UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

FEDERAL TRADE COMMISSION,

Plaintiff,

vs. Case No: 8:15-cv-2231-MSS-TBM

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

Defendants.

_____/

DEFENDANTS' MOTION TO DISSOLVE, OR IN THE ALTERNATIVE, MODIFY PRELIMINARY INJUNCTION AND INCORPORATED MEMORANDUM OF LAW

COME NOW the Defendants, ROCA LABS, INC., a corporation; ROCA LABS NUTRACEUTICAL USA, INC., a corporation; MUST CURE OBESITY, CO., a corporation; JURAVIN, INCORPORATED, a corporation; ZERO CALORIE LABS, INC., a corporation; DON JURAVIN, and GEORGE C. WHITING, by and through the undersigned counsel and pursuant to Federal Rule of Civil Procedure 65(b)(4), file this, their Motion to Dissolve and/or Modify Preliminary Injunction, and in support thereof state as follows:

BACKGROUND FACTS

1. Defendant DON KARL JURAVIN is the inventor of the Gastric Bypass ALTERNATIVE® weight loss regimen (the "GBA Regimen"), a non-medical, non-surgical option for morbidly obese individuals striving to achieve a healthy weight. The GBA Regimen is comprised of a combination of nutritional supplements, a diet and exercise program, as well as online support and coaching through both proprietary websites, as well as various social media platforms.

2. The GBA Regimen empowers its users (who are often morbidly obese) to achieve a healthy weight, without exposing them to the significant medical risks associated with gastric bypass or other bariatric surgical procedures.

3. Since launching the GBA Regimen, the Defendants in this case have provided more than eighty thousand (80,000) users with the tools necessary to succeed in their weight loss journey, without resorting to surgery. Users of the GBA Regimen are also active in the GBA Regimen's Facebook group, located at http://www.facebook.com/groups/lost100. The Facebook group is filled with success stories of GBA Regimen users that have finally succeeded in losing weight, where they had previously failed time and again.

PROCEDURAL HISTORY

4. On September 24, 2015, the Plaintiff filed its original Complaint (Dkt. 1)[1] and its Motion for Temporary Restraining Order (Dkt. 6). On October 29, 2015, this Court issued its Preliminary Injunction and Order for Other Equitable Relief (Dkt. 38) (the "Injunction").[2]

5. Despite the purported "temporary" or "preliminary" nature of the Injunction, the Injunction has, in effect, operated as a near-permanent, vast array of punitive restrictions on the Defendants' business.

6. The heart of Plaintiff's Complaint are various claims that Defendants allegedly engaged in unfair or deceptive practices in the marketing and sale of the GBA Regimen.

7. Included in these allegations is Plaintiff's contention Defendants have made various claims that the GBA Regimen is a cheaper, safer, and a better alternative to bariatric surgery, that the GBA Regimen can help people lose substantial amounts of weight, and implying the GBA Regimen was "medically approved" through the use of the caduceus symbol and photos of individuals wearing white lab coats, all without proper substantiation.

8. As such, among other things, the Injunction prohibits Defendants from making various claims[3] regarding the GBA Regimen in Defendants' promotional materials, unless such

---

[1] Although the Complaint was later amended on February 19, 2016 (Dkt. 48), the First Amended Complaint merely added additional parties, but was substantively identical to the original Complaint.

[2] While the Plaintiff later filed a Motion for Temporary Restraining Order with Other Equitable Relief and an Order to Show Cause Why the Preliminary Injunction Should Not be Modified (Dkt. 69), which later became this Court's Stipulated Preliminary Injunction Freezing Assets with Other Equitable Relief (Dkt. 90), as noted below, the substantive components of the instant Motion seek modification of provisions contained within the October 25, 2015 Injunction.

[3]Examples of claims that must be "substantiated" under the Injunction include: the GBA Regimen "is comparable or superior to bariatric surgery in providing weight-loss benefits"; and

claims are "substantiated." For purposes of the Injunction, a claim is "substantiated" when it is supported by "competent and reliable scientific evidence in the form of adequate, well-controlled, human clinical testing, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true." (Dkt. 38, p.7).

9. Since the imposition of the Injunction, the Plaintiff has had access to the Defendants' database of customers, purportedly for the purpose of identifying members of the consuming public that were allegedly deceived by the Defendants in their purchase and use of the GBA Regimen. Despite this access, out of a population of approximately eighty thousand (80,000) users, the Plaintiff has identified a ***de minimis*** number of individuals with substantive complaints regarding the GBA Regimen.

10. In fact, since the Plaintiff began monitoring the Defendants' business practices through the course of this litigation, the Plaintiff has not alleged, either informally or through these proceedings, that the Defendants have engaged in deceptive business practices.

11. To the contrary, as discussed below, the Defendants have self-imposed new marketing practices related to the GBA Regimen that are more stringent than those utilized by any other non-medical weight loss system available on the market today.

DR. MARCUS FREE'S INVOLVEMENT WITH THE GBA REGIMEN

12. Subsequent to the issuance of the Injunction, Defendants hired Dr. Marcus K. Free as the medical director for Defendant MUST CURE OBESITY CO. ("MCO"). Dr. Free, a

"enables the user to lose weight, including as much as 21 pounds in one month and as much as 100 pounds in seven to ten months." (Dkt. 38, p.6).

bariatric surgeon board certified by the American Board of Surgery with more than seventeen (17) years of experience in the medical and surgical treatment of obesity, also has experience as both a principal investigator in a human research study (clinical study) registered with the National Institutes of Health, and as a contributor to various special physician review projects for the United States Department of Justice. (Aff. of Dr. Marcus Kyle Free, ¶¶ 2, 3, 5, 8) (a copy of which is attached hereto as **Exhibit "A"**).

13. In his capacity as Medical Director, Dr. Free provides independent oversight and recommendations related to the GBA Regimen (Id, ¶ 3).

14. In his professional opinion, Dr. Free believes the GBA Regimen is safe and effective for significant weight loss, and that the GBA Regimen is safer, more effective, and superior in several ways to currently available bariatric surgical procedures. (Id., ¶ 6).

15. Most important for purposes of the instant motion, however, is Dr. Free's opinion that it is impossible to comply with the language of the Injunction quoted in paragraph 8 above, "due to the highly subjective, non-specific language of the Injunction." (Id., ¶ 5).

16. Specifically, Dr. Free opines:

> The Injunction's requirement for human clinical studies of the GBA Regimen prior to being able to market its success is, in my opinion, burdensome and unnecessary, and is equivalent to requiring a non-drug supplement to be subject to the FDA approval process for new drugs. Further, the language used by the Injunction of "adequate, well-controlled" human testing, that is "sufficient in quality and quantity based on standards generally accepted by experts in the relevant scientific fields" is so vague, subjective, and wide-ranging that, in my professional opinion as a medical professional and clinical researcher, no study, regardless of how well-designed and executed, would be able to garnish a consensus of experts such as to satisfy these requirements. (Id., ¶ 15).

17. According to Dr. Free, the practical effect of the clinical trial requirement to substantiate claims prior to marketing the success of the GBA Regimen, is to hold the GBA

Regimen to the same standard as a new medical or surgical treatment, when the GBA Regiment is, in fact, neither one of these. (Id., ¶ 14).

18. Nevertheless, in the spirit of cooperation, and in the interest of consumer safety, Defendants have taken numerous steps to rectify the concerns raised by the FTC in the marketing and sale of the GBA Regimen. For example, Defendants have completely redesigned the website that markets the GBA Regimen, http://www.gastric.care.

19. Additionally, under the direction of Dr. Free, Defendants require prospective users of the GBA Regimen complete a health application, designed in consultation with Dr. Free, that identifies and rejects prospective users who might be ill-suited for use of the GBA Regimen. (Id., ¶ 17-18).

20. Dr. Free also makes himself available through various social media platforms to answer specific questions that actual or potential GBA Regimen users might have about medically-related weight loss topics, or the GBA Regimen itself. (Id., ¶ 19).

21. Consequently, Defendants have complied with the spirit of the Injunction, if not the letter of it, by removing all potentially misleading advertising from their website, retaining Dr. Free as the Medical Director for the GBA Regimen, and implementing self-imposed measures to further ensure the safety of GBA Regimen users in ways that are required neither by statute nor by order of this Court (such as the health application),.

22. A district court has continuing jurisdiction over a preliminary injunction. *Canal Auth. of State of Fla. v. Callaway*, 489 F.2d 567, 578 (5th Cir. 1974). "In the exercise of that jurisdiction, the court is authorized to make any changes in the injunction that are equitable in

light of subsequent changes in the facts or the law, or for any other good reason." *Id.* (citation omitted).

23. As this Court correctly noted, "to obtain modification or dissolution of a preliminary injunction, a movant must demonstrate significant changes in fact, law, or circumstance since the previous ruling… modification of an injunction is proper only when there has been a change of circumstances between entry of the injunction and the filing of the motion that would render the continuance of the injunction in its original form inequitable." *CWI, Inc. v. LDRV Holdings Corp.*, 2013 U.S. Dist. Lexis 197361, *5-6 (M.D. Fla. October 16, 2013) (internal citations omitted).

24. In the case at bar, significant changes to the circumstances warrant dissolution or modification of the injunction. Since the imposition of the Injunction, Defendants have completely redesigned the website that serves as the primary marketing mechanism of the GBA Regimen. Additionally, the voluntary safeguards instituted by Defendants, through Dr. Free, combined with Dr. Free's expert opinion that compliance with the Injunction is an impossibility, warrant the modification of the Injunction to allow Defendants to freely market the GBA Regimen.

THE FTC'S HEIGHTENED DUTY IN THIS CASE

25. In evaluating the instant motion, it is telling that since this Court entered the Injunction, Plaintiff has not sought this Court's aid in curtailing or changing how the Defendants currently market the GBA Regimen. The reason is simple: the changes made by Defendants with regard to marketing the GBA Regimen cure any potentially misleading advertising of it. Unfortunately, the FTC has breached the duty that it owes to both this Court and Defendants

regarding Defendants' compliance with the Injunction, which would allow this small business greater freedom to market the GBA Regimen.

26. As discussed below, the FTC is more than just a "garden variety" plaintiff in the instant action. Rather, it is, effectively, a government prosecutor, and therefore has a heightened duty to ensure that justice is served in this matter, even if doing so is to its own detriment.

27. As noted in the Amended Complaint, Plaintiff's authority to bring the case at bar is derived from 15 U.S.C. § 56, (2017), which empowers the FTC to prosecute matters such as these in place of the Attorney General of the United States, when the Attorney General either declines, or fails, to prosecute such an action.[4]

28. Under such authority ordinarily reserved for the Department of Justice, the FTC has the ability to file a civil action such as this. However, it is well settled that, despite the classification of a particular case as "civil," it may, in fact, rather be considered as "quasi-criminal" in nature. As noted by the United States District Court for the Southern District of Florida:

> Because the SEC is seeking sanctions that would, if granted, yield "a very severe penalty," this civil case "can be considered 'quasi-criminal' in nature." United States v. Sanchez, 520 F. Supp. 1038, 1040 (S.D. Fla. 1981). *See also* SEC v. Snyder, No. H-03-04658, 2006 U.S. Dist. LEXIS 81830, 2006 WL 6508273, at *1 (S.D. Tex. Aug. 22, 2006) (recognizing "the quasi-criminal nature of this proceeding [seeking injunctive relief, disgorgement, and a monetary penalty for alleged securities fraud and insider trading] as well as the gravity of what is at state for Defendant").

[4] While the FTC will likely argue that it may seek injunctive relief without consulting with the Attorney General pursuant to 15 U.S.C. § 53(b) (2017), this exception applies only to injunctive relief, and not to other "equitable" relief the FTC seeks in this case, such as disgorgement.

SEC v. Merkin, 2012 U.S. Dist. LEXIS 80922, *14, n. 4 (S.D. Fla. June 12, 2012) (internal citations, analysis and emphasis in original); *see also* FTC V. Wyndham Worldwide Corp., 799 F.3d. 236, 255 n. 20 (3rd Cir. 2015).

29. The determination that this case, and others like it, are "quasi-criminal" in nature is supported by the Supreme Court's recent decision in Kokesh v. SEC, 137 S. Ct. 1635 (2017), and its progeny, including SEC v. Gentile, Case No.: 16-1619-JLL (U.S. Dist. N.J. December 13, 2017).[5] In Gentile, the court explained:

> Recently, the Supreme Court discussed Section 2462's applicability with respect to disgorgement. *See* Kokesh v. SEC, 137 S. Ct. 1635 (2017). While the remedy therein differs from the one in the matter sub judice (i.e. disgorgement verses injunction), the Supreme Court's reasoning is quite instructive. Consistent with the above law, the Court found that "[p]enal laws, strictly and properly, are those imposing punishment for an offense committed against the State." Kokesh, 137 S. Ct. at 1642 (citations and internal quotation marks omitted). The Court concluded,"[w]hen an individual is made to pay a noncompensatory sanction to the Government as a consequence of a legal violation, the payment operates as a penalty."

Id. at 1633 (emphasis added).

30. Because the FTC seeks similar relief as the SEC did in Kokesh and Gentile, it is appropriate to identify the relief requested as punitive, rather than remedial in nature. Thus, this case is, likewise, "quasi-criminal" in nature.

31. Having established that: 1), the FTC is, in this case, acting as a de facto United States Attorney; and 2), these proceedings are quasi-criminal, it is clear Plaintiff is not merely an advocate, but rather, is a "minister of justice." The Ninth Circuit Court of Appeals described the distinction as follows:

[5] While the analysis in Kokesh and Gentile was in the context of the statute of limitations, the reasoning of those decisions is applicable to the case at bar, for purposes of determining this case to be "quasi-criminal."

> [W]e note that the government has the obligation to see that all evidence relevant to a case is presented, even if unfavorable to its position. "A prosecutor has the responsibility of a minister of justice and not simply that of an advocate. This responsibility carries with it specific obligations to see that the defendant is accorded procedural justice and that guilt is decided upon the basis of sufficient evidence." Model Rules of Professional Conduct Rule 3.8 cmt. (1984).

U.S. v. Chu, 5 F.3d 1244, 1249 (9th Cir. 1993).

32. For more than two (2) years, Defendants have operated under the constraints of the Injunction, monitored closely by the FTC. During this litigation, the Plaintiff has not shied away from opposing modifications by the Defendants, seeking its own modification of the Injunction, or to request a show cause order from this Court for purported violations of the Injunction unrelated to the marketing of the GBA Regimen. *See* Motion for Temporary Restraining Order with Other Equitable Relief and an Order to Show Cause Why the Preliminary Injunction Should Not Be Modified (Dkt. 69); Memorandum in Opposition to Motion for Release of Funds (Dkt. 96); Memorandum in Opposition to Motion to Vacate Consent Preliminary Injunction (Dkt. 126); Memorandum in Opposition to Motion for Entry of an Order Authorizing the Sale of Frozen Assets (Dkt. 182). Surely, if Plaintiff believed Defendants were continuing to engage in marketing practices that violate the Injunction, it would have brought the matter to this Court's attention. The only logical explanation for not doing so is that Defendants are not marketing the GBA Regimen in such a way that violates the Injunction or the law.

33. In light of the above, and as a minister of justice, Plaintiff, which both sought the Injunction and continues to monitor the activities of Defendants to ensure compliance with it, should have sought to effectuate justice by allowing Defendants to market the GBA Regimen through such claims (among others) that the GBA Regimen is safe, allows users to lose weight, and is safer than bariatric surgical procedures such as gastric bypass. Instead, the FTC allowed

Defendants to suffer continual damages through the Injunction, to the detriment of both Defendants and the consuming public.

CONCLUSION

For the reasons articulated above, this Court should grant the instant motion.

REQUEST FOR EVIDENTIARY HEARING AND ORAL ARGUMENT

Pursuant to Local Rule 3.01(j), Defendants request an evidentiary hearing and oral argument on the instant motion. The undersigned believes that two (2) hour will be sufficient to allow both sides to adequately address the matters raised in this motion.

WHEREFORE, Defendants respectfully request this Court enter an Order dissolving and/or modifying the Injunction to allow them to make claims regarding the product under a more reasonable definition of "substantiation," and for such further relief as this Court deems just and proper.

/s/ Andrew C. Hill
Andrew C. Hill
Attorney for the Defendants
Florida Bar # 46755
6136 Cypress Hill Road
Winter Garden, Florida 34787
(813) 410-1648
legal8@gastric.care
pleadings@gastric.care

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been electronically filed with the Clerk of Court utilizing the CM/ECF this the 6th day of February, 2018 and which will electronically transmit an electronic copy to:

Carl H. Settlemyer, III, Esquire
Federal Trade Commission
600 Pennsylvania Avenue, N.W., CC-10528
Washington, D.C. 20580
Electronic Mail: csettlemyer@ftc.gov
Attorney for the Plaintiff

Paul B. Spelman, Esquire
Federal Trade Commission
600 Pennsylvania Avenue, N.W., CC-10528
Washington, D.C. 20580
Electronic Mail: pspelman@ftc.gov
Attorney for the Plaintiff

Michael Davis, Esquire
Federal Trade Commission
600 Pennsylvania Avenue, N.W., CC-10528
Washington, D.C. 20580
Electronic Mail: mdavis@ftc.gov
Attorney for the Plaintiff

/s/ Andrew C. Hill
Andrew C. Hill
ATTORNEY

LOCAL RULE 3.01(g) CERTIFICATION

Pursuant to Local Rule 3.01(g), the undersigned certifies that on February 5, 2018, he conferred, in good faith, with Carl Settlemyer, attorney for Plaintiff, regarding the instant motion, and that the Plaintiff does not consent to the relief requested.

/s/ Andrew C. Hill
Andrew C. Hill
ATTORNEY