

DECLARATION OF DR. THOMAS PARISI
IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION
FOR ENTRY OF A TEMPORARY INJUNCTION

I, DR. THOMAS PARISI, being over 18 years of age and competent to testify about the matters contained in this declaration, hereby state as follows:

PROFESSIONAL BACKGROUND

1. I am a board-certified physician with a practice focused upon internal medicine.
2. I received my Bachelors of Science degree from Widener University in 1996 and my Masters of Science degree in Microbiology from Thomas Jefferson University in 1998.
3. I graduated from University of St. Eustatius School of Medicine in 2001.
4. I attended medical school at St. Christopher's College of Medicine in Cambridge, England and graduated in 2002 with a Doctorate in Medicine.
5. I completed my residency at the University of Nevada, Reno in 2005.
6. I currently practice medicine with Las Vegas Vein and have done so since its inception in 2007. I am additionally a practicing physician at the Desert Springs Hospital Wound Care Center and am affiliated with St. Rose Dominican Hospital, Sunrise Hospital, Spring Valley Hospital, and Summerlin Hospital, all in Clark County, Nevada. I am an adjunct professor at Touro University Henderson, the University of Nevada, Las Vegas, and the College of Southern Nevada.

ASSIGNED TASK AND MATERIALS REVIEWED

7. Counsel for Defendant Opinion Corp. ("Opinion") in the matter entitled *Roca Labs, Inc. v. Consumer Opinion Corp., et al.*, Case No. 8:14-cv-2096-T-33EAJ, has requested that I examine and opine upon a diet product manufactured and marketed by

Plaintiff Roca Labs, Inc. (“Roca”) that Roca promotes as an alternative to gastric bypass surgery. To complete this task, I examined the following:

- a. Roca’s website, located on the World Wide Web at <rocalabs.com>;
- b. YouTube videos purportedly published by Roca: (1) *Weight Reduction for Diabetes by Roca Labs*,¹ (2) *Dr. Ross about Gastric Bypass NO surgery side effects/complications*,² (3) *What is Gastric Bypass NO Surgery by Roca Labs?*,³ (4) *How to Create a Gastric Bypass Effect with Roca Labs*,⁴ (5) *Active Ingredients in the Roca Labs NO Surgery Gastric Bypass Formula*,⁵
- c. Robert B. Saper et al., *Common Dietary Supplements of Weightloss*, American Family Physician, Vol. 70, Iss. 9, 1731-38 (2004);
- d. Karl H. Rahn et al., *How to Assess Glomerular Function and Damage in Humans*, Journal of Hypertension, Vol. 17, Iss. 3, 309-17 (1999);
- e. Robert L. Davidson, *Handbook of Water-Soluble Gums and Resins* (1980);
- f. National Institute of Health, Office of Dietary Supplements, *Dietary Supplement Fact Sheet: Vitamin B12*, available at: <ods.od.nih.gov/factsheets>;
- g. Hsiao-Ling Chen et al., *Supplementation of Konjac Glucomannan into a Low-Fiber Chinese Diet Promoted Bowel Movement and Improved Colonic Ecology in Constipated Adults: a Placebo-Controlled, Diet-Controlled Trial*,

¹ <youtube.com/watch?v=F7HQx2oZxY8&list=UU17sVLkpP6ivf1P8BIyPW_g>.

² <youtube.com/watch?v=sfZpZ-0zTus&list=UU17sVLkpP6ivf1P8BIyPW_g>.

³ < youtube.com/watch?v=gJ9UeimqSqs&list=UU17sVLkpP6ivf1P8BIyPW_g>.

⁴ <youtube.com/watch?v=h6uKkIRyYWk&list=UU17sVLkpP6ivf1P8BIyPW_g>.

⁵ <youtube.com/watch?v=0wNYozD1XEM>

Journal of the American College of Nutrition, Vol. 27, Iss. 1, 102
(2008);

- h. Customer complains regarding Roca's weight loss product that were provided to me by Opinion's counsel, and which are attached to this declaration as Exhibits B, C, D, E, F, G, H, and I.

ROCA'S PRODUCT

8. Roca sells an unnamed diet product on its website that it claims is an alternative to gastric bypass surgery and claims the "components are Guar Gum, Konjac, Inulin, Beta Glucan, Xanthan Gum, Maltodextrin, Vitamins B-6, B-12, C," and natural and artificial flavors (the "Product").⁶ Roca additionally claims that its Product contains "fibers [that] are activated by large amounts of water and occupy most of the stomach, leaving only 20% available for food intake."⁷

9. Roca is claiming that its dietary supplement, which consists primarily of industrial food thickening agents, expands and increases the viscosity of water. In other words, it operates under the principal that ingesting Roca's product will expand cause it to expand in the user's stomach, leaving her with no room or desire for anything else, thus prompting weight loss which renders gastric bypass surgery unnecessary.

10. To a layperson, Roca's weight-loss claims likely make logical sense, given that the Product fills the stomach up to 80% capacity with high-fiber, indigestible materials.

11. However, based upon my review of the Product and its ingredients, it could lead to health problems in some individuals, including gastrointestinal distress.

12. Moreover, based upon the ingredients contained in the Product, it could also cause additional unintended side effects in a large number of users, including diarrhea,

⁶ <youtube.com/watch?v=0wNYozD1XEM>

⁷ *Id.*

bloating, intestinal discomfort, gas, constipation, intestinal blockage, dehydration, headaches, and dizziness.⁸

13. Certain individuals are pre-disposed to being higher risk for complications and suffering negative side effects of use of the Roca product such as those suffering from autoimmune disorders, pregnant women, the elderly, etc. These individuals have a heightened need to be aware of any possible health risks.

14. Based upon my review and research of the ingredients contained in Roca's Product, most of its ingredients are useless for the promotion or maintenance of weight loss:

- a. **Guar Gum:** While it cannot be absorbed by the digestive tract, guar gum is ineffective for weight loss, and physicians should discourage its use as a weight loss aid. *See* RB Saper et al., *Common Dietary Supplements of Weightloss*, 70 *Am Fam Physician* 1731 (2004).
- b. **Inulin:** Inulin is typically used to diagnose kidney function. While it passes freely through the kidneys and is not absorbed by the body. However, there is no clinical data on the use of inulin to promote weight loss. I believe that it would be ineffective for that purpose. *See* KH Rahn et al., *How to Assess Glomerular Function and Damage in Humans*, 17 *J Hypertens* 309 (1999)
- c. **Beta Glucan:** Beta glucan, which is essentially seed husks or barley, may cause small reductions in LDL (or "bad") cholesterol when taken orally, but the sum of existing positive evidence is suggestive and not definitive. Moreover, short-term use of beta glucans does

⁸ <[youtube.com/watch?v=sfZpZ-0zTus&list=UUl7sVLkpP6ivf1P8BIyPW_g](https://www.youtube.com/watch?v=sfZpZ-0zTus&list=UUl7sVLkpP6ivf1P8BIyPW_g)>.

not appear to promote weight loss. *See* Robert L. Davidson, *Handbook of Water-Soluble Gums and Resins* (1980).

- d. **Xanthan Gum:** Xanthan gum is most commonly used as a food additive, particularly as a thickening agent (in salad dressings, for example), or as a stabilizer in other products to keep ingredients from separating (in cosmetic products, for example). There is no available evidence or clinical data indicating that it is effective in aiding weight-loss. *See* Robert L. Davidson, *Handbook of Water-Soluble Gums and Resins* (1980).
- e. **Vitamins B-6, B-12, and C:** There is no solid evidence that Vitamins B-6, B-12, or C promote or aid weight loss. *See* National Institute of Health, Office of Dietary Supplements, *Dietary Supplement Fact Sheet: Vitamin B12*, <ods.od.nih.gov/factsheets/>.
- f. **Konjac:** Konjac is essentially a Chinese laxative. Thus, it does increase bowel movements in constipated adults, which can cause weight loss. However, no competent medical physician would recommend regular use of it (or any laxative) as a treatment plan for weight loss. *See* HL Chen et al., *Supplementation of Konjac Glucomannan into a Low-Fiber Chinese Diet Promoted Bowel Movement and Improved Colonic Ecology in Constipated Adults: a Placebo-Controlled, Diet-Controlled Trial*, 27 J Am Coll Nutr 102 (2008).
- g. **Maltodextrin:** Maltodextrin is often used in commercially available protein shakes and similar products. However, because it contains

high-glycemic carbohydrates, intake of maltodextrin would typically be avoided in individuals trying to achieve weight loss.

- h. **Natural and Artificial Flavors:** Roca provides no indication of what these are and whether or how they would promote weight loss.

ROCA'S "GAG CLAUSE" REGARDING THE PRODUCT

15. Roca's Product is promoted on its website as a "nutraceutical." Most nutraceuticals, including Roca's Product, have not been approved by the Food and Drug Administration (the "FDA") and are not regulated in any significant way.

16. As such, many potential consumers will rely upon feedback from prior users of the Product to determine whether the Product will be effective or will cause adverse side effects.

17. In the absence of clinical trials, there is no way for potential users of a product to measure the efficacy or safety of that product without feedback from prior users. While consumer reviews are non-scientific (and potentially biased), they still create a record of trends that can provide at least some degree of predictability to a potential user.

18. Without feedback from prior users, potential users may have access to no information about the Product with the exception of promotional materials from Roca itself.

19. Lack of information from prior users of the Product places potential users at greater risk of harm, as they will not be capable of evaluating the risks involved in using the Product.

20. The terms and conditions contained on Roca's website contain a provision whereby Roca will give purchasers of the Product a large discount if they agree that they will never criticize Roca or its Product in any way.

21. I believe that this provision prevents potential users of the Product from obtaining information from prior users regarding the potential side effects and adverse effects of the Product.

22. It is unethical for a health care professional to take steps to hide the side effects of any medication or treatment from a patient.

USER COMPLAINTS ABOUT THE PRODUCT

23. Counsel for Opinion provided me with 8 sample customer complaints regarding the Product. I have observations on several.

24. With regard to the medical issues the customer complaints describe, there is a chance that they are true, particularly given that there is no data to suggest otherwise. While most of the ingredients of the Product are merely useless, konjac could certainly cause gastrointestinal distress, including bowel obstruction and ulcers, and excess vitamin intake (particularly of vitamin C) is also known to cause ulcer formation.


25. In the Third Customer Complaint,⁹ the user notes that, when ordering the Product, Roca forces the user to check a box stating that Roca will not be held liable for any adverse effects caused by the Product. It is both unethical and immoral for Roca to attempt to absolve itself from liability for harm it may cause to users of the Product.

26. In the Sixth Customer Complaint,¹⁰ the user attaches an email from Roca stating that the Product “always work[s]. ALWAYS.” This does not conform to a medical standard of practice, and it is irresponsible, at best, for Roca to make such statements.

⁹ Exhibit D

¹⁰ Exhibit G

I declare under penalty of perjury that the foregoing is true and correct.

DocuSigned by:

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Thomas Parisi, M.D.

Executed on September ^{9/18/2014}____, 2014 in Las Vegas, Nevada.