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

States." Id. It further alleges that Defendants Robert and Robyn Held are owners and Directors of WSN and that Robert Held is the President of WSN, while Robyn Held is its Secretary and Chief Financial Officer. Id. ¶¶ 7-8. According to the FTC, Robert and Robyn Held together developed

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

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

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

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

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

> In many of the human trials of various substances, e.g. vitamins, minerals, trace elements and plant extracts, both positive and

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On the question of relevance, the FTC contends the standard under Daubert and Rule 702 is higher than the general relevance requirement under Rule 402 of the Federal Rules of Evidence, requiring that the evidence "logically advance a material aspect of the proposing party's case," or

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

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

In its Opposition brief, WSN argues that Dr. Charles's claims are both relevant and reliable. As to relevance, WSN argues Dr. Charles need not limit his testimony to the claims that the FTC alleges were made by WSN in order to establish relevance. Id. at 4. Rather, it asserts, even if Dr. Charles did not address the specific claims alleged in the complaint – which WSN denies – Dr. Charles's opinions are relevant to broader issues in the case, such as whether the individual defendants "hoodwinked" their customers. Id. (citing FTC v. Swish Marketing, 2010 U.S. Dist. LEXIS 15016, at *9 (N.D. Cal. Feb. 22, 2010)). Further, WSN asserts, the opinions offered by Dr. Chay Dr. C

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

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

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

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

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

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

E. The FTC's Supplemental Brief

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

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

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

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

Defendants assert in response that the Court should not consider a document that did not exist at the time Dr. Charles prepared his expert report. Defendants' Response to Plaintiff's Supplemental Brief in Support of its Motion to

III. ANALYSIS

A. Legal Standard

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

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

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

> Faced with a proffer of expert scientific testimony, then, the trial judge must determine . . . whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.

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

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

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

IV. CONCLUSION

For the reasons stated above, the Court finds that Dr. Charles's Expert Report does not satisfy Rule 702 of the Federal Rules of Evidence and Daubert Therefore, the testimony of Dr. Charles shall be eknowledat Dr. CharlesDaubert