UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

FEDERAL TRADE COMMISSION,

Plaintiff,

v. Case No.: 8:15-cv-02231-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 Roca Labs, Inc., Roca Labs Nutraceutical USA, Inc., and Zero Calorie Labs, Inc.,

Defendants.
_____/

DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

Defendants, by and through their undersigned counsel, hereby file their Memorandum in Opposition to Plaintiff's Motion for Summary Judgment (Dkt. No. 141) and in support thereof state as follows:

I. INTRODUCTION

In the instant matter, the FTC makes frequent long leaps in logic and legal analysis in an obvious attempt to force multiple arguments to surround and support this case of first impression of an alleged violation of 15 U.S.C. § 45(a). The violation is the square peg of a prosecution for use of non-disparagement clauses in customer contracts in the round hole of the proposition that such clauses are an unfair business practice before the bill is signed into law. Conspicuously, this ex post facto allegation is buried as the third count of a multiple count complaint that mostly lists paltry allegations of deceptive practices. The agenda is thinly veiled and hammered violently by the Plaintiff at the expense of a small business owner and provider for his young family.

This business, family man is much, much more and it all started where Don Karl Juravin was born. Mr. Juravin was born in the Holy Land of Israel where Jesus of Nazareth and Moses originated and he has more in common with these religious icons then just a sacred birthplace. Mr. Juravin has been regularly heralded as a worker of miracles. To date, it is common place for Mr. Juravin to be showered with praise from the people whose lives he has saved by inventing, promoting and operating the gastric bypass alternative. DX 1

The Gastric Bypass Alternative or GBA is the non-surgical method of creating the same effect of bariatric surgery which is more commonly known by the more specific title of, "gastric bypass," an example of a more particular type of bariatric surgery. The common thread throughout bariatric surgery, gastric bypass, the Lap Band and Mr.

Juravin's GBA is simply the limitation of the capacity of the stomach. Plaintiff has devoted precious resources at the taxpayers' expense all because Defendants have the gall, nerve or *chutzpah* to find a way to duplicate the effect of bariatric surgery without being gutted by a scalpel to restructure or constrict a person's digestive system.

II. UNDISPUTED FACTUAL AND PROCEDURAL BACKGROUND

On September 24, 2015, Plaintiff filed this action in the Middle District of Florida Federal Court. (Dkt. No.1). On February 19, 2016, Plaintiff filed its Amended Complaint with the Court. (Dkt. No. 48). Both the Amended and Original Complaint alleged in Court Three that Defendants in this action had a contract which contained a non-disparagement closure clause that was harmful to consumers. *Id.* At the time of filing of the Complaint and Amended Complaint, there was no federal law prohibiting the use of a non-disparagement clause in any contract. In fact, the Courts – both state and federal –have supported non-disparagement clauses in contracts.[1] There was no authority on this issue in the State of Florida. In its Amended Complaint, Plaintiff alleges Defendants have utilized "gag clauses" in agreements with their customers and threatened litigation regarding violations of same. (Dkt. No. 48, ¶¶ 47-56; 67-69). In their Answer to the Amended Complaint, Defendants admitted that Roca Labs requires purchasers/its

[1] *FreeLife Int'l, Inc. v. Am. Educ. Music Publications Inc.*, 2009 WL 3241795 (D.Ariz. 2009); *Equal Employment Opportunity Commission v. Severn Trent Services, Inc*., 358 F.3d 438 (7TH Cir. 2004); *Patlovich v. Rudd,* 949 F.Supp. 585, 594-95 (N.D.Ill.1996); *Eichelkraut v. Camp,* 513 S.E.2d 267, 236 Ga. App. 721 (Ct.App.1999); *Tenneco Inc. v. Enter. Prods. Co*., 925 S.W.2d 640, 646 (Tex.1996); *Trump v. Trump*, 179 A.D.2d 201, 582 N.Y.S.2d 1008 (App. Div. 1992); *Schaller v. Russak*, No. 2:11-cv-59-FtM-38DNF (M.D. Fla. Oct. 11, 2013); *Miles v. Northwestern Mut. Life Ins. Co.,* 677 F. Supp. 2d 1312 (M.D. Fla. 2009)

customers to agree not to publicly disparage Roca Labs (Dkt. Nos. 58-64, ¶¶ 47, 67), and "filed lawsuits against customers who have breached their contracts with Roca Labs." (Dkt. Nos. 58-64, ¶ 47). Defendants also each admitted to having the terms and conditions which contain the disparagement clause accessible on their website (Dkt. Nos. 58-64, ¶ 48), that "Roca Labs has required its customers to agree to not publicly disparage Roca Labs" (Dkt. Nos. 58-64, ¶¶ 49-52), that the "Summary" attached to the Amended Complaint as Exhibit H contains an agreement to not write any negative reviews (Dkt. Nos. 58-64, ¶ 53), and that it has taken action to enforce its contract and its legal rights, (Dkt. Nos. 58-64, ¶¶ 54-55). With regard to the allegations in the Amended Complaint pertaining to Count Three, Defendants have only denied that they have "published or disclosed any protected health information" (Dkt. Nos. 58-64, ¶ 56), and the legal conclusions stated in paragraphs 68 & 69 of the Amended Complaint (Dkt. Nos. 58-64, ¶¶ 68-69).

Dr. Jay Hoffman was hired by Defendants as an expert and his report pertains to the issues relevant in this case, including the effectiveness of coaching in achieving weight loss (DX3 - 97:11-25, 98:1-19), the effectiveness of the ingredients in Roca Labs' Products in achieving weight loss, (DX3 - 100:17-25; 101; 102:1-7; 104-110), and the science supporting Defendants' claims relating to its Products and/or Regimen (DX3 - 112:22-25; 113-114). Plaintiff has not challenged the validity or reliability of these studies.Plaintiff has offered no evidence to contradict Dr. Hoffman's testimony regarding the efficacy of the Regimen, instead focusing solely on the ingredients in the Products

which, as described in the challenged claims, are merely one aspect of the Regimen. Dkt. No. 48 ¶ 27a (referring to "weight loss regimen"). The FTC's expert, Dr. Steven Heymsfield testified that the components of the Roca Labs Regimen, a 1,200 calorie a day diet, plus exercise, plus a behavior modification portion, including coaching, would result in weight loss with compliant users. DX4 90:21-25, 91:1-3.5.

Throughout 2014, Defendants' Terms and Conditions stated, "your information will not be shared or sold ***for as long as you do not breach the Terms and we will have to use the information provided.***" Dkt. No. PX6-344 (emphasis added). The Terms and Conditions explicitly and repeatedly warned potential customers that there were no refunds and that Defendants may "institute legal or collection proceedings" for chargebacks and for violations of its non-disparagement clause or to protect its legal rights.. PX6-350-351, 353, 362, 367, 369, 370, and 383. Defendants had a detailed privacy policy, including specific language regarding children's privacy, the use of cookies and pixel tags, on its website, and information that would be disclosed under certain circumstances. Dkt. No. 141, PX6-367-371.

Finally, Plaintiffs are not able to provide evidence of substantial consumer harm for any of its claims.

III. LEGAL STANDARD

The Court may grant summary judgment when the movant can show there is no genuine issue as to any material fact and that it is entitled to judgment as a matter of law. Fed.R.Civ.P. 56(c). Which facts are material depends on the substantive law applicable to

the case. *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 248 (1986). The moving party bears the burden of showing no genuine issue of material fact exists. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Plaintiff has not met this burden. If the non-movant's response consists of nothing "more than a repetition of his conclusional allegations," summary judgment is not only proper, but required. *Morris v. Ross*, 663 F.2d 1032, 1034 (11th Cir. 1981), cert. denied, 456 U.S. 1010 (1982).

Once the moving party has met its burden, the burden shifts to the nonmoving party to designate specific facts showing that there is a genuine issue for trial." *Id.* at 324 (internal quotation marks omitted). There is a genuine issue if the combined body of evidence, viewed in the light most favorable to the nonmoving party, would allow a reasonable jury to find in favor of the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986). In other words, the relevant inquiry is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." Id. at 251-52. When, as here, a district court is presented cross motions for summary judgment on the same issues, "[t]he court must rule on each party's motion on an individual and separate basis, determining, for each side, whether a judgment may be entered in accordance with the Rule 56 standard." 10A Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure § 2720, at 335-36 (3d ed. 1998) (footnote omitted).

IV. CONFLICT OF LAW

A. There is a conflict of laws that cannot allow for a Motion for Summary

Judgment in this case

1. FDA v FTC

The Plaintiff knows that there is a conflict of law in the Federal system regarding the regulation and advertising of supplements, but has purposefully failed to bring this issue to the attention of the Court. The FDA and FTC have been in conflict for a bit of time now regarding supplements and other "alternative medicine" therapies. And no one knows this better than the two agencies involved. The only ones who don't seem to realize this situation is the average business owner who believes that they are complying with the FDA laws, only to find out later that the FTC is playing by a different rulebook.

The FDA, not Plaintiff, determines what is a supplement and what supplements are able to claim. The FDA is the agency that regulates supplements, which is what the Defendants here supply to the public as part of its Regimen.[2] FDA has defined supplements as a food, and not a drug.[3] The FDA also has given companies who distribute supplements guidelines as to what they may claim, how they may label and how they may advertise.[4] Defendants state that a supplement may state the following: "DSHEA provides that when the dietary ingredients in a supplement are considered to be

[2] The FDA has regulated the terms "supplement", "natural" and labeling for supplements. See https://www.fda.gov/AboutFDA/Transparency/Basics/ucm193949.htm, https://www.fda.gov/AboutFDA/Transparency/Basics/ucm194355.htm, https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/default.htm, https://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm237623.htm.

[3] Id.

[4] https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm070613.htm, https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm073168.htm.

a proprietary blend, just the total amount of the blend need be stated" and "Foreign research could be sufficient to substantiate a claim as long as the design and implementation of the foreign research are scientifically sound and the foreign research pertains to the dietary supplement at issue". Also the FDA allows for the Defendants to make claims based on the individual ingredients contained within a product, and not just on the product itself.[5] This is exactly what the Defendants in this case have done and are able to provide. The FTC has applied a higher standard than what the FDA has stated should be applied to supplements. This is where the conflict begins.

The FTC admitted in an FDA hearing on homeopathic medicines that there is a conflict of these laws. The Plaintiff states in its report to the FDA the following:

> "The FTC staff is concerned that the FDA's existing regulatory framework may conflict with the Commission's advertising substantiation policy in ways that may harm consumers and **create confusion for advertisers**"[6] (emphasis added)

This has been a continuous aggravating issue for advertisers of natural products. See National Advertising Division Case Report #4650 (04/02/07), Similisan Corp. USA, Earache Relief Drops, Exhibit A. (where the company was confused about the applicable standard in advertising homeopathic natural cures).[7]

At this point, the FTC also acknowledged that they are indeed stepping on the

[5] www.fda.gov
[6] Comments of the Staff of the FTC Submitted to the FDA Dept. of Health and Human Services – In Response to a Request for Comments Related to its Public Hearing on Homeopathic Product Regulation: Evaluating the Food and Drug Administration's regulatory Framework After a Quarter-Century. 80 Fed. Reg. 16327 (Mar. 27, 2015, Submitted August 21, 2015)
[7] *Id.*

FDA's proverbial shoes to enforce a broader, more strict interpretation than what the FDA has informed companies who produce supplements and homeopathic remedies. This conflict has caused multiple problems within the industry for business owners such as the Defendants in this case. The FTC admits this in their report to the FDA. The Plaintiff stated as follows:

> "At the very least, the potential conflict between the FDA's homeopathic CPG and the FTC's substantiation requirement creates enforcement challenges for the FTC. This conflict also may create uncertainty for advertisers and consumers, which may substantially harm the interests of both."[8]

Companies, such as the Defendants, find themselves caught between 2 large Federal Agencies, like Odysseus between Scylla and Charybdis trying to navigate troubled and uncertain advertising waters. They do this without any guidance as to which Agencies guidelines and rules control in these types of situations until it is too late.

When there is a conflict of Federal Agency laws, the Courts have held that, just because one is broader than another, doesn't mean they automatically win. "It is sufficient for this case to observe that the Board has not been commissioned to effectuate the policies of the Labor Relations Act to single-mindedly that it may wholly ignore other and equally important congressional objectives." *Southern S.S. Co. v. NLRB*, 316 U.S. 31 at 47 (1942) (where the Supreme Court held that the NRLB overstepped its authority and its chosen remedy, "trenches upon federal statute or policy outside the Board's competence to administer, the Board's remedy may be required to yield." *Hoffman*

[8] *Id.*

Plastic Compounds, Inc. v NLRB, 535 U.S. 137 (2002). [9]

Defendants argue that there are several areas of law that conflict in this case, which cannot be resolved through Summary Judgment. None of this is even mentioned, or discussed in any of the pleadings put forth by the FTC. Defendants have stated on multiple occasions that they believed they were following the correct law and that if they had known that what they were doing was wrong, or had received a warning letter from Plaintiff, they would have changed course and followed the letter of the law. Defendants, in fact, changed their website multiple times to comply with varying state and local laws even though they are not business savvy.

Q: Do you remember talking to him [Whiting] about the possibility of starting a business to market your invention?

A: It didn't start like this. I don't remember exactly how it started. But I told him that I have ideas. I have inventions. I want to do business. But I don't like and cannot run a business well. And I thought I'm not familiar enough with business, how to run a business in the U.S. Not even how to start a company….[10]

Q: Why do you caveat with "for the most part"? Was somebody else involved with that?

A: Yes. Because when you go to an FDA registered facility, you cannot bring whatever you want. You can say this is what I want. But then the importer needs to coordinate with the facility to see if the facility agrees, because the facility is obligated to the FDA. I can ask anything I want. But they can say no because whatever reason.[11]

The FTC would like this Court to believe that there is no conflict of law, while at

[9] See also, *Dastar Corp. v 20th Century Fox*, 539 U.S. 23 (2003), where Dastar would be in violation of either the Lantham Act or Copyright law and therefore did not have a good solution to the "origin" issue because they would still end up in court.

[10] DX2 416:16-22

[11] Id. at 428:6-13

the same time admitting that there **is** a conflict behind closed Agency doors. This is a familiar pattern with the FTC in this case as this Court will soon see.

2. Old FTC Law v New FTC Law

The FTC knew when they filed this action on September 24, 2015, that there was a new federal law making its way through Congress, made at the request of the Plaintiff in this action. This new law was not signed until December 14, 2016 – over a year after the filing of this action.[12]

What the Plaintiff has done in the instant case is purposefully hide this information from the Court in an effort to get a "win" on the books and look good before Congress. To further promote this contention, they stated that this case was "settled" before Congress.[13]

It seems the Agency itself cannot make up its mind as to if they need a new law to help protect citizens, or if the laws that are currently in place are sufficient. As my mother would say - you can't talk out of both sides of your mouth. [14] "Unexplained inconsistency is, at most, a reason for holding an interpretation to be an arbitrary and capricious change from agency practice under the Administrative Procedure Act." *National Cable & Telecommunications Assn. v. Brand X Internet Services*, 545 U.S. 967, 981, (2005). *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117 (2016). Defendants argue that at the

[12] Consumer Review Fairness Act of 2016.
[13] H.R. 5111 – House Committee Notes (May 24, 2016. Testimony of Commissioner Edith Martinez before the 114th House of Representatives Subcommittee on Commerce, Manufacturing, and Trade).
[14] The FTC brought this action at the same time they were petitioning Congress to provide a law that applies to the same issues in this case.

very least, this issue of contradicting laws[15] should be considered in the least favorable light of the Plaintiff and not find in favor of summary judgment for the Plaintiff in this issue.

3. Internal Guideline Conflict at the FTC

Even the internal guidelines and laws conflict within the FTC. The Plaintiff has cited old guidelines from years ago regarding glasses and telemarketing, but has failed to cite their own "Online Advertising Rules". These guidelines are what the Defendant would be using in this action, but these guidelines are not mentioned because this is unfavorable to the Plaintiff's position.[16]

The rules are there specifically for online retailers, such as the Defendants, to help them avoid FTC actions.[17] Defendants, who have attempted to keep up with the ever-changing laws of online shops, believe that they complied with what the FTC requested. The Plaintiff has stated in its own guidance literature that, "The type of evidence needed to substantiate a claim may depend on the product, the claims, and what experts in the relevant field believe is necessary."[18]

It seems that the Plaintiffs are not sure what internal laws, rules, or guidelines

---

[15] See also, the CLEAR ACT, a House Bill for more transparency in the FTC and https://www.ftc.gov/public-statements/2003/05/ftcs-use-unfairness-authority-its-rise-fall-and-resurrection

[16] FTC, ".com Disclosures, How to Make Effective Disclosures in Digital Advertising" March 2013.

[17] The guidelines do not address non-disparagement clauses because this was addressed in state courts at this time. The FTC also clearly stated in the same guidelines that "This staff guidance document only addresses disclosures required pursuant to laws that the FTC enforces. It does not address disclosures that may be required pursuant to local, state (*e.g.*, many sweepstake requirements), or other federal laws or regulations (*e.g.*, regulations issued by the Consumer Financial Protection Bureau or the Food and Drug Administration)"

[18] Id.

they would like to follow. If this is the case, then it is clear that there is a conflict of laws that must be resolved before this Court and summary judgment is not proper.

V. SUBSTANTIATION (COUNTS I AND II)

> A health-related efficacy claim, which states that the product yields the benefit promised, likely will mislead a reasonable consumer if the claim is false or if the advertiser lacks competent and reliable scientific evidence to substantiate the claim. If the FTC alleges that a claim lacks competent and reliable substantiation, the defendant must produce the evidence on which he relied for substantiation. If the defendant produces evidence of substantiation, the FTC must prove the inadequacy of that evidence.

NPB Adver., Inc., 2016 U.S. Dist. LEXIS 151840 *4-5. (internal citations omitted).

In NPB Adver., Inc., the court found the FTC expert sufficient proved the inadequacy of the evidence of substantiation provided by the defendant and therefore found the claims material and likely to mislead the consumer. *Id.* at *10. Defendant in that case sold a green tea extract product, representing that it caused substantial weight loss. *Id.* at *2. The evidence of substantiation he presented were studies performed on green tea extract, but not his particular product. *Id.* at *3. The FTC's expert witness testified in detail as to the inadequacy of the defendant's evidence of substantiation. *Id.* at *8-9. The defendant did not rebut the FTC's expert's testimony. *Id.* at *10.

In this case, Defendants' expert, Dr. Jay Hoffman, relied on numerous published scientific articles in developing his opinions. See, DX3 - 96:4-9, 23-25; 97; 99:18-25; 100; 101:11-25; 102:15-25; 104:12-25; 105; 106; 107; 108:7-13; 109:9-25; 111:21-25, 112; 113; 114; 115; 116. These studies are thoroughly analyzed in Dr. Hoffman's report and pertain to the issues relevant in this case, including the effectiveness of coaching in

achieving weight loss (DX3 - 97:11-25, 98:1-19), the effectiveness of the ingredients in Roca Labs' Products in achieving weight loss, (DX3 - 100:17-25; 101; 102:1-7; 104-110), and the science supporting Defendants' claims relating to its Products and/or Regimen (DX3 - 112:22-25; 113-114). Plaintiff has not challenged the validity or reliability of these studies.

Plaintiff has offered no evidence to contradict Dr. Hoffman's testimony regarding the efficacy of the Regimen, instead focusing solely on the ingredients in the Products which, as described in the challenged claims, are merely one aspect of the Regimen. Dkt. No. 48 ¶ 27a (referring to "weight loss regimen"); Dkt. No. 48 ¶ 27c ("Depending on your commitment to the recommended rules for suggested use, a loss of 21 lb a month is possible"); Dkt. No. 48 ¶ 27e ("Your full commitment is necessary along with a daily exercise routine"). Dr. Hoffman testified that looking at the Roca Labs Products without considering the Regimen was not helpful in determining the efficacy of Roca Labs, stating while the dietary fibers in the Products may help users "maintain a low caloric diet, . . . it's very important to take a look at Roca Labs as not the supplement by itself. It is my understanding and belief that Roca Labs sold the program. And when you look at the program, that when you combine a high-fiber diet with a hypocaloric diet, you have a greater chance of achieving weight loss." DX3 - 77:7-20. The FTC's expert, Dr. Steven Heymsfield testified that the components of the Roca Labs Regimen, a 1,200 calorie a day diet, plus exercise, plus a behavior modification portion, including coaching, would result in weight loss with compliant users. DX4 90:21-25, 91:1-3.5.

VI. HEALTH CLAIMS (COUNTS IV AND V)

A. Plaintiff cannot claim that there is no material issue of fact regarding the scientific claims made by Defendants

Plaintiff in this case has taken several liberties when describing Defendants' Regimen in an effort to distract from the truth of the matter that FTC overreach is becoming commonplace, even when in conflict with other Federal Agencies.

First, Plaintiff have mischaracterized Defendants' product. Defendants have always sold and promoted the **entire Regimen**[19] – which includes drinking three liters of water, 30 minutes of exercise and eating less overall. Since its inception, the Regimen has included these things not only for the effect, but also for the health and safety of Defendants customers. What is also very ironic is that this is also the very same advice given to those who also participate in bariatric surgery, for the exact same reason - health and safety.[20]

- "You will need to drink up to 8 cups (2L) of water or otherwise calorie free liquids every day
- Do not snack between meals
- Do not eat foods that have a lot of fats, sugar or carbohydrates

[19] See DX4 p.3 where he describes the entire Regimen as "restrictive calorie diet…exercise program…coaching…counseling…mitigated hunger." See also DX3, p.4, where he also describes the product as a "program"

[20] http://www.mayoclinic.org/tests-procedures/bariatric-surgery/in-depth/gastric-bypass-diet/art-20048472, see also https://medlineplus.gov/ency/patientinstructions/000173.htm, citing Mechanick JI, Kushner RF, Sugerman HJ, et al. American Association of Clinical Endocrinologists, The Obesity Society, and American Society for Metabolic & Bariatric Surgery medical guidelines for clinical practice for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric surgery patient. *Obesity (Silver Spring)*. 2009;17 Suppl 1:S1-70. PMID: 19319140 www.ncbi.nlm.nih.gov/pubmed/19319140, Heber D, Greenway FL, Kaplan LM, et al. Endocrine and nutritional management of the post-bariatric surgery patient: an Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2010;95(11):4823-4843. PMID: 21051578 www.ncbi.nlm.nih.gov/pubmed/21051578, Thompson CC, Morton JM. Surgical and endoscopic treatment of obesity. In: Feldman M, Friedman LS, Brandt LJ, eds. *Sleisenger & Fordtran's Gastrointestinal and Liver Disease*. 10th ed. Philadelphia, PA: Elsevier Saunders; 2016:chap 8.

- Avoid carbonated drinks"

Defendants also clearly state that they are not promotion a surgery of any kind, nor are they promoting any sort of medical procedure or advice. Defendants state repeatedly that they are offering a natural alternative [21] to those options instead, in the hopes of saving customers thousands of dollars in an irreversible surgery. Even if the person finds that they cannot keep to the Regimen, they will at the very least think twice before jumping recklessly into a possibly dangerous surgery at a time when most media outlets continuously downplay its serious nature.[22]

In addition, the "effect" of Defendants' product is true to form. The description of the Regimen and what it does is exactly what it is supposed to do – which is reduce the capacity available in the stomach for food. Plaintiffs in this case want facts set by an arbitrary standard which any company that is not backed by a large pharmaceutical would be hard pressed to do. The courts have stated, "we agree with appellants that the APA requires the agency to explain why it rejects their proposed health claims—to do so adequately necessarily implies giving some definitional content to the phrase "significant scientific agreement." We think this proposition is squarely rooted in the prohibition under the APA that an agency not engage in arbitrary and capricious action. *See* 5 U.S.C. § 706(2)(A) (1994). It simply will not do for a government agency to declare—without explanation—that a proposed course of private action is not approved. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43, 103 S. Ct. 2856, 77

[21] The closing plate to all videos state that the Formula is a "natural alternative". See PX's
[22] http://www.everydayhealth.com/news/things-your-doctor-wont-tell-you-about-weight-loss-surgery/

L.Ed.2d 443 (1983) ("[T]he agency must . . . articulate a satisfactory explanation for its action. . . ."). To refuse to define the criteria it is applying is equivalent to simply saying no without explanation." *Pearson v Shalala*, 164 F.3d 650 (1999).

Defendants have provided studies and can prove that the Regimen, as a whole can, cause weight loss similar to the claims made on the website. Even the Plaintiffs own experts stated it was possible. Dr. Steven Heymsfield stated in his February 24, 2017 deposition the following:

> **Q: So, in light of that [describing the entire Regimen in the prior answer], would you agree that those components of the Roca Labs regimen, a 1200 calorie a day diet, plus exercise, plus behavior modification portion, including coaching, would be likely or would absolutely result in weight loss with compliant users?**
>
> A: The – the answer is yes, but is says nothing about whether or not the Roca Labs product contributes to that weight loss.[23]

Dr. Hoffman also supported the claims of the Defendant

> **Q: All right It's the FTC's position, as we stated in our complaint, that Roca Labs is claiming that use of its product, including the Roca Labs Formula and Anti-Cravings, enables consumers to reduce food intake by 50 percent and lose substantial amounts of weight quickly, including as much as 21 pounds in one month and as much s 100 pounds in seven to ten months. Are you offering an expert opinion that there is a competent and reliable scientific evidence to substantiate that claim?**
>
> A: I believe there's scientific evidence to support that those – that possibility of a subject at a certain body mass within the 95 percent comparables of weight loss published, that they can lose up to that

[23] It was after this point that Plaintiff's expert, Dr. Heymsfield attempted to change the "goal post" so to speak to evaluate "long term" weight loss instead of simple weight loss.

amount of weight. That is very credible.

And on Page 13 of DX3

> **Q: You said in the Walsh study, on 31, paragraph 31, the last sentence, "this study appeared to be one of the first to indicate the efficacy of glucomannan." You're not using the word indicate" to mean prove the efficacy of, are you?**
>
> A; They're the first study to publish that glucomannan had a positive effect on weight loss.
>
> **Q: When you say "indicate", do you mean establish, prove efficacy, or do you mean indicate?**
>
> A: Suggest. Generally, in science you want to speak – indicate what had – what occurred. Their results indicate. IT doesn't make it validated, it indicated. The results indicated that glucomannan caused a significant increase in weight loss. It wasn't suggested, they actually showed a significant increase. So, it was indicated. [24]

Even these scientists cannot disclaim the effect of the entire Regimen. Even though the Plaintiff continued to question study after study with Dr. Hoffman, the study results did not magically change, and therefore neither could his answers.[25] Defendants have cited repeatedly to study after study, and can provide each one to the Court for review, on the ingredients within the Formula, as well as intermittent fasting, reduced caloric intake, the effect of the increase of fiber in the diet – all which are a part of the Defendant's Regimen. This is what the Plaintiff does not want to discuss. Because by admitting, even in small part, that Defendants' claims may be true and supported by real evidence, they may lose this case and look bad to Congress after stating this same case

[24] DX3, p. 13
[25] Id at 13-15

was "settled'. And no one likes to look bad in front of the boss.

The side effect of the Regimen is the weight loss, not the actual product itself. And the Regimen really works. Sharon King, who was deposed by the Plaintiff in this case provided multiple stories from people who actually lost weight on the Regimen[26]

> A: Sometimes, you know, I would – the one woman that was a nun, Sister…
>
> **Q: Sister Ann?**
>
> A: Sister Ann. She approached me – she didn't lose the weight, she asked if she could have the product for free because she didn't have the money. You know, you take a vow of poverty. She wanted – she said: I don't care if its expired I just need help. I'm a school teacher, I can't keep up the my kids. So, I offered to send her product for free, you know, to help her out. So, that's just one.
>
> And the one that you don't – that her face I covered she lost 90 pounds. So, these people were real people that really lost the weight and we asked them to be coaches. Same with Darlene Glo (ph), they want a reorder and that's how I approached them.
>
> **Q: Do you think it was more than 50?**
>
> A: Oh yeah.
>
> **Q: More than a hundred?**
>
> A: Yeah. I had one man that lost 200 pounds and went skydiving. I mean A lot of people are so private about their weight loss they don't want people to know. He showed me this video, said: Don't tell anybody. I don't want to be a coach. I don't want you to show my pictured to your boss or anything its just between me and you Sharon. You know, I didn't even tell Don. You know, it was just like I had the communication with him, so you know.
>
> **Q: Do you think it was more than like maybe a couple a month or thereabouts?**

[26] DX5 149-150

> A: It was more than a couple a month. I would say, you know, maybe about 20 a month. I would say about 20 a month.

By misconstruing the claims of the Defendants and creating a moving target for the Defendants to hit, the Plaintiffs have rigged the game in their favor. Like a carnival game with very high stakes, the Defendants have to continually attempt to reach an even higher bar than what was set before to make the Plaintiff happy. It does not matter that there are scientific studies on the ingredients, there now must be scientific studies on the Formula, It doesn't matter that there is a study on the Formula, now it must be a study that lasts over a year. It doesn't matter that there are studies on animals on the efficacy of the individual ingredients, there must be multiple studies on humans – and of the same weight and sex and height and ***eye color*** as what the Defendants claim.

There is a material issue of fact in this case. Defendants, their experts, the Plaintiff's expert and the studies that are the true subject of this debate bring into question many triable issues that should be considered by the Court and are not appropriate for Summary Judgment. It's time to stop moving the goal and focus on the issues.

VI. PRICE POINT (COUNT VII)

1. Plaintiff has failed to show that Defendants' price point structure is deceptive.

The FTC has attempted to, "pile on," with an additional and thin argument regarding an allegation of a deceptive pricing structure. There is no sin committed by the Defendants in this allegation by their tireless efforts to promote the Roca Labs' Gastric Bypass Alternative as any business would attempt in proper marketing of their product in

the highly competitive area of online commerce. Plaintiff correctly states Defendants regularly offered the Roca Labs package for the total price of $480 with certain conditions. (Dkt. No. 141 at page 11) Plaintiff also provides numerous references to the record regarding search advertisements, display advertisements served through Google and Bing, and advertisements on Facebook. (Dkt. No. 141 at pages 11-12) In order to set up the invalid argument of deceptive pricing, Plaintiff attempts to vilify Defendants' reasonable marketing campaign with the pervasive nature of their online advertisements.

The FTC continues this transparent assertion with the dramatic revelation that there was a mysterious and secret pricepoint hidden on the website which could not possibly be unearthed. The following step in Plaintiff's attempts to smear the Defendants' mission to save the lives of obese persons, is to provide a negative discussion about the *clickwrap* (emphasis added) feature of the website designed to efficiently allow customers to affirmatively agree and accept the purchase qualifications and terms of the transaction. Plaintiff correctly states that the website includes at the bottom of the purchase selection screen and above the, "Submit," button was an unchecked box next to the statement, "I have checked and do not have any medical reason that can prevent me from using the Gastric Bypass Alternative procedure and I have read and agree to the terms, privacy and money back reward / return policy." (Dkt. No. 141 at 12) Additionally, it is true that customers were not required to read the, "Terms and Conditions" which are fully available by a hyperlink at the bottom of each webpage. Plaintiff's Exhibit to Complaint (Dkt. 2, Part II, pages 12,16,22,25,32, 36,46, 48, 56; Part I, pages 3,10, 12, 16,

22, 26, 29, 34, 37, 47) Defendants did not hide the, "set price," of $1580 or the terms for which the subsidized price of $480 could be achieved. Plaintiff's Exhibit to Motion for Summary Judgment (Dkt. No. 141-7, pages 319 - 320) On the contrary, access to the terms and conditions were consistently and prodigiously provided by hyperlink throughout the online site.

The FTC dramatically brings this tale to a conclusion with an untruthful contention that the customer's first opportunity to know the set price of $1580 and conditions to qualify for the subsidized price point is in the printed, "Terms and Conditions," included in the packaging of the delivered product. (Dkt. No. 141 at page 12) Plaintiff's fatally flawed argument completely depends on the assumption that the customer did not click on the hyperlink provided on the website and did read the printed materials in the shipment. Both opportunities to learn of the, "Terms and Conditions," are equally accessible and fare the same chance of being ignored by the customer.

Additionally, Plaintiff's bewildering argument teeters upon the precipice of the legality of clickwrap agreements. Courts have previously decided multiple cases on clauses contained within a "clickwrap" contract online. "Clickwrap" has been defined by the courts as an "agreement (that) appears on an internet webpage and requires that a user consent to any terms or conditions by clicking on a dialog box on the screen in order to proceed with the internet transaction." *Specht v. Netscape Comms. Corp*., 306 F.3d 17, 22 (2d Cir. 2002). In addition, courts have also found that such agreements are enforceable by applying the traditional principles of contract law. See, *Specht*, 306 F.3d at 28-30;

Forrest v. Verizon Communications, Inc., 805 A.2d 1007, 1010 (D.C. Cir. 2002); *Barnett v. Network Solutions, Inc.*, 38 S.W.3d 200 (Tex. App. 2001); *Caspi v. Microsoft Network, L.L.C.,* 323 N.J. Super. 118, 125-26 (App. Div. 1999); John M. Norwood, "A Summary of Statutory and Case Law Associated with Contracting in the Electronic Universe," 4 DePaul Bus. & Comm. L.J. 415, 439-49 (2006) (discussing clickwrap cases); 1-2 Computer Contracts §2.07 (2006) (analyzing clickwrap cases). Also, the Courts have found that failure to read an enforceable clickwrap agreement will not excuse compliance with its terms. See, *Specht*, 306 F.3d at 30; *Lazovick v. Sun Life Ins. Co. of Am*., 586 F. Supp.918, 922 (E.D. Pa. 1984); *Barnett*, 38 S.W.3d at 204; *Siedle v. Nat'l Assoc. of Sec. Dealers, Inc.*, 248 F. Supp. 2d 1140, 1143 (M.D. Fla. 2002); *Management Computer Controls, Inc. v. Charles Perry Constr., Inc.*, 743 So.2d 627 (Fla. 1st DCA 1999) Defendants mention multiple times on their website that the consumer is required to read the "terms and conditions" prior to purchase. Plaintiff's Complaint Exhibits (Dkt. 2, Part II, pages 11,12,16, 22, 32,34, 35, 36, 46, 47, 48 and 56.) Defendants' actions are in clear compliance of contract law as stated in *Feldman v. Google, Inc*., 513 F. Supp. 2d 229, Dist. Court, ED Pennsylvania 2007, citing *Forrest v. Verizon Communications, Inc.,* 805 A.2d 1007, 1010-11 (D.C. Cir. 2002) (holding that adequate notice was provided of clickwrap agreement terms where users had to click "Accept" to agree to the terms in order to subscribe), *Caspi v. Microsoft Network, L.L.C.,* 323 N.J. Super. 118, 122, 125-27 (App. Div.1999)(finding that reasonable notice of the terms of a clickwrap agreement was provided where the user had to click "I agree" before proceeding with registration.). The

record substantiates Defendants' clear intention to establish a valid agreement and sufficiently notice the customer of the set price of $1580 as well as the conditions to receive the subsidized price of $480.

The FTC draws this empty accusation out by a string of baseless arguments that stack like a house of cards. First, Plaintiff points out Defendants' pervasive attempts to market online a business that saves lives in a manner that suggests deception about a price point that was used regularly in sales. Second, Plaintiff denigrates the lawful and widely utilized mechanism of the clickwrap agreement by unconscionably characterizing the programmed feature as inherently deceptive. Thirdly, Plaintiff untruthfully state that the set price is not revealed to the consumer until after delivery of the shipment is received and opened. Despite Plaintiff's attempt to manufacture a deceptive price point allegation in this matter, it is clear factually, logically and legally that Plaintiff failed to demonstrate that Defendants designed and implemented a deceptive pricing structure.

VII. ENDORSEMENTS (COUNT IV AND V)

A. Plaintiff Has Failed to Show the Defendants' Endorsements were Deceptive

Plaintiff claims Defendants' endorsements were deceptive and therefore violated Section 5(a) of the FTC Act, 15 U.S.C. § 45(a). Dkt. No. 141 pp. 8-9, 21, 32. The facts cited by Plaintiff as evidence for this deception were Defendants' information about bariatric surgery and "alternatives to surgery", use of testimonials, and omissions of disclosure on GastricBypass.me site. Dkt. No. 141 pp. 8-9. Plaintiff claims Defendants violated section 5(a) of the FTC Act, 15 U.S.C. § 45(a) when they ran an "informational"

website educating consumers about gastric bypass surgery while promoting Roca Labs products, and using testimonials. Dkt. No. 141 pp. 21, 33.

Defendants were dedicated to educating people about negative effects of bariatric surgery and "alternatives to surgery". Defendants admit GastricBypass.me did not state it was affiliated with RLI. There is a dispute of fact as to whether some of the "satisfied consumers" in the videos were paid "independent contractors." Roxie initially became acquainted with Roca Labs as a customer, as evidenced in her deposition stating as follows:

> Q. When did you first become acquainted with Roca Labs as a business or any of its products?
>
> **A. It was in the summer of 2012**.
>
> Q. Okay. And how did you become acquainted with Roca Labs?
>
> **A. I was researching gastric bypass on the Internet, and it popped up and it looked interesting, so I checked it out, and I purchased as a customer.**

"Roxie" later became a Success Coach, as evidenced in her deposition:

> Q. Okay. How did you come to -- you later came to work with Roca Labs, that's correct?
>
> **A. Yes.**
>
> Q. How did that come about?

A. After the first three months, I was -- I ran out of my formula, probably four months, and I called in to do a reorder. I then received an e-mail from Sharon King wanting to know about my success, how I was doing, and how much weight I had

lost. And then she asked if I would be interested in becoming a success coach in 2013, around April.

Dkt. 141, PX12-7(30:9-18), pg. 8(32:17-25); (33:1-3), pg. 8-9. While her video was recorded subsequent to her employment, the account of her success related to results acquired prior to becoming an employee of the Defendants.

Plaintiff claims Defendants ran a fake "informational" website, purporting to educate consumer while promoting Roca Labs products is vague, violates due process, and fails to explain how such conduct violates the law. Information found on Defendants' site aided to informing customers regarding potentially serious, life-changing, body altering decisions, such as gastric bypass surgery.

Further, even if the Court finds the endorsements were deceptive, Plaintiff has offered no evidence showing the endorsements have caused or will likely cause substantial injury to consumers as required by the FTC Act, nor can it. Additionally, Plaintiff cannot show any harm came as a result of Defendants sharing information about bariatric surgery while promoting Roca Labs products. Nor can Plaintiff show that any harm came as a results of Defendants use of their endorsements. Furthermore, it does not even try to allege any harm was caused as a result of the endorsements.

Based on the foregoing, Plaintiff has not met its burden to show there are no issues of material fact relating to Defendants' endorsements and its alleged misrepresentation of same and its Motion for Summary Judgment with respect to Counts IV and V should be DENIED.

VIII. PRIVACY POLICY (COUNT VI)

Plaintiff claims Defendants' privacy promises were deceptive and therefore violated Section 5(a) of the FTC Act, 15 U.S.C. § 45(a). Dkt. No. 141 pp. 9-11, 21-22, 33. The facts cited by Plaintiff as evidence for this deception were Defendants' use of information provided by customers in a pre-purchase qualification form completed by potential Regimen users. Dkt. No. 141 pp. 10-11. Plaintiff claims Defendants violated section 5(a) of the FTC Act, 15 U.S.C. § 45(a) when they used certain information in the forms of four customers in litigation and other customers in defending credit card disputes with credit card companies. Dkt. No. 141 pp. 21-22, 33.

Defendants admit certain information about certain customers that was found in the qualification form was included in complaints filed in Florida state court against four customers and in communications with credit card companies in order to defend against payment disputes made by certain customers. There is no evidence in the record that Defendants disclosed information that was not otherwise publicly available, nor is there evidence that Defendants disclosed information about customers other than as required to protect their own legal rights in litigation and/or disputes with credit card companies that were initiated by customers. There is no evidence that Defendants sold private health information to third party vendors nor that it publicly disseminated any information other than in court documents. In fact, Plaintiff is not even accusing Defendants of engaging in such activities. Dkt. No. 140, pp. 9-11, 21-22, 33.

Further, even if the Court finds the privacy promise was deceptive, Plaintiff has

offered no evidence showing the privacy promise has caused or will likely cause substantial injury to consumers as required by the FTC Act, nor can it. "In the early 2000s, the FTC de-emphasized its fair information practices approach as the primary means of addressing privacy issues, and shifted its focus to a "harm-based approach" for protecting consumer privacy. The approach was designed to target harmful uses of information – those presenting risks to physical security or economic injury, or causing unwarranted intrusions in our daily lives – rather than imposing costly notice and choice for all uses of information. The Commission's privacy agenda began to focus primarily on: (1) data security enforcement; (2) identity theft; (3) children's privacy; and (4) protecting consumers from spam, spyware, and telemarketing." Prepared Statement of the Federal Trade Commission on Consumer Privacy Before the Committee on Commerce, Science, and Transportation, United States Senate, Washington, D.C., July 27, 2010, p. 5.

Until this case, the FTC has been focused on privacy as it relates to data security breaches, identity theft, children's privacy, and "unwanted intrusions" (spam, telemarketing calls, etc.). Id. at pp.6-13.[27] It appears Defendants are the first and only

[27] The FTC has taken action against companies for failing to disclose they were selling/sharing consumer's information to third parties (see e.g., In the Matter of Geocities, FTC Docket No. C-3850, 1999; In the Matter of Facebook, Inc., FTC Docket No. C-4365, 2012), misrepresenting the anonymity of financial information collected from minors (see e.g., In the Matter of Liberty Financial Companies, Inc., FTC Docket No. C-3891, 1999), misrepresenting the level of online security and encryption used to protect consumers' private information (see e.g., FTC v. Rennert, Sandra L., et al., (D. Nev. Case No. 00-cv-0861-JBR), using information collected from millions high school students to market services to those students (see e.g., In the Matter of The National Research Center For College and University Admissions, Inc., and Don M. Munce, FTC Docket No, C-4071, 2003), participating in identity theft scams (FTC v. Hill, SD Texas Case No. 03-cv-5337), placing tracking software on consumers' computers without disclosing same, (In the Matter of Sears Holdings Management Corporation, a corporation, FTC Docket No. 4264, 2009) not taking appropriate steps to protect consumers' private information (see e.g., In the Matter of CVS Caremark Corporation, a corporation, FTC Docket No., C-4259, 2009; In the Matter of Google, Inc., FTC Docket No., C-4336, 2011), collecting information from consumers without disclosing

entities against which Plaintiff has ever pursued a privacy policy violation in which the only instances in which the consumer information was shared was in a court pleading or in defense of customer credit card chargebacks. It is well-established that "an agency literally has no power to act . . . unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n v. F.C.C.*, 476 U.S. 355, 374 (1986). Moreover, "a fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required." *F.C.C. v. Fox Television Stations, Inc.*, 132 S. Ct. 2307, 2317 (2012).

The customer questionnaire cited by Plaintiff in its Motion stated, "[t]his information will be kept confidential and will NOT be shared," immediately after which Defendants placed a link to their privacy policy. Dkt. 141-10, PX6-829. Don Juravin testified that this was in place at some point in 2014. (DX6, 154:14-155:25.) Throughout 2014, Defendants' Terms and Conditions stated, "your information will not be shared or sold ***for as long as you do not breach the Terms and we will have to use the information provided.***" Dkt. No. 141-PX6-344 (emphasis added). The Terms and Conditions explicitly and repeatedly warned potential customers that there were no refunds and that Defendants may "institute legal or collection proceedings" for chargebacks and for violations of its non-disparagement clause or to protect its legal rights.. PX6-350-351, 353, 362, 367, 369, 370, and 383. Moreover, Defendants had a much more detailed

---

said information was being collected (see e.g., FTC v. Vizio, Inc. et al., Dist. NJ Case No. 17-cv-00758), publicly posting personal health information on the Internet without consent (In the Matter of Practice Fusion, Inc., FTC Docket No. C-4591, 2016), and publicly posting nude photos on the Internet without the subject's consent (In the Matter of Craig Brittain, C-4564, 2016).

privacy policy than Plaintiff would have the Court believe, including specific language regarding children's privacy, the use of cookies and pixel tags, on its website, and information that would be disclosed under certain circumstances. Dkt. No. 141, PX6-367-371.

Additionally, Plaintiff cannot show any harm came as a result of Defendants sharing information necessary to protect its legal rights. It does not even try to allege any harm was caused beyond the mere disclosure of the information in court documents and to credit card companies.

Based on the foregoing, Plaintiff has not met its burden to show there are no issues of material fact relating to Defendants' privacy policy and its alleged misrepresentation of same and its Motion for Summary Judgment with respect to Count VI should be DENIED.

VII. NON-DISPARAGEMENT CLAUSE (Count III)

Defendants filed a Motion for Partial Summary Judgment relating to Count III (Dkt. No. 143). Defendants will not rehash all their arguments contained in their motion in this Response, but do incorporate that motion herein.

A. Plaintiff has not shown Defendants violated 15 U.S.C. § 45(a) – unfair practices

Plaintiff argues Defendants engaged in "unfair practices" by having a non-disparagement clause in their agreement with customers and by enforcing that agreement when it was breached. In addition to Defendants' arguments stated in their

Motion for Partial Summary Judgment that they have not violated 15 U.S.C. § 45(a) because only the recently signed Consumer Review Fairness Act of 2016 actually applies to the non-disparagement clause in the contract, Plaintiff has not met its summary judgment burden as to the elements of an unfair practice.

Section 5(n), sets forth the test for "unfair" practices. In it, Congress explicitly provided the Commission "***shall have no authority***" to declare an act or practice "unfair" "unless the act or practice [1] causes or is likely to cause substantial injury to consumers[,] [2] which is not reasonably avoidable by consumers themselves[,] and [3] not outweighed by countervailing benefits to consumers or to competition." 15 U.S.C. § 45(n) (emphasis added). Plaintiff seeks to have the Court eviscerate several of these critical limits.

1. **Plaintiff provides no evidence of tangible consumer harm**

In regard to Section 5(n)'s first prong, there is no evidence that the non-disparagement clause, and the enforcement of same, caused any tangible consumer harm (meaning economic or physical injury). To address this evidentiary gap, Plaintiff argues that the *intangible* harm of unknown and unnamed potential consumers not being able to view all negative reviews, truthful or not, is "substantial injury" under Section 5(n). (Dkt. No. 141, pp.35-37). This is clearly not the type of injury contemplated by Section 5(n).

First, the FTC's interpretation of "substantial injury" contravenes the term's plain meaning. The plain meaning of "substantial injury," as used by Congress when it enacted

Section 5(n) in 1994, must be derived from the FTC's then-operative definition of "substantial injury" as set forth in the FTC's prior policy statements to Congress on this very question. See *United States v. Myers*, 972 F.2d 1566, 1572 (11th Cir. 1992) ("Congress is deemed to know the executive and judicial gloss given to certain language and thus adopts the existing interpretation unless it affirmatively acts to change the meaning."). And the FTC's pre-enactment policy statements are crystal clear that, as of the enactment of Section 5(n), the FTC defined "substantial injury" to require "tangible injury."

Specifically, the FTC's 1980 Policy Statement on Unfairness (the "Policy Statement"), Letter from FTC to Senators Ford and Danforth (Dec. 17, 1980), appended to *In re Int'l Harvester Co.,* 104 F.T.C. 949, 1984 WL 565290, at *95 (1984), expressly stated in its discussion of the meaning of the term "substantial injury" that "[e]motional impact and other more subjective types of harm . . . will not ordinarily make a practice unfair," Policy Statement, 1984 WL 565290, at *97, *104 n.16. Similarly, the FTC's 1982 policy letter clearly stated that, "as a general proposition substantial injury "does not cover subjective examples of harm." Letter from FTC Chairman J.C. Miller, III to Senators Packwood and Kasten (March 5, 1982) ("Policy Letter"), reprinted in H.R. Rep. No. 156, pt. 1, 98th Cong., 1st Sess. 27, 32 (1983) (hereinafter cited by reference to H.R. Rep. No. 156). Commissioner Olhausen testified in 2012, that in the Policy Statement, the Commission "specifically advised Congress that absent deception, it will not enforce Section 5 against alleged intangible harm." Stmt. of Commissioner Maureen K.

Ohlhausen to Senate Committee on Commerce, Science & Transportation, 2012 WL 1612706 (May 9, 2012).

Second, if the statute's plain meaning were not dispositive, the FTC's interpretation of "substantial injury" as including intangible injury is directly at odds with Section 5(n)'s legislative history, which states in no uncertain terms that intangible injuries are not cognizable as "substantial injury" under Section 5(n). See, e.g., S. Rep. 103-130, 1993 WL 322671, at *13 (1993) ("Emotional impact and more subjective types of harm alone are not intended to make an injury unfair."). Subsequent legislative enactments also make clear that "substantial injury" does not include intangible injury. See *F.T.C. v. Wyndham Worldwide Corp.*, 799 F.3d 236, 248 (3d Cir. 2015) (noting that the Gramm-Leach-Bliley Act, which the FTC enforces, "relieves some of the burdensome [Section 5(n)] requirements for declaring acts unfair" because it permits the FTC to establish standards protecting not only against "substantial harm," but also against "inconvenience" to consumers).

Even if intangible harm could be "substantial injury" under Section 5(n), moreover, there is no evidence that Defendants caused any such harm here. Plaintiff provides the Court with no basis upon which to find that any consumer or potential consumer actually suffered any such intangible harm as a result of the alleged chilling effect of the disparagement clause. (DX7 - 111:22-112:12.) In fact, there is ample evidence that the disparagement clause did not work, and as a result, there were, and still

are, negative reviews posted online by Defendants' customers.[28] Accordingly, even if intangible harm could qualify as substantial injury, which it cannot, Plaintiff's assertion that Defendants' non-disparagement clause caused substantial injury would still fail.

2. **Plaintiff Failed to Accurately Conduct the Cost-Benefit Analysis Required by Section 5(n)'s "Countervailing Benefits" Prong**

By barring the FTC from declaring a practice "unfair" where any substantial consumer injury caused or likely to be caused by the practice is "outweighed by countervailing benefits to consumers or to competition," Section 5(n)'s"countervailing benefits" prong "informs parties that the relevant inquiry [under that prong] is a cost-benefit analysis . . . that considers a number of relevant factors, including the probability and expected size of reasonably unavoidable harms to consumers given a certain level of cybersecurity and the costs to consumers that would arise from investment in stronger cybersecurity." *Wyndham,* 799 F.3d at 255. In applying this prong, the FTC must also "take into account costs related to a prospective remedy, including but not limited to direct costs to the parties." Policy Letter at 32; see Policy Statement, 1984 WL 565290, at *97.

In this case, Section 5(n) requires the Court to compare (1) the sum of (a) the costs to Defendants of false negative reviews and (b) the additional costs associated with Defendants' compliance with any order forbidding the disparagement clause going forward (collectively, the "Relevant Costs"), with (2) the magnitude of any substantial

[28] Hence, Plaintiff's argument that not seeing negative reviews of the Regimen is "not reasonably avoidable by consumers" also fails.

consumer injury caused or likely to be caused by the disparagement clause and the attempts to enforce same (the "Relevant Benefits"). Plaintiff has made no attempt to make this analysis nor provided the Court with the evidence it needs to make the analysis itself.

3. FTC Could Not Impose Its Novel Interpretations of Section 5n, on Defendants, who Lacked Fair Notice of Those Interpretations Under the Due Process Clause

Even if the FTC's interpretations of its Section 5 authority are otherwise sound, the Commission could not apply them to Defendants because between 2010 to September 2015—the only relevant time period in this case—Defendants did not have fair notice the FTC would adopt these interpretations in this case. "A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required." *F.C.C. v. Fox Television Stations, Inc.*, 132 S. Ct. 2307, 2317 (2012). The fair notice doctrine "prevents . . . deference from validating the application of a regulation that fails to give fair warning of the conduct it prohibits or requires." *Gates & Fox Co., Inc*. v. O.S.H.R.C., 790 F.2d 154, 156 (D.C. Cir. 1986).

Moreover, where a court defers to an agency interpretation of its governing statute or its own regulation, and based on that interpretation the agency proposes to hold a party liable, the Due Process Clause requires that the agency's interpretation must have been knowable with "ascertainable certainty" at the time the party committed the alleged violation. See *Ga. Pac. Corp. v. O.S.H.R.C.*, 25 F.3d 999, 1005–06 (11th Cir. 1994). This

means that, "by reviewing the regulations and other public statements issued by the agency, a regulated party acting in good faith would be able to identify, with 'ascertainable certainty,' the standards with which the agency expects parties to conform." *Howmet Corp. v. E.P.A.*, 614 F.3d 544, 553–54 (D.C. Cir. 2010).

Prior to the beginning of the Relevant Period in 2010 the FTC had never provided Defendants with any ability to know with "ascertainable certainty" of the FTC's interpretation that intangible and even purported conceptual consumer injuries can constitute "substantial injury." See *Ga. Pac.*, 25 F.3d at 1005–06; *Gen. Elec. Co. v. E.P.A.*, 53 F.3d 1324, 1330 (D.C. Cir. 1995); *PMD Produce Brokerage Corp. v. U.S.D.A.*, 234 F.3d 48, 54 (D.C. Cir. 2000). Indeed, as shown above, the FTC had consistently publicly stated the exact opposite.

DISGORGEMENT

You can't always get what you want
But if you try sometimes…
Well you just might find
You get what you need

Rolling Stones – "You Can't Always Get What You Want" – Let It Bleed Album (1969)

Plaintiff has failed to show that disgorgement is the proper remedy in this case

Plaintiff has stated within its pleadings that disgorgement is the correct remedy for the alleged violations of the FTC Act by the collective Defendants. Defendants argue that this is incorrect.

Defendants state Plaintiff has failed to provide this Court with even the most basic

of elements to support disgorgement. Plaintiff must provide the Court with at least some calculation for disgorgement to be proper. The 11th Circuit Court in *C.F.T.C. v Sidoti* stated, "There must be a "relationship between the amount of disgorgement and the amount of ill-gotten gain…" and "the disgorgement amount must be limited to the time frame for which the party seeking disgorgement presented evidence of the defendant's bad acts.", *C.F.T.C. v. Sidoti,* 178 F.3d 1132, 1138 (11th Cir. 1999). In addition, the Court's power is not unlimited. In *S.E.C. v. ETS Payphones, Inc.* the 11th Circuit Court stated that disgorgement can amount to a penalty if not applied correctly. "Therefore, a court's power to order disgorgement is not unlimited. It extends only to the amount the defendant profited from his wrongdoing…Any additional sum is impermissible as it would constitute a penalty." *S.E.C. v. ETS Payphones, Inc.,* 408 F.3d 727, 735 (11th Cir. 2005).

Defendants argue that a different standard should be applied, and has been in other FTC cases. The correct standard is damages and not disgorgement. See *Millsap v McDonnell Douglas Corp*., 368 F.3d 1246 (10th Cir. 2004), See also *Proudfoot Consulting Co. v. Gordon*, 576 F.3d 1223 (11th Cir. 2009)[29] This is not the only time this Circuit has limited the disgorgement requests of the FTC. *Id*.

Contrary to what Plaintiff would like the Court believe, Defendants have actually helped quite a few people and some of the people helped did pay full price for the Regimen. Defendants believe that the financial records will show that 1-5% of their

[29] The District Court in this case granted an injunction and damages instead of disgorgement.

customers have chosen to pay full price for the Regimen. In addition to this, Defendants can accurately show there have been over 300 success stories from actual users of the product. In Sharon King's deposition on p. 149-150 she stated the following[30]:

> Q: In your experience, how representative was a story like Sharon Hensley's about the magnitude of weight loss. Was that something that was unusually or something that you saw frequently?
>
> **A: No, I saw it frequently. I saw a lot of customers that had success. Sarah, Sarah Durso was one.**
>
> **I mean the thing is I would see a lot that had success at first, you know, were doing good. Same thing with Brian, I am going to bring him up because Brian came and wrote a letter -- a thank you letter saying that, you know, this is the best thing that has ever happened to him. You know, he didn't think he would ever lose the weight.**
>
> **I mean that's how I found them from losing weight. Same thing with Tarez (ph), you know, I found them from reordering, I – you know, they lost weight, so, I would recruit them that way. I didn't go about, you know, looking at You Tube, I didn't want to get them that way.**
>
> …
>
> Q: More than a hundred?
>
> **A: Yeah. I had one man that lost 200 pounds and went skydiving. I mean A lot of people are so private about their weight loss they don't want people to know. He showed me this video, said: Don't tell anybody. I don't want to be a coach. I don't want you to show my pictured to your boss or anything its just between me and you Sharon. You know, I didn't even tell Don. You know, it was just like I had the communication with him, so you know.**
>
> Q: Do you think it was more than like maybe a couple a month or thereabouts?

[30] DX5, pages 149-150

A: It was more than a couple a month. I would say, you know, maybe about 20 a month. I would say about 20 a month.

Based simply on the reorders alone, from the testimony of Sharon King, Defendants state that hundreds of customers reordered the Regimen because it worked for them. Comparatively, the FTC alleges that there have been "multiple" complaints against Defendants. Defendants have had the opportunity to review the alleged "multiple complaints" from the BBB. They have found that of the 33 BBB complaints, 2 were related to advertising. All the rest were related to the physical effect that the Formula had on the customer's body, shipping, or customer service.[31]

Defendants state that the request of Plaintiff for disgorgement is over and beyond what should be allowed in this action and hereby strenuously object. Even if the Court did simple math and multiplied the actual complaints in relation to this action by 10 times the actual harm, it would not even come close to what the FTC is requesting.[32]

Plaintiff is attempting to downplay the actual good that the Defendant has done for hundreds of people and punish them for the few disgruntled customers. (see PX# - Declarations of success stories). Defendants have stated that their intention was to help save people from an expensive surgery that was not guaranteed to work.[33] When

---

[31] https://www.bbb.org/west-florida/business-reviews/weight-control-services/roca-labs-nutraceutical-usa-in-sarasota-fl-90092885/reviews-and-complaints (May 8, 2017)

[32] Multiply 33 BBB complaints by cost of 3-4 month Regimen at full price of $1580 x 10 for possible damages = $521,400.

[33] https://asmbs.org/patients/bariatric-surgery-procedures#learnmore (May , 2017). See also "Cost of Bariatric Surgery: 2014 Surgeon Survey & Key Findings", J Quinlan, Bariatric Surgery Source, January 2015 and "Healthcare utilization and outcomes after bariatric surgery", Encinosa WE, Bernard DM, Chen CC, Steiner CA Medical care (2006). Approximately 50% of people who undergo bariatric surgery regain the weight in 5 years.

questioned in deposition regarding the amount of effect Defendants have had in people's lives, they stated the following[34]:

> Q: No wait. Can you tell me what Exhibit 144 consists of?
> **A: Sample of inspiring posts or comments from gastric -- from the group website. From the Facebook group.**
> Q: Is that the Facebook group that Facebook.com/groups/Lost100?
> **A: Yes.**
> Q: You said you started Roca Labs essentially to help people, correct?
> **A: I started because I want to make a difference in people's live, yeah.**
> Q: Do you feel like you have made a difference in people's lives?
> **A: Anybody that reads it, big time.**

Defendants have also attempted to comply with the laws as they understood them. Each time a state changed either their state law, or case law regarding the non-disparagement clause, the Defendants changed their website to reflect this new information.

Defendants have also attempted to comply with the law regarding the advertising each time they were informed. However, in this case the FTC has put the cart before the horse and failed to provide any warning letter or submission of any kind to Defendants. If the FTC had provided a warning letter, as contemplated and now enforced through new laws, the website would have changed and we would not be here today.[35] Instead the FTC

[34] DX2, 606:25-607:13

[35] Consumer Review Fairness Act of 2016 requires that the FTC sends a warning letter to any companies who are not in compliance and has given a full year for compliance to take effect. The FTC is not able to prosecute any companies until 2018.

chose to make an example of Defendants' small company to look good in front of Congress in order to get a new law on the books.[36]

It is clear that Defendant have been drawn into a Federal Agency dispute and is simply trying to avoid being smashed under the wheels of government bureaucracy. Disgorgement is not the correct remedy for a company who simply got caught in the middle of a Federal Agency tug-of-war involving a new and rapidly changing industry. Defendants respectfully request that this Court applies the correct standard in its decisions involving this case.

XIII. CONCLUSION

Defendants respectfully request this Court to DENY Plaintiffs' Motion for Summary Judgment and grant Defendants Motion for Partial Summary Judgment as to Count Three of the Amended Complaint. Further, Defendants request that this Court award Defendants' attorney fees and costs for their defense of Plaintiff's Complaint, as well as provide any further relief the Court deems necessary.

/s/ Glenn A. Reid
GLENN A. REID
Attorney for the Defendants
Florida Bar # 0629898
Post Office Box 950554
Lake Mary, Florida 32795
(386) 235-1920
glenn@thereidlawoffice.com
attorneygreid@gmail.com

[36] Consumer Review Fairness Act of 2016, H.R. 5111 – House Committee Notes (May 24, 2016. Testimony of Commissioner Edith Martinez before the 114th House of Representatives Subcommittee on Commerce, Manufacturing, and Trade).

CERTIFICATE OF SERVICE

The undersigned counsel certifies that on May 8, 2017, the foregoing was electronically filed with the clerk of Court using the CM/ECF system, which will automatically send e-mail notification of such filing to the attorneys of record:

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

/s/ Glenn A. Reid
GLENN A. REID