

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE**

FEDERAL TRADE COMMISSION, and
STATE OF MAINE,

Plaintiffs,

v.

HEALTH RESEARCH LABORATORIES, LLC, a
limited liability company, and

KRAMER DUHON, individually and as an owner
and officer of HEALTH RESEARCH
LABORATORIES, LLC,

Defendants.

Case No. 2:17-cv-00467-JDL

**PLAINTIFFS' MOTION FOR AN ORDER TO SHOW CAUSE WHY HEALTH
RESEARCH LABORATORIES, LLC, WHOLE BODY SUPPLEMENTS, LLC,
AND KRAMER DUHON SHOULD NOT BE HELD IN CONTEMPT FOR
VIOLATING THE FINAL JUDGMENT AND ORDER FOR PERMANENT
INJUNCTION**

I. INTRODUCTION

Brazenly ignoring the Court's order barring them from making unsubstantiated claims for their dietary supplements, Defendants Health Research Laboratories, LLC ("HRL") and Kramer Duhon have continued promoting their products with outrageous claims that they effectively cure, mitigate, or treat life-threatening diseases. Defendants violated Section II.H of the Order, which unambiguously requires them to have at least one randomized, double-blind, placebo-controlled trial ("RCT") testing the same product or an essentially equivalent product prior to making any claim that their dietary

supplements cure, mitigate, or treat a disease. As explained in detail below, Defendants and Whole Body Supplements, LLC (“WBS”) (collectively, “Contempt Defendants”) disregarded the Order by making baseless claims that their Neupathic, Black Garlic Botanicals, BG18, and The Ultimate Heart Formula (“UHF”) products treat, cure or mitigate several diseases without having anything close to the required substantiation.

As a result, Plaintiffs Federal Trade Commission (“FTC” or “Commission”) and the State of Maine move the Court for an order to show cause why Contempt Defendants should not be held in contempt of the Court’s January 16, 2018 Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief (“Order”) (Dkt. 15, PX 1). Plaintiffs seek a finding of civil contempt and sanctions in the form of compensatory monetary relief for consumers harmed by the contumacious conduct. Plaintiffs have concurrently filed a Motion to Modify the Order pursuant to Fed. R. Civ. P. 60(b).

II. STATEMENT OF FACTS

A. Underlying Action and Order

The original Complaint in this case alleged HRL and its owner, Kramer Duhon, made deceptive health and disease-related claims for two products, BioTherapex and NeuroPlus. Among other things, HRL represented that BioTherapex caused weight loss, treated rheumatism, arthritis, and osteoarthritis, and relieved joint pain, back pain, and muscle pain. HRL also represented that NeuroPlus protected the brain against Alzheimer’s disease and dementia, reversed memory loss, and improved memory, concentration, and cognitive performance.

On January 16, 2018, this Court entered the Order prohibiting HRL and Mr. Duhon from representing that a product “cures, mitigates, or treats any disease ... unless the representation is non-misleading, and at the time of making such representation, they possess and rely upon competent and reliable scientific evidence substantiating that the representation is true.” PX 1, § II.¹ Section II further provides that “competent and reliable scientific evidence” must consist of human clinical testing of the product or an “Essentially Equivalent Product.” The Definitions section of the Order clearly states that to qualify as an Essentially Equivalent Product, the product tested in trials must be one that “contains the identical ingredients, except for inactive ingredients ... in the same form and dosage, and with the same route of administration (*e.g.*, orally, sublingually) ... as the Covered Product[.]” *Id.* at 5. Section II also requires the clinical testing to be: (1) randomized, double-blind, and placebo-controlled; as well as (2) conducted by researchers qualified by training and experience to conduct such testing.

Despite these unambiguous court mandates, to which HRL and Mr. Duhon agreed, Contempt Defendants represented their UHF, BG18, and Black Garlic Botanicals products cure, treat, or mitigate cardiovascular disease, atherosclerosis, and hypertension without having substantiation in the form of a RCT testing these products or Essentially Equivalent Products. Their ads also claim that Neupathic cures, treats, or mitigates diabetic neuropathy and treats or mitigates diabetes without the required substantiation. Given the potentially life-threatening consequences of the diseases Contempt Defendants claim their products remedy, the contumacious conduct is especially egregious.

¹ The evidentiary documents referred to herein are attached as Plaintiffs’ Consolidated Exhibits in Support of Motion for Order to Show Cause and Motion to Modify. They are identified by Exhibit Number “PX ____.”

B. Parties to the Current Action: Contempt Defendants

HRL is a limited liability corporation that has sold more than three dozen nutritional products and dietary supplements on its website and via direct mail to consumers since entry of the Order, including Black Garlic Botanicals, UHF, and Neupathic. PX 2, Lewis Decl., Att. B, C. Kramer Duhon is the sole owner of HRL and serves as its Chief Operating Officer. Lewis Decl., Att. B.

WBS is a limited liability corporation. Lewis Decl., Att. B, N. Although WBS was not a party in the underlying action, Mr. Duhon is its sole owner and serves as the company's Chief Operating Officer and Managing Member. *Id.* WBS markets and sells a number of dietary supplements including a product at issue in this case known as BG18. Lewis Decl., Att. C. WBS and HRL operate from the same business address in Dallas, Texas. Lewis Decl., Att. B.

C. Black Garlic Botanicals and BG18

Black Garlic Botanicals and BG18 have identical ingredients: aged black garlic powder ("black garlic"), gelatin, rice flour, vegetable stearate, and silica. PX 2, Lewis Decl., Att. G (HRL004915-4916). Each capsule contains 600 mg of the active ingredient black garlic, and Contempt Defendants recommend consumers take two capsules per day. *Id.*

Black garlic is fermented garlic prepared by treating garlic cloves at high temperature and high humidity for 30 or more days. PX 3, Sacks Report, p. 7.² This process causes

² The BG18 mailer emphasizes that black garlic is different from other types of garlic and is "fermented for a precise period of time at a high temperature, and under high humidity. This process turns garlic cloves dark, gives them a sweet taste, and alters their consistency. And it also makes them more potent and

the garlic cloves to turn purple or black and eliminates the pungent smell and taste of fresh garlic. *Id.* The process greatly alters the chemical composition of fresh garlic, making black garlic substantially different chemically from fresh garlic, aged garlic extract,³ or other garlic preparations. PX 3, Sacks Report, p. 6-8.⁴

Contempt defendants advertised their BG18 and Black Garlic Botanical products using multi-page mailers sent to consumers⁵ throughout the United States. The mailers contained a variety of claims about the dangers of cardiovascular disease⁶ and represented the products cure, mitigate, or treat cardiovascular disease as well as the diseases of hypertension and atherosclerosis. These advertised claims highlight the supposedly positive effects of black garlic on artery health, cholesterol levels, and blood pressure including:

Black Garlic Botanicals Mailer⁷

beneficial.” PX 6, Prunty Decl., Att. 1 (FTC0003); *see also* PX 2, Lewis Decl., Att. H (HRL004989) (Black Garlic Botanicals mailer containing similar statements).

³ Aged garlic extract is prepared by slicing fresh raw garlic cloves and incubating them in ethyl alcohol for up to 20 months at ambient temperature. PX 3, Sacks Report, p.8.

⁴ Indeed, Contempt Defendants’ ads repeatedly emphasize the unique properties of black garlic. For example, the BG18 mailer states: “[W]hen normal white garlic is fermented it undergoes an amazing transformation that COMPLETELY alters the chemical makeup ... and turns it into a supreme superfood!” PX 6, Prunty Decl., Att. 1 (FTC0003) (original emphasis and capitalization).

⁵ *See* PX 2, Lewis Decl, Att. F, ¶5. In addition, HRL sold Black Garlic Botanicals through its website: <https://www.hrlsupplements.com>, and WBS sold BG18 through its website: <https://www.wholebodysupplement.com>. *See* Lewis Decl., Att. B; PX 5, Rottner Decl., Att. B, D.

⁶ For example, the Black Garlic Botanicals mailer’s front page features a large photograph of a distressed, older man clasping his chest below large banner headlines stating that: “Every 90 seconds, someone dies from heart disease in the U.S. – are you next?” and “1 in 7 people die from heart disease.” PX 2, Lewis Decl., Att. H (HRL004984).

⁷ PX 2, Lewis Decl., Att. H.

- **Healthy Arteries**
Plaque build-up in arteries can lead to unhealthy heart conditions. Black Garlic helps keep blood vessels barrier-free to create smooth flow, which could address symptoms of fatigue. It may also inhibit calcium binding, which is responsible for arterial plaque formation. (HRL004990).
- **Want Healthy Blood Pressure & Cholesterol? Black Garlic helps maintain healthy blood pressure, cholesterol and triglyceride levels. (HRL004990).**
- **BLACK GARLIC**
A BREAKTHROUGH FOR:
 - Cholesterol
 - Blood Sugar
 - Blood Pressure
 - The Heart
 - The Brain (HRL004990).
- “I made the switch to Black Garlic Botanicals and within the span of 3 months my LDL levels have reduced from 300 to 150. This product works!” ~ Gerald W. (HRL004993).⁸
- “I now have my blood pressure under control with Black Garlic Botanicals. This is a quality product!” ~ Rolf M. (HRL004995).
- If you’re serious about protecting your heart and arteries with a natural solution, it’s important to act now, because there really is no time to waste. (HRL004995).

BG18 Mailer⁹

- Black Garlic is a proven miracle for . . . Cholesterol . . . Hypertension . . . Your Heart (FTC0002).
- [Black Garlic] can help reverse plaque build-up in arteries – not just slow it down. (FTC0004).

⁸ HRL uses individual consumer testimonials to make some of the strongest disease claims in the Black Garlic Botanicals mailer. HRL’s inclusion of the statements “[r]esults may vary depending on your body type” (PX 2, Lewis Decl., Att. H (HRL004993)) and “[t]he products offered in this publication are not intended to cure or diagnose health problems,” (HRL004995) are inconspicuous in comparison to the amount of content touting the purportedly beneficial effects of the product. They do not effectively counteract the impression that consumers can expect results similar to those featured in testimonials.

⁹ PX 6, Prunty Decl., Att. 1.

- Black Garlic helps reduce high blood pressure and lowers high levels of bad cholesterol and triglycerides. (FTC0004).
- Yes, Black Garlic is a true miracle for cardiovascular health! Just 1 capsule knocks down cholesterol and high blood pressure within days. It can also unblock, clean, and strengthen your arteries. (FTC0008).

By describing the danger of cardiovascular disease and touting barrier-free blood vessels, dramatic reductions in LDL-cholesterol, and blood pressure control, the ads represent Black Garlic Botanicals and BG18 will cure, mitigate, or treat cardiovascular disease as well as the distinct diseases of atherosclerosis and hypertension.¹⁰

D. Contempt Defendants Lack Required Substantiation for Their Black Garlic Claims.

In response to FTC requests for substantiation to support the claims in their BG18 and Black Garlic Botanicals mailers, Contempt Defendants provided various articles and materials related to black garlic and other forms of garlic. Dr. Frank Sacks, a Professor of Medicine at Harvard Medical School and a Professor of Cardiovascular Disease Prevention at the Harvard T.H. Chan School of Public Health, reviewed all of this purported substantiation. He found it does not come close to supporting claims that the product cures, mitigates, or treats cardiovascular disease, atherosclerosis, or hypertension. PX 3, Sacks Report, p. 2-3, 6-10. He also performed literature searches in an effort to identify any RCT that tested black garlic and measured endpoints related to

¹⁰ Cardiovascular disease generally refers to heart attack, angina pectoris (chest pain due to heart disease), heart failure, and stroke. PX 3, Sacks Report, p. 5. Cardiovascular disease also includes disease afflicting the large arteries that supply blood to the heart and brain. *Id.* Hypertension and atherosclerosis are also well-recognized diseases. Hypertension is commonly referred to as high blood pressure, and the disease damages blood vessels and the heart. *Id.* Atherosclerosis occurs when blood flow through arteries is reduced by blockages caused by cholesterol deposits from high levels of low-density lipoproteins (“LDL”) and the resulting inflammatory and thrombotic reactions in vessel walls. *Id.* High blood pressure and high LDL-cholesterol concentration in blood are two of the most important causes of atherosclerosis, heart attack, and stroke. *Id.*

cardiovascular disease, hypertension, or atherosclerosis. *Id.* at 9. Dr. Sacks only found two such trials, both involved significantly higher doses of black garlic than the daily dose in BG18/Black Garlic Botanicals. PX 3, Sacks Report, p. 9-10. Further, the results of one trial actually showed that black garlic had no effect on endpoints related to cardiovascular disease, while the positive results in the other trial have not been independently replicated. *Id.*

Finally, most of the clinical trials relied upon by Contempt Defendants tested a different ingredient, aged garlic extract. *Id.* at 8-9. Aged garlic extract is not only not identical to black garlic, but actually has distinct chemical components. *Id.* at 6-9.

Following a thorough review of the relevant scientific literature and based on his professional experience, Dr. Sacks confirms that there is no competent and reliable scientific evidence suggesting that black garlic effectively cures, mitigates, or treats cardiovascular disease, hypertension, or atherosclerosis, and there is no reason to believe that the small dose in Black Garlic Botanicals/BG18 would be effective if tested in a properly randomized, double-blind, and placebo-controlled trial. *Id.* at 2-3, 10.

E. The Ultimate Heart Formula

HRL and Mr. Duhon also promoted a second product as a “revolutionary NEW and NATURAL treatment”¹¹ for cardiovascular disease, as well as the diseases of atherosclerosis and hypertension. Specifically, after entry of the Order, they advertised and sold UHF, a dietary supplement containing Vitamins C, E, and B12 as well as garlic extract (25 mg); Tetrasodium EDTA (40 mg), Ubiquinol (CoEnzyme Q-10 or “CoQ10”)

¹¹ PX 2, Lewis Decl., Att. I (HRL005069).

(5 mg), and Nattokinase (10 mg).¹² As with Black Garlic Botanicals, HRL advertised UHF by sending consumers lengthy mailers and additionally marketed their product to consumers on its website.¹³

The UHF mailer contains a variety of claims that the product cures, mitigates, or treats cardiovascular disease, atherosclerosis, and hypertension by touting the product's supposedly beneficial effect on arteries, cholesterol, and blood pressure, as well as symptoms of cardiovascular disease such as chest pain and heart rhythm problems. PX 2, Lewis Decl., Att. I. As with the BG18/Black Garlic Botanicals ads, the UHF mailer devotes substantial content to the life-threatening consequences of cardiovascular disease. For example, the front page features a large photograph of an older woman grasping her chest beside illustrations of increasingly occluded arteries, while the second page features a photograph of an older man doubled over and holding his chest. *Id.* at HRL005068-5069. These dramatic pictures are followed by a torrent of claims, including:

- SEE INSIDE to discover a natural nutrient that is up to 95% EFFECTIVE at maintaining clear arteries and reducing risk of a heart problem! (HRL005068).
- Instead, right before you is a simple, safe, inexpensive, non-painful and preventative option that could help you say goodbye to your heart surgeon and avoid an angioplasty. (HRL005070).
- The Ultimate Heart Formula is an all-natural combination of 19 powerful herbs and essential nutrients that counter the causes of poor cardio health. The Ultimate Heart Formula's unique "Senior Formula" is made with ingredients specifically shown to help improve the effects of a weakened heart, clogged arteries, high blood pressure and high cholesterol for older people! (HRL005077).

¹² It also contains: Aloe Barbadensis Leaf (Aloe Vera Gel), Vaccinium Myrtillus (Bilberry) Extract, Cayenne (Capsicum Frutescens) Extract, Zingiber Officinale (Ginger) Extract, Macrocystis Pyrifera (Kelp) Extract, Viscum Album (Mistletoe) Extract, Allium Sepa (Onion) Bulb Extract, Mentha Piperita (Peppermint) Oil, and Bromelain. *See* PX 2, Lewis Decl., Att. K.

¹³ *See* PX 5, Rottner Decl., Att. C.

- In another CoQ10 study, reported in the medical journal, Clinical Investigator, 100% of patients with serious heart problems experienced an improvement in their symptoms. And 80% experienced beneficial blood pressure levels. (HRL005073).
- In even MORE studies, heart patients taking CoQ10 were found to have less than one-third as much chest pain and 75% fewer heart rhythm problems than those not taking CoQ10. (HRL005075).
- The Ultimate Heart Formula also contains a powerful, clot-busting agent! The Ultimate Heart Formula gives you the power of a Japanese soy plant called Natto, with a 1,000-year-old medicinal history! And recent scientific studies have shown it has the uncanny ability to liquefy blood-clots and help prevent them from occurring at all! (HRL005073).
- EDTA is up to 95% effective at maintaining clear arteries and helping to reduce the risk of a heart problem! It's true, Ethylene Diamine Tetraacetic Acid – or EDTA has shown to be 95% effective in helping maintain arteries in over 1,823 scientific studies. EDTA is a natural amino acid that eliminates dangerous blockages from your veins and arteries – blockages that prevent blood and oxygen from reaching your heart and brain – helping to reduce your risk of a heart attack. (HRL005075, HRL005077).
- With our Ultimate Heart Formula ...You get it ALL ... Amazing heart and artery protection ... without side effects! (HRL005079).
- Yes, with the Ultimate Heart Formula, a lifetime of plaque build up could disappear before you know it! (HRL005079).

High blood pressure, high levels of LDL-cholesterol in blood, and the related accumulation of deposits of cholesterol and inflammatory responses in blood vessel walls, cause heart attack, stroke, and atherosclerosis. PX 3, Sacks Report, p. 5. By claiming UHF reduces blockages and plaque deposits in blood vessels as well as high blood pressure, particularly in close proximity to content about the dire consequences of disease, Defendants represent that their product can cure, mitigate, or treat cardiovascular disease and atherosclerosis. A product that lowers blood pressure, of course, also cures

or treats the disease of hypertension. Defendants drive home these claims by juxtaposing them with pictures of elderly individuals having heart attacks.

F. HRL and Mr. Duhon Lack Required Substantiation for UHF Claims.

Unsurprisingly, HRL's extraordinary claims for UHF are unsupported by an RCT testing either UHF or an Essentially Equivalent Product.¹⁴ HRL instead relies on various articles and materials related to a few of UHF's individual ingredients (including CoQ10, EDTA, nattokinase, and garlic). Again, Dr. Sacks reviewed all of HRL's purported substantiation. He also conducted a thorough literature search to identify any RCTs testing the same doses of CoQ10, EDTA, nattokinase, and garlic extract found in UHF. PX 3, Sacks Report, p. 11, 15-17. Based on this review, Dr. Sacks confirmed: (1) there are no RCTs testing UHF or the same combination of active ingredients in UHF; and (2) there are no RCTs testing the same doses of CoQ10, EDTA, nattokinase, or garlic extract found in UHF to support claims that these individual ingredients would cure, treat, or mitigate cardiovascular disease, atherosclerosis, or hypertension. *Id.* at 10-20. Furthermore, Dr. Sacks confirms that there is no reason to believe that any of the individual ingredients in UHF would be effective in curing, mitigating, or treating cardiovascular disease, atherosclerosis, or hypertension. *Id.* at 21.

G. Neupathic

After entry of the Order, HRL also sold Neupathic, a dietary supplement advertised as curing, mitigating, or treating the disease of diabetic neuropathy and

¹⁴ Testing the product or the same combination of ingredients is important in determining the efficacy of a product because, even in cases where individual constituent ingredients have been shown in other formulations to be efficacious or safe for the treatment of a particular condition, those same ingredients may not have the same properties or effects when combined with other ingredients. PX 4, Burant Report, p. 11; *see also* PX 3, Sacks Report, p. 11.

mitigating or treating diabetes. Diabetic neuropathy is nerve damage associated with persistent elevations of blood glucose in both type 1 and type 2 diabetes. PX 4, Burant Report, p. 7. Individuals with diabetic neuropathy experience symptoms such as tingling, pricking, chilling, burning, or numb sensation on the skin. *Id.* at 8. Some individuals experience debilitating burning and sharp pain. *Id.*

HRL made a variety of claims extolling the magical powers of Neupathic.¹⁵ By representing that Neupathic soothes and otherwise addresses various types of pain related to diabetic neuropathy or diabetes as outlined below, HRL claimed Neupathic cures, mitigates, or treats the disease of diabetic neuropathy and mitigates or treats diabetes.

For example, HRL's mailer (PX 2, Lewis Decl., Att. J) claims:

- This "Perfect" Nerve Pain easing pill combines special nutrients to restore circulation and soothe nerve pain associated with diabetes! (HRL005036).
- Studies show that there IS a natural, effective treatment for diabetic nerve pain! (HRL005036).
- If you have diabetic nerve pain, you could suffer with any or all of the symptoms below.
 - ✓ Shooting pain
 - ✓ Burning
 - ✓ Pins and needles
 - ✓ Electric shock-like pain
 - ✓ Extra sensitivity
 - ✓ Numbness
 - ✓ Throbbing
 - ✓ Tingling
 - ✓ Stinging
 - ✓ Stabbing
 - ✓ Radiating

¹⁵ Neupathic contains six purportedly active ingredients: Vitamin E, Vitamin B1 (thiamine), Vitamin B6, folic acid, Vitamin B12, and Evening Primrose Oil. See PX 2, Lewis Decl., Att. G (HRL004913).

Neupathic was specifically formulated with 6 distinct nutrients to help address ALL these issues and more. (HRL005039).

- A “perfect” nerve pain supplement that was formulated from the ground up to improve your circulation and ease the numbness, tingling, itching, burning and swelling from excess fluid trapped in your legs. (HRL005039).
- Respond now if your nerve pain is driving you crazy! You’ll get completely natural, real relief from your discomfort. All natural Neupathic is 100% effective and safe to use every day! Remember, it has (*sic*) shown to help reverse damaged nerves to help you feel great all day and all night. (HRL005048).
- “Great reduction of pain. No more nerve pain in my feet. I also hardly notice any leg cramps. This product is great!” — Ruth J. (HRL005044).
- “No burning, stabbing pain. No more stiffness. More energy. Move better. Neupathic is fantastic. I love it! It should be available at the drug store.” — Naomi R. *Id.*
- “Neupathic is a great ‘miracle-like product’ which starts working the very first day you use it. Then it continues to control your pain every day. My feet have began [*sic*] to feel normal. Neupathic has improved my life. My nerve pain is gone and I will continue to take Neupathic until my numbness is gone too!” — Gloria R. *Id.*
- “My feet no longer burn, especially after an hour or so of inactivity. I definitely feel more comfortable.” — Margaret J. *Id.*

HRL’s mailer does not state that the consumer testimonials reflect atypical experiences or that consumers should expect different results.¹⁶ By claiming that the product alleviates pain associated with diabetic neuropathy and placing those claims proximate to unqualified testimonials, HRL represents that Neupathic cures, mitigates, or treats diabetic neuropathy or mitigates or treats diabetes.

¹⁶ The statement “Results may vary. These are real users with real results.” appears in small print after the last testimonial on page 9 of the Neupathic mailer. PX 2, Lewis Decl., Att. J (HRL005044).

H. HRL and Mr. Duhon Lack Substantiation for Neupathic Claims.

In response to FTC requests for substantiation, HRL provided various articles and materials about specific ingredients in Neupathic, but provided no RCTs testing Neupathic or the same combination of active ingredients found in the product. Dr. Charles Burant, a Professor of Internal Medicine in the Division of Metabolism, Endocrinology, and Diabetes at the University of Michigan, School of Public Health, reviewed all of the purported substantiation. He also conducted a thorough review of scientific literature for clinical trials testing individual active ingredients found in Neupathic. PX 4, Burant Report, p. 20, 23. Crucially, Dr. Burant found no RCTs testing the same combination of active ingredients found in Neupathic and confirmed that all of the trials testing individual ingredients submitted by HRL involved different doses of the individual ingredients or were not randomized, double-blind, and placebo-controlled. *Id.* at 12.

III. LEGAL DISCUSSION

This Court has the authority to enforce its own orders through civil contempt. *Spallone v. United States*, 493 U.S. 265, 276 (1990) (quoting *Shillitani v. U.S.*, 384 U.S. 364, 368 (1966)). Parties and nonparties bound by an order may be held in civil contempt if the movant demonstrates by clear and convincing evidence that “(1) the alleged contemnor had notice of the order, (2) the order was clear and unambiguous, (3) the alleged contemnor had the ability to comply with the order, and (4) the alleged contemnor violated the order.”

Hampshire, Comm'r, 665 F.3d 25, 31 (1st Cir. 2012) (internal quotes and citations omitted). The facts here squarely establish all four elements.

A. The Order Binds Each of the Contempt Defendants.

Section II of the Order binds “Defendants, Defendants’ officers, agents, employees, and all other person in active concert or participation with any of them, who receive actual notice [.]” As parties to the underlying action, Kramer Duhon and HRL are clearly bound by the Order and had actual notice of its injunctive provisions. Fed. R. Civ. P. 65(d)(2)(A); PX 2, Lewis Decl., Att. A. Nonparties, such as WBS, are equally bound if they had actual notice of the Order and are in “active concert and participation with” a party. Fed. R. Civ. P. 65(d)(2); *Goya Foods, Inc. v. Wallack Management, Co.*, 290 F.3d 63, 75 (1st Cir. 2002) (citation omitted). The latter requirement is satisfied if the nonparty is either legally identified with a party or “aided and abetted” the party in the enjoined conduct. *Goya Foods*, 290 F.3d at 75; *Gemco Latinoamerica, Inc. v. Seiko Time Corp.*, 61 F.3d 94, 98 (1st Cir. 1995).

Here, WBS had actual notice of the Order through its owner and principal, Mr. Duhon. *See FTC v. Neovi, Inc.*, 06-CV-1952-JLS, 2012 WL 28599872012, *7 (S.D. Cal. July 11, 2012) (finding nonparty companies had actual notice of order because they were controlled and operated by individual party defendants in contempt case). In addition to being the sole owner of WBS, Mr. Duhon serves as its Managing Member and Chief Operating Officer. PX 2, Lewis Decl., Att. B, N. He, therefore, controls and operates the company. Further, WBS acted in concert and participated with Mr. Duhon in selling and marketing BG18 to consumers using unsubstantiated claims that violated the Order. *See*

G. & C. Merriam Co. v. Webster Dictionary Co., 639 F.2d 29, 35 (1st Cir. 1980) (“To hold a nonparty bound by an injunction it is ... essential to prove either that the nonparty participated in the contumacious act of a party or that the nonparty was subject to the injunction because legally identified with a party.”) Therefore, the Order binds WBS.

B. The Order’s Provisions are Clear and Unambiguous, and Contempt Defendants Had the Ability to Comply.

As discussed *supra*, the Order clearly and unambiguously requires Contempt Defendants to have at least one RCT testing the same product or an Essentially Equivalent Product to substantiate claims that their products cure, mitigate, or treat any disease. PX 1, Section II.H. Further, Contempt Defendants had the ability to comply with the requirements of Section II.H of the Order in at least two ways: advertising with claims that it could substantiate, or refraining from selling the products altogether. Contempt Defendants instead chose to ignore the injunction and continued to profit from deceptively advertising their dietary supplements to the public.

C. Clear and Convincing Evidence Establishes that Contempt Defendants Violated Section II.H of the Order.

Clear and convincing evidence establishes that Contempt Defendants made numerous unsubstantiated disease claims in violation of Section II.H of the Order. The contumacious conduct in this case is especially egregious because Contempt Defendants violated one of the core injunctive provisions of the Order by disseminating grossly unsubstantiated advertising claims for multiple products beginning shortly after the Court entered the Order.

(1) Unsubstantiated Disease Claims Related to BG18 and Black Garlic Botanicals Violate the Order.

As discussed above in Section II.C, Contempt Defendants' ads contain numerous claims that BG18 and Black Garlic Botanicals cure, mitigate, or treat cardiovascular disease as well as the related diseases of atherosclerosis and hypertension. For example, the BG18 mailer claims that the product "can help reverse plaque build-up in arteries." PX 6, Prunty Decl, Att. 1 (FTC0004). The mailer also extravagantly claims "Black Garlic is a true miracle for cardiovascular health! Just 1 capsule knocks down cholesterol and high blood pressure within days. It can also unblock, clean, and strengthen your arteries." (FTC0008). Similarly, the Black Garlic Botanicals mailer states that "[p]laque build-up in arteries can lead to unhealthy heart conditions" and that "Black Garlic helps keep blood vessels barrier-free to create smooth flow[.]" PX 2, Lewis Decl., Att. H (HRL004990). The ad also promotes black garlic as a "breakthrough" for cholesterol, blood pressure, and the heart. *Id.* In addition, the Black Garlic Botanicals mailer features testimonials suggesting that consumers using the product should expect to experience reductions in blood pressure and LDL-cholesterol. (HRL004993, HRL004995).

Contempt Defendants amplify these disease claims in their mailers by combining them with banner headlines, photographs, and graphics emphasizing the dangers of cardiovascular disease, atherosclerosis, and hypertension. Contempt Defendants' ads create the unmistakable net impression that BG18 and Black Garlic Botanicals will cure, mitigate, or treat cardiovascular disease, atherosclerosis, and hypertension. *See Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1496-97 (1st Cir. 1989) (focusing on "common-sense net impression" of an allegedly false and deceptive advertisement); *FTC*

v. Nat'l Urological Group, Inc., 645 F. Supp.2d 1167, 1189 (N.D. Ga. 2008) (stating that “[w]hen assessing the meaning and representations conveyed by an advertisement, the court must look to the advertisement’s overall, net impression”) (citations omitted).

However, as Dr. Sacks explains, Contempt Defendants do not have a RCT testing their product or the same dose of the purportedly active ingredient in BG18/Black Garlic Botanicals, aged black garlic, to support their claims. PX 3, Sacks Report, p. 9-10. Instead, Contempt Defendants rely on trials testing aged garlic extract, which has very different chemical components and therefore is not an “identical ingredient” or the same “form” of the ingredient as required by the Order. *Id.* at 6-9; PX 1, p. 5, ¶9.

(2) Unsubstantiated Disease Claims Related to Ultimate Heart Formula Violate the Order.

As discussed in Section I.E, UHF ads contain numerous claims that the product will cure, mitigate, or treat cardiovascular disease, atherosclerosis, and hypertension. For example, the mailer promotes the product as delivering “[a]mazing heart and artery protection ... without side effects” and claims that with “Ultimate Heart Formula, a lifetime of plaque build up could disappear before you know it!” PX 2, Lewis Decl, Att. I (HRL005079). Elsewhere, the mailer features the claims “The Ultimate Heart Formula’s unique ‘Senior Formula’ is made with ingredients specifically shown to help improve the effects of a weakened heart, clogged arteries, high blood pressure and high cholesterol for older people!” (HRL005077). HRL reinforces these claims with customer testimonials claiming UHF will help reduce chest pain, irregular heartbeats, reduce heart palpitations, and reduce cholesterol levels. (HRL005076, HRL005079). HRL further reinforces the net impression of the cure and treatment claims with prominent banner

headlines, photographs, and graphics highlighting the perils of cardiovascular disease, atherosclerosis, and hypertension.

However, once again, HRL and Mr. Duhon do not come close to having the substantiation, much less the RCT required by Section II of the Order, for such disease claims. They do not have a single RCT testing UHF or a product with the same combination of active ingredients in UHF as required by the Order. Instead, they rely on ingredient-specific studies testing of garlic, nattokinase, and CoQ10 which did not test the same doses of the ingredients found in UHF. PX 3, Sacks Report, p. 11-16. Further, the ingredient-specific studies related to EDTA tested different doses *and* different methods of administration (*i.e.*, intravenous administration in chelation rather than oral administration). *Id.* at 16-17.

(3) Unsubstantiated Disease Claims Related to Neupathic Violate the Order.

As discussed in Section II.G, the Neupathic mailer contains numerous claims that the product cures, mitigates, or treats diabetic neuropathy and mitigates or treats diabetes. For example, HRL and Mr. Duhon advertised the product as a “perfect nerve pain supplement that was formulated from the ground up to improve your circulation and ease the numbness, tingling, itching, burning and swelling from excess fluid trapped in your legs.” PX 2, Lewis Decl., Att. J (HRL005039). Defendants’ mailer claims the product has been “shown to help reverse damaged nerves” (HRL005048) and was “specifically formulated” to address a long list of symptoms of “diabetic nerve pain” (HRL005039). Again, Defendants feature testimonials to reinforce the claim that consumers should generally expect Neupathic to eliminate symptoms of diabetic neuropathy and/or diabetes

including pain, numbness, and burning. (HRL005044). Thus, the net impression created by the content of the mailer is unmistakably that Neupathic will cure, mitigate, or treat the disease of diabetic neuropathy and mitigate or treat diabetes.

Once again, HRL and Mr. Duhon do not have anything close to sufficient substantiation for such claims under Section II. They do not have any RCTs testing Neupathic or the same combination of active ingredients found in Neupathic as required by the Order. Instead, they rely on ingredient-specific studies that, with one exception, did not test the same dose of the ingredients found in Neupathic. As Dr. Burant explains, the single study identified by HRL that tested the same dosage of Evening Primrose Oil found in Neupathic was not double-blinded or randomized. PX 4, Burant Report, p. 22. Dr. Burant's analysis shows that HRL and Mr. Duhon do not come close to having competent and reliable scientific evidence to support their Neupathic claims.

D. Contempt Defendants Owe Compensatory Sanctions

The Court has broad authority to impose sanctions for violations of its orders, including compensation for losses sustained because of a contemnor's failure to comply. *See, e.g., Int'l Union, United Mine Workers v. Bagwell*, 512 U.S. 821, 829 (1994); *Goya Foods*, 290 F.3d at 78 (1st Cir. 2002) (citing *United States v. United Mine Workers*, 330 U.S. 258, 303-304 (1947)). Consumer loss is the proper measure of compensation in FTC-initiated contempt proceedings. *See FTC v. Trudeau*, 662 F.3d 947, 950 (7th Cir. 2011); *FTC v. Kuykendall*, 371 F.3d 745, 765 (10th Cir. 2004); *McGregor v. Chierico*, 206 F.3d 1378, 1388-89 (11th Cir. 2000). Because Contempt Defendants' misrepresentations concerning BG18, Black Garlic Botanicals, UHF, and Neupathic were

widely disseminated in mailers across the United States, the law presumes all consumers relied upon Contempt Defendants' misrepresentations and were therefore injured. *See, e.g., FTC v. Trudeau*, 579 F.3d 754, 773 n.15 (7th Cir. 2009); *FTC v. BlueHippo Funding, LLC*, 763 F.3d 238, 244-45 (2d Cir. 2014). Thus, compensatory sanctions equal the amount that consumers spent on Black Garlic Botanicals, BG18, UHF, and Neupathic (*i.e.*, Contempt Defendants' revenues) minus chargebacks and refunds. Based on the information provided by HRL,¹⁷ Plaintiffs therefore seek compensatory monetary sanctions jointly and severally from Mr. Duhon and HRL in the amount of \$2,133,263 (net revenues of Black Garlic Botanicals, Neupathic and UHF) and jointly and severally from Mr. Duhon and WBS in the amount of \$604,205 (net revenues of BG18).

IV. CONCLUSION

Given Contempt Defendants' flagrant violations of Section II.H of the Order, Plaintiffs respectfully request that the Court grant the motion for an order to show cause and set a hearing in this matter. Depending on whether Contempt Defendants present factual disputes in opposition to this motion, it is possible that Plaintiffs may seek permission from the Court to conduct very limited discovery prior to a hearing.

¹⁷ *See* PX 2, Lewis Decl., Att. L, M.

Respectfully submitted,

Dated: Dec. 17, 2019

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CERTIFICATE OF SERVICE

I hereby certify that on this date, the foregoing was served via U.S. Mail and email upon the following:

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