UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

FEDERAL TRADE COMMISSION,

Plaintiff,

v. **Case No: 8:15-cv-2231-T-35CPT**

ROCA LABS, INC., a corporation, ROCA LABS NUTRACEUTICAL USA, INC., a corporation, DON JURAVIN, individually, DON JURAVIN, as an officer of Roca Labs, Inc. and Roca Labs Nutraceutical USA, Inc. Must Cure Obesity, Co and Juravin, Inc., GEORGE C. WHITING, individually, GEORGE C. WHITING, as an officer of Roca Labs, Inc. and Roca Labs Nutraceutical USA, Inc. and Zero Calorie Labs, Inc., MUST CURE OBESITY, CO., a corporation, JURAVIN, INCORPORATED, a corporation, and ZERO CALORIE LABS, INC., a corporation,

Defendants.

ORDER

THIS CAUSE comes before the Court for consideration of Plaintiff's Motion to Exclude Expert Testimony of Dr. Jay Hoffman, (Dkt. 140), and the Response in opposition thereto filed by Defendants. (Dkt. 163) Upon consideration of all relevant filings, case law, and being otherwise fully advised, the Plaintiff's Motion for Miscellaneous Relief is **GRANTED in substantial part and DENIED in limited part**.

I. BACKGROUND

On September 24, 2015, the Federal Trade Commission ("FTC") filed this action, alleging that Defendants had and were engaged in acts and practices that violated Sections 5 and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45, 52, in connection with the advertising and sale of weight-loss products and the use of contractual provisions prohibiting purchasers from providing negative commentary. (Dkt. 1) On February 19, 2016, the FTC filed its First Amended Complaint for Permanent Injunction and Other Equitable Relief ("Complaint"), naming three additional corporate defendants. (Dkt. 48)

In the Complaint, the FTC alleges that Defendants marketed a dietary supplement as "Gastric Bypass No Surgery" using deceptive claims about substantial weight loss. (Dkt. 48) Specifically, the FTC alleges in Count I that Defendants made five false and misleading weight-loss claims:

> a. Use of Defendants' products, including Roca Labs Formula and Roca Labs Anti-Cravings, enables the user to reduce food intake by fifty percent and to lose substantial amounts of weight quickly, including as much as 21 pounds in one month, and as much as 100 pounds in seven to ten months;
> b. Ninety percent of users of Defendants' products, including Roca Labs Formula and Roca Labs Anti-Cravings, will lose substantial amounts of weight;
> c. Defendants' products, including Roca Labs Formula and Roca Labs Anti-Cravings, are comparable or superior to bariatric surgery in providing weight-loss benefits; and
> d. Defendants' products, including Roca Labs Formula and Roca Labs Anti-Cravings, are safe and effective for weight loss in children as young as six years old.

(Dkt. 48 at 27–28) In Count II, the FTC alleges that Defendants falsely claimed that their products are "scientifically proven to have a ninety-percent success rate in forcing users to eat half their usual food intake and cause substantial weight loss." (Id. at 28)

In this action, Defendants hired Jay Hoffman, Ph.D. ("Dr. Hoffman") to provide expert opinions regarding the efficacy of the Roca Labs weight-loss system. (Dkt. 163-2 at 6) Defendants also retained Dr. Hoffman to opine whether Defendants' advertising claims for the supplements are substantiated by the competent and reliable scientific evidence. (Id.) Additionally, Dr. Hoffman reviewed the issues raised by the FTC and the report created by the FTC's expert, Dr. Steven B. Heymsfield ("Dr. Heymsfield"). (Id. at 6–7) On January 18, 2017, Dr. Hoffman signed the expert report. (Id.) On February 21, 2017, Dr. Hoffman sat for his deposition. (Dkt. 163-3; Dkt. 140-2)

On March 24, 2017, the FTC filed the instant motion, contending that Dr. Hoffman's opinions fail to meet the requirements for admissibility pursuant to Federal Rule of Evidence 702 and Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993). The FTC alleges that Dr. Hoffman's opinions are irrelevant and unreliable as a matter of law. (Dkt. 140) Defendants oppose the motion, contending that Dr. Hoffman's opinions are relevant and would assist the trier of fact as to Defendants' claims. (Dkt. 163)

II. LEGAL STANDARD

Rule 702 of the Federal Rules of Evidence controls the admission of expert testimony and provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

Rule 702 compels courts to perform a "gatekeeping" function—specifically, to determine whether the proffered expert testimony is reliable and relevant. Daubert, 509 U.S. at 589 n. 7. The Eleventh Circuit has highlighted the importance of the gatekeeping function; it is because expert witnesses are free to opine without firsthand knowledge, while relying upon inadmissible hearsay, that courts must carefully judge the intellectual rigor employed by the expert. United States v. Frazier, 387 F.3d 1244, 1260 (11th Cir. 2004). In determining the admissibility of expert testimony under Federal Rule of Evidence 702, the court applies a "rigorous" three-part inquiry. Id. Expert testimony is admissible if (1) the expert is qualified to testify on the topic at issue, (2) the methodology used by the expert is sufficiently reliable, and (3) the testimony will assist the trier of fact through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue. Id. The Eleventh Circuit describes these three distinct concepts separately as "qualification, reliability, and helpfulness." Id.

III. DISCUSSION

Because the FTC does not challenge Dr. Hoffman's qualifications to testify as an expert in this case, the Court will focus its inquiry on the challenges to the reliability and helpfulness of Dr. Hoffman's opinions.

A. Reliability of Dr. Hoffman's Methodology

The FTC claims that Dr. Hoffman's opinions are unreliable because they are based on incomplete information, faulty assumptions, and speculation or faulty extrapolation. (Dkt. 140) Additionally, the FTC alleges that Dr. Hoffman fails to even address the specific claims that the FTC challenges. (Id.) Defendants contend that Dr. Hoffman's opinions are based on techniques generally applied in the scientific community, such as

the review of published scientific articles. (Dkt. 163) Defendants also argue that Dr. Hoffman's opinions should be admitted because he was retained in part to evaluate the opinions offered by FTC's expert, Dr. Heymsfield. (Id. at 7–8)

In considering proffered expert testimony, the court should be mindful that "[t]he burden of laying the proper foundation for the admission of expert testimony is on the party offering the expert, and the admissibility must be shown by a preponderance of the evidence." McCorvey v. Baxter Healthcare Corp., 298 F.3d 1253, 1256 (11th Cir. 2002) (quoting Allison v. McGhan Med. Corp., 184 F.3d 1300, 1306 (11th Cir. 1999)).

The Daubert Court identified four factors to consider in determining if a specific methodology is reliable under Rule 702:

> (1) whether the methodology can and has been tested; (2) whether the methodology has been subjected to peer review and publication; (3) the known or potential rate of error and the existence and maintenance of standards controlling operation of the methodology; and (4) whether the methodology has gained general acceptance in the scientific community.

McCorvey, 298 F.3d at 1256 (citing Daubert, 509 U.S. at 593–94). These factors are not meant to be a "definitive checklist or test." Daubert, 509 U.S. at 593. Courts have "considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152 (1999). While the inquiry is "a flexible one," the focus "must be solely on principles and methodology, not on the conclusions that they generate." Daubert, 509 U.S. at 594–95. However, "conclusions and methodology are not entirely distinct from one another . . . [and] nothing in either Daubert or 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." Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997). "Rather, the trial court is

free to 'conclude that there is simply too great an analytical gap between the data and the opinion proffered.'" Hendrix ex rel. G.P. v. Evenflo Co., 609 F.3d 1183, 1194 (11th Cir. 2010) (citing Joiner, 522 U.S. at 146).

Here, the Court finds Dr. Hoffman's opinions to be unreliable for several reasons. First, Dr. Hoffman's opinion is not based on any clinical trials of the Roca Labs products. Dr. Hoffman testified that he was told there were no clinical trials of the Roca Labs products. (Id.) Second, Dr. Hoffman does not set forth any reliable methodology or scientific explanation of the studies cited in his report to support conclusions regarding the specific effect of the Roca Labs products. (Id. at 15) For example, Dr. Hoffman opines that, based on "supplement studies," combining multiple ingredients increases the chance for efficacy. (Dkt. 163-2 at 12) However, Dr. Hoffman does not discuss whether these multiple ingredients are similar to those found in Roca Labs products. Thus, he is unable to demonstrate how the "supplement studies" would substantiate Defendants' weight-loss claims. Dr. Hoffman's opinions focus broadly on lifestyle changes, including exercise and dietary restrictions, because "[c]hanges in lifestyle appear to be the primary focus on well-designed weight loss regimens." (Id. at 12–13) In his deposition, Dr. Hoffman emphasizes that his opinion about the possibility of a person who weighs "upwards of 400 pounds" losing 100 pounds in seven to ten months is not based on the person's consumption of the Roca Labs supplement alone. (Dkt. 163-3 at 6, 30:24–32:23) "I'm talking about the combination of dietary restriction in combination, or by itself, with either a supplement that's similar to what Roca Labs has produced, that could potentially result in a client losing upwards to that amount of weight that was claimed." (Dkt. 163-3 at 6, 32:3–23) Significantly, Dr. Hoffman testified that he "didn't find anything

to substantiate the claims by the substance itself." (Dkt. 163-3 at 8, 87:22–24) Dr. Hoffman cites to a few studies on three of the dietary fibers in Roca Labs products (β-glucan, guar bean, and glucomannan); however, he fails to provide any analysis on or draw any conclusions from the studies that would support Defendants' claims. (Dkt. 163-2 at 19–23) Dr. Hoffman does not compare the doses of fiber in those studies to the amounts of comparable fiber in Roca Labs products. In his deposition, Dr. Hoffman stated that he was unaware of Defendants' claims that their products provide a "gastric bypass effect by expanding in the stomach and limiting stomach volume." (Dkt. 163-3 at 9, 89:5–90:9) Therefore, the Court finds that Dr. Hoffman's opinions, although based on his review of scientific studies, are unreliable because they fail to provide any scientific analysis that substantiates Defendants' claims about Roca Labs products.

B. Helpfulness of Dr. Hoffman's Testimony

The FTC alleges that Dr. Hoffman's opinion is not helpful to the trier of fact because his report fails to mention any of the five claims at issue and fails to opine that the Roca Labs products have any effect on weight loss. (Dkt. 140) Defendants argue that Dr. Hoffman sufficiently opined on the validity of the claims. (Dkt. 163)

Under the helpfulness prong, "expert testimony is admissible if it concerns matters that are beyond the understanding of the average lay person. Proffered expert testimony generally will not help the trier of fact when it offers nothing more than what lawyers for the parties can argue in closing arguments." Frazier, 387 F.3d at 1262–63. Thus, when the trier of fact is entirely capable of determining issues in the case without the technical assistance of an expert, exclusion of the proffered expert testimony is appropriate. Id. The purpose of this requirement is to prevent the trier of fact from giving the expert

testimony undue weight due to the expert's special status. See Cook v. Sheriff of Monroe County, 402 F. 3d 1092, 1111 (11th Cir. 2005).

Dr. Hoffman's report fails in this respect. Dr. Hoffman offers statements on various topics in his report; he claims (1) there is a lack of patent protection for dietary supplements, which forces the industry to rely on existing research; (2) Roca Labs marketed lifestyle changes, which are the focus of "well-designed weight loss regimens" and include making dietary changes, exercising, and taking dietary supplements; and (3) Roca Labs offered feedback to customers, which appears to "add to weight loss" based on published evidence that motivation can be an effective weight loss aid. (Dkt. 163-2 at 10–12, 17) In his deposition, Dr. Hoffman states that he makes no claims about "the use of [Roca Labs] products by themselves" and their potential impact weight loss, but about the use of using supplements along with a reduced diet and exercise. (Dkt. 163-3 at 6, 32:4–10; 8, 87:19–21)

His report does not discuss any of the five advertising claims challenged by the FTC in Count I of the Complaint. At his deposition, Dr. Hoffman confirmed that he was not offering an expert opinion regarding four of the five Defendants' advertising claims. (Dkt. 140-2 at 18:7–19:20) He provided a qualified response to a question about only one of the advertising claims. As discussed above, Dr. Hoffman testified that it was possible that someone can lose 21 pounds in one month and as much as 100 pounds in seven to ten months, but his answer was based on the assumption that a person "weighed upwards of 400 pounds" and the person restricted his or her diet regardless of the consumption of the Roca Labs supplement. (Dkt. 163-3 at 6, 30:19–32:23) Although

Dr. Hoffman was provided some advertisements to review,[1] Dr. Hoffman also testified that he did not use Defendants' advertisements as a basis for developing his report, he did not review Defendants' website, and he was not aware of Defendants' marketing claims made regarding pregnant women and children. (Dkt. 163-3 at 5, 21:23–22:1; Dkt. 163-3 at 6; Dkt. 163-3 at 9, 89:5–90:2) Without any opinions regarding the substantiation of advertising claims, Dr. Hoffman's report would offer no assistance to the trier of fact in determining the basis of the claims. Further, Dr. Hoffman's report heavily relied on studies that focus on dietary restrictions, exercise, or both, to discuss the effects on weight loss results, but not on the efficacy of Defendants' products. (Dkt. 163-2 at 12–19) He testified that the most impressive studies he reviewed focused on the efficacy of dietary restriction on weight loss. (Dkt. 163-3 at 10, 93:19–94:3) "It's pretty common knowledge" that restricting food intake can cause weight loss. (Dkt. 163-3 at 10, 94:4–6) For these reasons, the Court finds that Dr. Hoffman's testimony would not assist the trier of fact in determining whether Defendants' advertising claims were substantiated by credible, scientific evidence. Accordingly, Dr. Hoffman's testimony must be excluded as unhelpful to the trier of fact.

Defendants contend that Dr. Hoffman's expert opinion is admissible because it, in part, challenges Dr. Heymsfield's opinion. An expert may properly challenge another expert's testimony, even if he does not offer a competing opinion regarding the central issue. Wiand v. Waxenberg, 611 F. Supp. 2d 1299, 1315 (M.D. Fla. 2009). In Wiand, the court permitted the expert's opinion to identify weaknesses in the other expert's

[1] Dr. Hoffman testified that he received some advertisements, along with other documents, in an email from Defendant Don Juravin. (Dkt. 163-3 at 5, 21:15–24) It is unclear what advertisements Dr. Hoffman received and reviewed because he did not list them in his report. (Id.)

analysis after finding the opinion was "relevant and helpful to the trier of fact for the limited purpose for which it was offered." Id.

Here, Dr. Hoffman challenges Dr. Heymsfield's opinion in two areas. First, he disputed the parameters of a "well-designed and properly conducted" clinical trial that Dr. Heymsfield said is required to establish proof of weight loss claims about a particular product or method. (Dkt. 163-2 at 7) In his report, Dr. Hoffman stated that such a clinical trial—one that is "placebo-controlled and double-blind" —is not required for sports or dietary supplements based on his review of scientific publications on PubMed, a website that publishes peer-reviewed papers. (Dkt. 163-3 at 6, 29:14–17) Within the past ten years, Dr. Hoffman stated that a majority of the 1,757 scientific publications he examined on PubMed that contain the words "weight loss and supplementation" and "fat loss and supplementation" were not clinical studies. (Dkt. 163-2 at 7) However, Dr. Hoffman does not set forth any reliable methodology or scientific explanation of conducting an online search of scientific publications to support his conclusion that clinical studies are not required for sports or dietary supplements or for weight loss claims.

Second, Dr. Hoffman challenged the "large [sample] size" of 80 participants that Dr. Heymsfield opined should be included in a valid trial and stated that such a sample size is "often not the case in supplement research." (Id. at 7) Dr. Hoffman stated a "power analysis" is often performed to determine the appropriate sample size. (Id. at 8–9) Yet, Dr. Hoffman's report fails to address whether Defendants used a "power analysis" to determine an appropriate sample size for any clinical studies of Roca Labs products or studies on weight loss. Although Dr. Hoffman testified that he was told there were no clinical trials of Roca Labs products, Dr. Heymsfield's report identified one clinical

trial of Roca Labs products and discussed it extensively. (Dkt. 140-3 at 16–20) Despite Dr. Hoffman's review of Dr. Heymsfield's full report, Dr. Hoffman did not comment at all on that clinical trial, including the design of the study and the sample size. (Dkt. 163-3 at 5, 22:22–23) It is unclear what value such a limited critique could serve ultimately if Defendants offer no substitute analysis or independent clinical trial results to support the validity of their advertisement claims. Nevertheless, the Court finds that Dr. Hoffman's opinion could be offered for the limited purpose of identifying weaknesses in Dr. Heymsfield's methodology of preparing his report.

IV. CONCLUSION

While it is possible that Dr. Hoffman is qualified to render an expert opinion on obesity or weight loss, his testimony regarding the substantiation of the claims discussed in Count I and Count II of the FTC's Complaint must be excluded as insufficient to meet the legal standard for reliability and assistance to the trier of fact. The Court declines to strike that portion of Dr. Hoffman's opinion that it is used only as a critique of Dr. Heymsfield's analysis.

Therefore, in light of the foregoing, it is **ORDERED** that Plaintiff's Motion to Exclude Expert Testimony of Dr. Jay Hoffman, (Dkt. 140), is **GRANTED in substantial part DENIED in limited part**.

DONE and **ORDERED** in Tampa, Florida, this 27th day of March, 2018.

MARY S. SCRIVEN
UNITED STATES DISTRICT JUDGE

Copies furnished to:
Counsel of Record
Any Unrepresented Person