow his instructions, Dr. Charles testified that they do,

> [p]rimarily because it's so easy. Because, see, the medications I give them have end points, and those end points are in their blood or urine. So I can actually measure it. So I can tell when they're fiddling. I can even tell when they're fiddling with their diet. Because I can get a 24-hour urine, which I do all the time to find out. I can tell if they're fiddling with their Vitamin D, I can tell if they're fiddling with their oral agents, et cetera, et cetera. Yeah, there's all kind of ways to make sure.

Holmes Dec. ¶6, Ex. E at 158:4-13.

This testimony was consistent with Dr. Charles's testimony regarding how, as a treating physician, he could tell if the Wellness products were benefiting a patient:

> So you can measure their sugar, you can measure their A1c or for the other cardiovascular risk factors, you can look at the blood test to see if people are actually using that. So in an individualized patient care setting, if somebody were using, for example, the Wellness Support product or some other medical food, you could tell about the right dose and whether they were using it because you can follow the end point like the A1c or the blood glucoses that they can actually measure at home or you can measure in the laboratory. The A1c you can measure in the laboratory.
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> ***So as long as there's somebody supervising that patient like -- and that's the concept of medical supervision, that supervisor would know whether the product was having an effect or not.***

Id. at 222:2-17; (emphasis added).

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[6] Here, Dr. Charles refers to FDA's Request for Public Comment concerning medical foods, found at Fed.Reg. 60669.

For Dr. Charles, in the same exact way that Congress and FDA addressed the issue, the question of whether a medical food works is answered by how the patient reacts to it. As the FDA has stated, "the intended use of a medical food is for the dietary management of a patient receiving active and ongoing medical supervision…The physician determines that the medical food is necessary to the patient's overall medical care, and the patient consults with the physician on a recurring basis." 61 Fed.Reg. 60668. In this case, Wellness unquestionably represented its products to be medical foods designed for the dietary management of diabetes which are to be used under the supervision of a physician. Faced with a void of regulations governing the requirements for the substantiation of a medical food, but ample authority indicating that such products are designed for patients under ongoing medical supervision, Dr. Charles rightfully opined that the question of whether a medical food is useful for a diabetic can only be answered by patient observation. Moreover, given the amplitude of studies establishing the usefulness of the Wellness products' individual ingredients, Dr. Charles rightfully opined that the products themselves were useful for their intended use. His testimony should not be stricken.

B. Dr. Charles's Opinions are Reliable and Should Not be Stricken.

In its Motion, the FTC complains that it was improper for Dr. Charles to review federal statute and FDA regulatory announcements because he is not a lawyer and any opinion he would develop from such writings would be an inappropriate "legal conclusion." Motion, at 9-10. FTC would clearly prefer the experts in this case to perform like its own expert, Dr. Garvey, who prior to his deposition had never heard of a "medical food," had no idea how medical foods are regulated, and relied on his own legal conclusion that in evaluating the truth or substantiation of a claim, whether the product is a food, drug, medical device, dietary supplement or medical food is irrelevant; *see* Holmes Dec.¶5, Ex. D, at 199:14-22.

1. The Ninth Circuit's jurisprudence addressing expert witness testimony confronting legal issues makes clear that Dr. Charles's testimony is perfectly permissible and should not be stricken.

Fortunately, no case stands for the overly simplistic, broad sweeping proposition sponsored by FTC. This makes sense, given that treating physicians – not lawyers – are the FDA's intended audience when issuing guidances:

> FDA guidances are documents that explain the agency's interpretation of, or policy on, a regulatory issue. The FDA prepares guidances primarily for

> industry, but also for other stakeholders and its own staff, and uses them to address such matters as the design, manufacturing, and testing of regulated products; scientific issues; content and evaluation of applications for product approvals; and inspection and enforcement policies.

FDA Fact Sheet: FDA Good Guidance Practices, December 2011.[7] Thus, the Ninth Circuit has held that the line separating "what is law and what is application or practice may be difficult to ascertain" especially when, as here, "the issues involve not only a statute and formally promulgated regulations, but also guidelines, handbooks, advisory rulings, interpretive bulletins, general counsel's letter opinions, informational notices and similar accoutrements of the modern bureaucratic state." *Nieves-Villanueva v. Soto-Rivera*, 133 F.3d 92, 100 (1st Cir. 1997).

The Ninth Circuit has also made plain that "a witness may refer to the law in expressing an opinion without that reference rendering the testimony inadmissible. Indeed, a witness may properly be called upon to aid the jury in understanding the facts in evidence even though reference to those facts is couched in legal terms." *Specht v. Jensen*, 853 F.2d 805, 809 (9th Cir. 1988); *citing United States v. Buchanan,* 787 F.2d 477, 483 (10th Cir. 1986) (permitting "an expert to testify that a certain weapon had to be registered with the Bureau of Alcohol, Tobacco, and Firearms.") Rather than creating a *per se* rule regarding expert testimony which confronts legal issues, the Ninth Circuit has held that the proper question is whether the expert would "invade the court's authority by discoursing broadly over the entire range of the applicable law." *Specht*, 853 F.2d at 809. In other words, "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 function." *Id.,* at 809-810. Dr. Charles makes no effort to do that here.

Furthermore, even if Dr. Charles had testified regarding a "matter of law," no *per se* rule exists which would require the Court to bar the testimony. *Flores v. Arizona*, 516 F.3d 1140, 1166 (9th Cir. 2008);[8] *citing Aguilar v. Int'l Longshoremen's Union Local No. 10*, 966 F.2d 443, 447 (9th Cir. 1992). For instance, in cases like this one involving "highly complex and technical matters," the Ninth Circuit has held that it is indeed proper for trial judges to utilize "limited and controlled mechanisms, and as a matter of trial management, permit[] some testimony seemingly at variance with the general rule."

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[7] Available at: http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/ucm285282.htm

[8] *Reversed on other grounds by Horne v. Flores*, 557 U.S. 433 (2009).

Flores, 516 F.3d at 1166; *quoting Nieves-Villanueva v. Soto-Rivera*, 133 F.3d 92, 101 (1st Cir. 1997). Additionally, in cases like this one which will be decided via bench trial rather than before a jury, the Ninth Circuit has held that such testimony would not be prejudicial because there would be "no danger that a jury might give too much credence to a legal expert." *Flores*, 516 F.3d at 1166; *citing Nieves-Villanueva,* 133 F.3d at 99. Moreover, in matters like this one which will involve an inquiry into how medical foods are regulated, such testimony would help, not hurt; *Flores,* 516 F.3d at 1166.

This well settled jurisprudence makes clear that Dr. Charles's testimony should not be stricken even if it does confront certain legal issues. First, this case will be resolved via bench trial, and there exists no risk that the Court might impart undue reliance on the aspects of Dr. Charles's testimony which abuts legal issues. Second, rather than a legal conclusion, Dr. Charles's testimony takes notice of a variety of authorities, including guidance documents and Federal Register notices issued by FDA, FTC and non-governmental establishments. It was perfectly permissible for him to consider these authorities in issuing his opinion in this case. Third, Dr. Charles does not seek to "invade the court's authority by discoursing broadly over the entire range of the applicable law." Instead, he has testified on a very limited basis regarding how the applicable law has governed his evaluation of the Wellness products. The fact that Dr. Charles has confronted these issues makes his testimony more helpful, not less. Dr. Charles's testimony should not be stricken.

2. The FDCA, FDA regulations, and FDA guidance documents are absolutely relevant in this case.

In its Motion, at 9, FTC also argues that Dr. Charles's testimony should be stricken because he relies upon "the regulation of medical foods by the [FDA]" when, according to the FTC, "neither Dr Charles' nor anyone else's parsing of FDA law is relevant." For a variety of reasons, the FTC's argument on this point must fail.

First, the jurisprudence relied upon by FTC to buttress its argument has no bearing on this case as it involves a different type of product, a different procedural posture and a different type of advertising. In *Bristol Meyers Co. v. FTC*, 738 F.2d 554 (2d Cir. 1984), the FTC issued an order

relating to the Bristol Meyers's "comparative advertising"[9] which touted Bristol Meyers over-the-counter (OTC) drugs as being better than competitor products with less side effects and recommended by doctors with greater frequency. *Bristol Meyers*, 738 F.2d at 557-558. In upholding the FTC order as being supported by substantial evidence and rejecting Bristol Meyers's argument that FDA policy should trump the factual findings made by FTC during its administrative hearing, the Second Circuit held as follows: "Insofar 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, ***and not with the questions of comparative safety and efficacy that arise in OTC drug advertising.***" *Bristol Meyers*, 738 F.2d at 559; (emphasis added).[10] The Second Circuit's holding on this issue does not stand for a universal proposition that the FDCA and FDA regulations and guidance documents are irrelevant in all matters involving the FTC. Its holding was specific to comparative efficacy claims, and should not be interpreted to mean anything more than that; *see Thompson Medical Co. v. FTC*, 791 F.2d 189, 193 (D.C. Cir. 1986) (explaining *Bristol Meyers*).

Additionally, the Second Circuit was careful to note that it was speaking in general terms when discussing the mission of the FDA. However, this case does not fall within that general rule. As it relates to medical foods, FDA has made clear that it is concerned with far more than "absolute safety and efficacy." Indeed, FDA – *the* agency charged by Congress with regulating medical foods – has made overt efforts to regulate and develop standards for medical food claims. On November 29, 1996, FDA issued a Federal Register notice regarding the regulation of medical foods and discussed, among other things, substantiation and claims; *see* 61 Fed.Reg. 60661, 60668-60670. In that announcement, the FDA made clear that claims made regarding medical foods should require at least as much substantiation as claims made for medical foods, but not as much substantiation as claims made for drugs. 61 Fed.Reg. 60669. In response to that announcement, FDA received dozens of comments from the interested

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[9] "[C]omparative advertising is defined as advertising that compares alternative brands on objectively measurable attributes or price, and identifies the alternative brand by name, illustration or other distinctive information." FTC, Statement of Policy Regarding Comparative Advertising, August 13, 1979.

[10] In its Motion, that FTC replaced the final phrase of this holding ("and not with the questions of comparative safety and efficacy that arise in OTC drug advertising") with ellipses.

public, many of which addressed the substantiation issue. Dr. Charles reviewed both the Federal Register notice and numerous public comments while preparing his expert reports in this case.

In contrast, the FTC has never said a word about medical foods, and it appears that this case represents its very first attempt at regulating them. In this case, FTC takes a totally different approach than FDA, and seeks to hold medical foods to the same exact standards as all other products, regardless of the fact that it has no jurisdiction over the medical food statute and regardless of the fact that the federal agency which does – the FDA – has explicitly stated otherwise. As such, this case is not like *Bristol Meyers*, where the Second Circuit found that FDA had ceded its jurisdiction over comparative OTC claims to FTC; *see Thompson Medical Co.*, 791 F.2d at 193. Here, rather than simply ignoring the FDCA and FDA's guidance documents, the Court should "focus on the circumstances before it to strike a balance that disrupts the two statutory schemes as little as it can." *Pom Wonderful LLC v. Coca Cola*, 679 F.3d 1170, 1176 (9th Cir. 2012).[11]

3. The substance of Dr. Charles's position is correct.

In its Motion, the FTC complains that Dr. Charles opined that the level of substantiation required for a medical food claim is less than that which is required for the substantiation of a drug claim. Despite the FTC's complaints, Dr. Charles is actually correct on this point.

First, as the FTC notes in its Motion, one of the reasons why Dr. Charles opined that the level of substantiation required for a medical food claim is less than that which is required for the substantiation of a drug claim is because subjecting a medical food to a study designed for a drug would "potentially require [the] product to be classified as a drug, and thus require FDA approval prior to marketing and sales." Motion, at 9-10; *quoting* Charles Report, Holmes Dec.¶8, Ex. G, at 7. On this point, Dr. Charles is correct. In fact, FDA has stated as follows: "The general rule is that an article that has been authorized for investigation as a new drug or as a biologic before being marketed as a food or as a dietary supplement cannot be marketed as a dietary supplement if substantial clinical investigations of the article have begun and the existence of such investigations has been made public." FDA, *Draft*

[11] To the extent that the FTC would have the Court believe that FDA is never concerned with the truth or falsity of the advertising of health products, that is simply not the case. FDA routinely brings such cases; *see e.g. United States v. Nutri-Cology*, 1993 U.S. Dist. LEXIS 21448 (N.D. Cal. 1993).

Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues, July 2011.

However, contrary to how the FTC described his testimony, that was not Dr. Charles's sole basis for opining that the level of substantiation required for a medical food claim is less than that which is required for a drug claim. As previously stated, FDA has written that the level of substantiation required for a medical food claim is greater than that which is required for a conventional food, but less than that which is required for a drug. 61 Fed.Reg. 60669. Dr. Charles explicitly relied on that FDA guidance in rendering his opinion, and in his rebuttal report, at 6, cited to the FDA's notice governing this issue. So, again, Dr. Charles was quite right in opining as he did.

4. Dr. Charles's treatment of the available studies was perfectly reasonable and consistent with the manner by which he treats diabetic patients.

In its Motion, at 11-13, the FTC argues that the manner by which Dr. Charles evaluated the available studies did not comport with the standards set forth in *Daubert* and its progeny. We disagree.

As a threshold matter, we address the FTC's contention that "Dr. Charles fails to analyze the numerous studies that show that the ingredients have no effect." FTC Motion, at 11. In preparing his expert reports and in preparing to be deposed, Dr. Charles reviewed in excess of 160 studies into the individual ingredients in the Wellness products, all of showed that the individual ingredients in the Wellness products had at least some beneficial effect on diabetic indications. The FTC complains, however, that Dr. Charles did not "analyze the numerous studies that show the ingredients have no effect." FTC Motion, at 11. Thus, according to FTC, Dr. Charles's testimony should be stricken. The FTC's position on this issue is incorrect.

First, no case stands for the broad sweeping proposition that an expert must exclude every possible alternative in evaluating a given issue. In fact, the opposite is true; *see Bitler v. AO Smith Corp.*, 391 F.3d 1114, 1124-1125, n.6 (10th Cir. 2004); *quoting* Stephen A. Saltzburg et al., Federal Rules of Evidence Manual 702-33 (8th ed. 2002). Indeed, "to require otherwise 'would mean that few experts would ever be able to testify.'" *Id.* The issue raised by the FTC should go to the weight of Dr. Charles's testimony, not its admissibility; *Kennedy v. Collagen Corp.* 161 F.3d 1226, 1230-1231 (9th Cir. 1998) ("In arriving at a conclusion, the factfinder may be confronted with opposing experts, additional tests,

experiments, and publications, all of which may increase or lessen the value of the expert's testimony. But their presence should not preclude the admission of the expert's testimony - they go to the weight, not the admissibility."); *citing McCullock v. HB Fuller Co.* 61 F.3d 1038, 1044 (2d Cir. 1995) ("Disputes as to the strength of [an expert's] credentials, faults in his use of [a particular] methodology, or lack of textual authority for his opinion, go to the weight, not the admissibility, of his testimony.")

Second, Dr. Charles did adequately consider the available alternatives. Again, taking both parties at their words, Dr. Charles possessed roughly 160 studies showing that the individual ingredients in the Wellness products have a positive impact on various diabetic indications, while the FTC has "numerous studies that show the ingredients have no effect." FTC Motion, at 11. In analyzing Wellness's products, Dr. Charles did not render an opinion on the *absolute* efficacy of the individual ingredients, as that was not his task and absolute efficacy is not what this case is about. *Bristol Meyers*, 738 F.2d at 559. Instead, Dr. Charles testified that the products would be useful as one star among a "constellation" of a diabetic's medical regimen. Taking everything before him into consideration, including the federal statute defining medical food and various FDA policy statements regarding its regulation of medical foods, Dr. Charles adopted a "moderate [and] rational medical and regulatory position." Holmes Dec.¶9, Ex H, at 6.

Ultimately, Dr. Charles opined "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." Holmes Dec. ¶8, Ex. G at 10. This testimony was not only consistent with the federal definition of medical food, but it was also consistent with his deposition testimony regarding the incredible complexity of diabetes. On the one hand, Dr. Charles described the extraordinary difficulties associated with conducting randomized trials with diabetes patients because the diabetic condition necessarily includes so many variables. Holmes Dec. ¶6, Ex. E at 92:12 – 93:22. Consequently, trials and tests performed among diabetic patients are not as reliable as trials and tests performed among diabetic patients, and doctors are often required to recommend treatment modalities which have never been proven to work; *see e.g. Id.* at 87:23-88:5.

Additionally, Dr. Charles testified that the best way of knowing whether a product is working is by monitoring the patient, which is exactly what Congress had in mind when defining medical foods:

see 21 U.S.C. § 360ee(b)(3) (a medical food "…is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements…are established by medical evaluation."); *see also* Holmes Dec. ¶6, Ex. E, at 222:2-17 ("So as long as there's somebody supervising that patient like -- and that's the concept of medical supervision, that supervisor would know whether the product was having an effect or not.") This is also precisely what FDA has had in mind in its own efforts to regulate medical foods and medical food claims; 61 Fed.Reg. 60669.

So, rather than recommending the Wellness products or any other product as a cure-all, Dr. Charles opined that treating a patient with diabetes should include a "constellation" of treatments, including medical foods. Holmes Dec. ¶6, Ex. E, at 78:19-22; ¶8,Ex. G, at 10. Dr. Charles further opined that Wellness's products could indeed be useful as a star among such a constellation. As such, Dr. Charles did not "disregard" neutral studies, and there was no "bias" built into his methodology. Rather, in the face of 160 studies showing the individual ingredients in the Wellness products to be helpful to diabetics, and "the numerous studies that show the ingredients have no effect," Dr. Charles evaluated the issue exactly as he should have, i.e. as a doctor with the understanding that the products are medical foods and designed to be provided to his patients under his own medical supervision. Dr. Charles's testimony is perfectly reliable and should not be excluded.

IV. CONCLUSION

For the foregoing reasons, the Defendants respectfully submit that Dr. Charles's testimony is relevant, complete and reliable. Accordingly, the Court should deny the FTC's motion to strike.

Dated: July 26, 2013

FUERST ITTLEMAN, PL

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