

**UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION**

COMMISSIONERS: **Lina Khan, Chair**
 Noah Joshua Phillips
 Rohit Chopra
 Rebecca Kelly Slaughter
 Christine S. Wilson

In the Matter of

HEALTH RESEARCH LABORATORIES, LLC,
 a limited liability company,

WHOLE BODY SUPPLEMENTS, LLC,
 a limited liability company, and

KRAMER DUHON,
 individually and as an officer of
 HEALTH RESEARCH LABORATORIES, LLC
 and WHOLE BODY SUPPLEMENTS, LLC.

DOCKET NO. 9397

COMPLAINT COUNSEL’S PROPOSED ORDER

Definitions

For purposes of this Order, the following definitions apply:

- A. “Covered Product” means any Food or Drug.
- B. “Corporate Respondent” means Health Research Laboratories, LLC, or Whole Body Supplements, LLC.
- C. “Dietary Supplement” means:
 - 1. any product labeled as a dietary supplement or otherwise represented as a dietary supplement; or
 - 2. any pill, tablet, capsule, powder, softgel, gelcap, liquid, or other similar form containing one or more ingredients that are a vitamin, mineral, herb or other botanical, amino acid, probiotic, or other dietary substance for use by humans to supplement the

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diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above, that is intended to be ingested, and is not represented to be used as a conventional food or as a sole item of a meal or the diet.

- D. “Drug” means: (a) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (c) articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and (d) articles intended for use as a component of any article specified in (a), (b), or (c); but does not include devices or their components, parts, or accessories.
- E. “Essentially Equivalent Product” means a product that contains the identical ingredients, except for inactive ingredients (e.g., inactive binders, colors, fillers, excipients), in the same form and dosage, and with the same route of administration (e.g., orally, sublingually), as the Covered Product; *provided that* the Covered Product may contain additional ingredients if reliable scientific evidence generally accepted by experts in the field indicates that the amount and combination of additional ingredients are unlikely to impede or inhibit the effectiveness of the ingredients in the essentially equivalent product.
- F. “Food” means: (a) any article used for food or drink for humans or other animals; (b) chewing gum; and (c) any article used for components of any such article.
- G. “Individual Respondent” means Kramer Duhon.
- H. “Negative Option Feature” means, in an offer or agreement to sell any good or service, a provision under which the consumer’s silence or failure to take affirmative action to reject a good or service or to cancel the agreement is interpreted by the seller or provider as acceptance or continuing acceptance of the offer.
- I. “Respondents” means Health Research Laboratories, LLC, Whole Body Supplements, LLC, and Kramer Duhon, individually, collectively, or in any combination.

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Provisions

I.

IT IS ORDERED that Respondents must not advertise, market, promote, or offer for sale any Dietary Supplement or assist others in the advertising, marketing, promoting, or offering for sale of any Dietary Supplement.

II.

IT IS FURTHER ORDERED that Respondents, whether acting directly or indirectly, in connection with the advertising, marketing, promoting, or offering for sale of any product, must not make any representation, expressly or by implication, that a product cures, treats, mitigates, prevents, or reduces the risk of any disease.

III.

IT IS FURTHER ORDERED that subject to the prohibitions in Parts I and II of this Order, Respondents, Respondents' officers, agents, and employees, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, must not make any representation expressly or by implication, about the health benefits, safety, performance, or efficacy of any Covered Product, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant condition or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of this Provision, "competent and reliable scientific evidence" means tests, analyses, research, or studies that (1) have been conducted and evaluated in an objective manner by experts in the relevant condition or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the Covered Product or of an Essentially Equivalent Product, when such experts would generally require such human clinical testing to substantiate that the representation is true. In addition, when such tests or studies are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as set forth in Part V of this Order must be available for inspection and production to the Commission. Respondents have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

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IV.

IT IS FURTHER ORDERED that subject to the prohibitions in Parts I and II of this Order, Respondents, Respondents' officers, agents, employees, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with advertising, marketing, promoting, offering for sale, sale, or distribution of any Covered Product must not make any misrepresentations expressly or by implication:

- A. That the performance or benefits of any Covered Product are scientifically or clinically proven or otherwise established; or
- B. The existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research.

V.

IT IS FURTHER ORDERED that, with regard to any human clinical test or study ("test") upon which Respondents rely to substantiate any claim not banned by Parts I or II, but covered by Part III, Respondents must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, including:

- A. All protocols and protocol amendments, reports, articles, write-ups, or other accounts of the results of the test, and drafts of such documents reviewed by the test sponsor or any other person not employed by the research entity;
- B. All documents referring or relating to recruitment; randomization; instructions, including oral instructions, to participants; and participant compliance;
- C. Documents sufficient to identify all test participants, including any participants who did not complete the test, and all communications with any participants relating to the test; all raw data collected from participants enrolled in the test, including any participants who did not complete the test; source documents for such data; any data dictionaries; and any case report forms;
- D. All documents referring or relating to any statistical analysis of any test data, including any pretest analysis, intent-to-treat analysis, or between-group analysis performed on any test data; and
- E. All documents referring or relating to the sponsorship of the test, including all communications and contracts between any sponsor and the test's researchers.

Provided, however, the preceding preservation requirement does not apply to a reliably reported test, unless the test was conducted, controlled, or sponsored, in whole or in part by: (1) any Respondent; (2) any Respondent's officers, agents, representatives, or employees; (3)

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any other person or entity in active concert or participation with any Respondent; (4) any person or entity affiliated with or acting on behalf of any Respondent; (5) any supplier of any ingredient contained in the product at issue to any of the foregoing or to the product's manufacturer; or (6) the supplier or manufacturer of such product.

For purposes of this Provision, "reliably reported test" means a report of the test has been published in a peer-reviewed journal, and such published report provides sufficient information about the test for experts in the relevant field to assess the reliability of the results.

For any test conducted, controlled, or sponsored, in whole or in part, by Respondents, Respondents must establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of any personal information collected from or about participants. These procedures must be documented in writing and must contain administrative, technical, and physical safeguards appropriate to Corporate Respondents' size and complexity, the nature and scope of Respondents' activities, and the sensitivity of the personal information collected from or about the participants.

VI.

IT IS FURTHER ORDERED that Respondents must notify customers as follows:

- A. Respondents must identify all consumers who purchased Black Garlic Botanicals, BG18, The Ultimate Heart Formula, and Neupathic on or after January 17, 2018 ("Eligible Customers").
 1. Such Eligible Customers, and their contact information, must be identified to the extent such information is in Respondents' possession, custody or control;
 2. Eligible Customers include those identified at any time through the eligibility period, which runs for 1 year after the issuance date of the Order.
- B. Respondents must mail all Eligible Customers the letter in the form shown in Attachment A. Each such mailing must comply with the following:
 1. The envelope containing the letter must be in the form shown in Attachment B.
 2. The mailing of the notification letter must not include any other enclosures other than a copy of this Order.
 3. The mailing must be sent by first-class mail, postage prepaid, address correction service requested with forwarding and return postage guaranteed. For any mailings returned as undeliverable, Respondents must use standard address search methodologies such as re-checking Respondents' records and the Postal Service's National Change of Address database and re-mailing to the corrected address within 8 days.

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4. Each such notice must be mailed within 120 days after the effective date of this Order.
- C. Respondents must report on their notification program under penalty of perjury as follows:
1. Respondents must submit a report at the conclusion of the program, but in no event later than 180 days after the effective date of this Order, detailing its compliance with this Provision.
 2. If a representative of the Commission requests any information regarding the program, including any of the underlying customer data, Respondents must submit the requested information within 10 days of the request.
 3. Failure to provide required notices or any requested information will be treated as a continuing failure to obey this Order.

VII.

IT IS FURTHER ORDERED that Respondents and their officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, must not disclose, use, or receive any benefit from customer information including the name, address, telephone number, e-mail address, social security number, or other identifying information or any data that enables access to a customer's account (including a credit card, bank account or other financial account) that any Respondent obtained prior to the issuance of this Order in connection with sales of Black Garlic Botanicals, BG18, The Ultimate Heart Formula, or Neupathic. Respondents must also preserve such identifying information together with records of the product(s) individual customers purchased and the date and amount of payments made to Respondents until receipt of written notice from Commission staff to destroy the information. Once Commission staff notify Respondents to destroy such customer information, Respondents will have five days to comply.

Provided, however, that Respondents may disclose such customer information to the FTC or any law enforcement agency, or as required by any law, regulation, or court order.

VIII.

IT IS FURTHER ORDERED that, consistent with Part VII, Respondents must immediately cancel any subscription plan with a Negative Option Feature related to Black Garlic Botanicals, BG18, The Ultimate Heart Formula, or Neupathic.

IX.

IT IS FURTHER ORDERED that Respondents obtain acknowledgments of receipt of this Order:

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- A. Each Respondent, within 10 days after the effective date of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.
- B. For 20 years after the issuance date of this Order, the Individual Respondent, for any business that such Respondent, individually or collectively with any other Respondent, is the majority owner or controls directly or indirectly, and each Corporate Respondent, must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees having managerial responsibilities for the manufacturing, labeling, advertising, marketing, distribution, or sale of any Covered Product, and all agents and representatives who participate in manufacturing, labeling, advertising, marketing, distribution, or sale of any Covered Product; and (3) any business entity resulting from any change in structure as set forth in Part X. Delivery must occur within 10 days after the effective date of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.
- C. From each individual or entity to which a Respondent delivered a copy of this Order, that Respondent must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

X.

IT IS FURTHER ORDERED that Respondents make timely submissions to the Commission:

- A. One year after the issuance date of this Order, each Respondent must submit a compliance report, sworn under penalty of perjury, in which:
 1. Each Respondent must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission may use to communicate with Respondent; (b) identify all of that Respondent's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, including the goods and services offered, the means of advertising, marketing, and sales, and the involvement of any other Respondent (which Individual Respondent must describe if they know or should know due to their own involvement); (d) describe in detail whether and how that Respondent is in compliance with each Part of this Order, including a discussion of all of the changes the Respondent made to comply with the Order; and (e) provide a copy of each acknowledgment of the Order obtained pursuant to this Order, unless previously submitted to the Commission.
 2. Additionally, the Individual Respondent must: (a) identify all his telephone numbers and all his physical, postal, email, and Internet addresses, including all residences; (b) identify all his business activities, including any business for which such Respondent performs services whether as an employee or otherwise and any entity in which such Respondent has any ownership interest; and (c) describe in detail such Respondent's

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- involvement in each such business activity, including title, role, responsibilities, participation, authority, control, and any ownership.
- B. Each Respondent must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:
1. Each Respondent must submit notice of any change in: (a) any designated point of contact; or (b) the structure of any Corporate Respondent or any entity that Respondent has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.
 2. Additionally, the Individual Respondent must submit notice of any change in: (a) name, including alias or fictitious name, or residence address; or (b) title or role in any business activity, including (i) any business for which such Respondent performs services whether as an employee or otherwise and (ii) any entity in which such Respondent has any ownership interest and over which Respondents have direct or indirect control. For each such business activity, also identify its name, physical address, and any Internet address.
- C. Each Respondent must submit notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Respondent within 14 days of its filing.
- D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: “I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____” and supplying the date, signatory’s full name, title (if applicable), and signature.
- E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: In re Health Research Laboratories, Dkt. 9397.

XI.

IT IS FURTHER ORDERED that Respondents must create certain records for 20 years after the issuance date of the Order, and retain each such record for 5 years, unless otherwise specified below. Specifically, the Corporate Respondents and Individual Respondent for any business that such Respondent, individually or collectively with any other Respondents, is a majority owner or controls directly or indirectly, must create and retain the following records:

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- A. Accounting records showing the revenues from all goods or services sold, the costs incurred in generating those revenues, and resulting net profit or loss;
- B. Personnel records showing, for each person providing services in relation to any aspect of the Order, whether as an employee or otherwise, that person's: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;
- C. Copies or records of all consumer complaints and refund requests, whether received directly or indirectly, such as through a third party, and any response;
- D. All records necessary to demonstrate full compliance with each Provision of this Order, including all submissions to the Commission; and
- E. A copy of each unique advertisement or other marketing material making a representation subject to this Order.
- F. For 5 years from the date of the last dissemination of any representation covered by this Order:
 - 1. All materials that were relied upon in making the representation; and
 - 2. All tests, studies, analysis, other research or other such evidence in Respondents' possession, custody, or control that contradicts, qualifies, or otherwise calls into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.
- G. For 5 years from the date created or received, all records, whether prepared by or on behalf of Respondents, that tend to show any lack of compliance by Respondents with this Order.

XII.

IT IS FURTHER ORDERED that, for the purpose of monitoring Respondents' compliance with this Order:

- A. Within 10 days of receipt of a written request from a representative of the Commission, each Respondent must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury, and produce documents for inspection and copying. Respondents will answer interrogatories and sit for investigational hearings within 30 days of a written request from Commission staff.
- B. For matters concerning this Order, representatives of the Commission are authorized to

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communicate directly with each Respondent. Respondents must permit representatives of the Commission to interview anyone affiliated with any Respondent who has agreed to such an interview. The interviewee may have counsel present.

- C. The Commission may use all other lawful means, including posing through its representatives as consumers, suppliers, or other individuals or entities, to Respondents or any individual or entity affiliated with Respondents, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

XIII.

IT IS FURTHER ORDERED that this Order is final and effective upon the date of its publication on the Commission's website (www.ftc.gov) as a final order. This Order will terminate 20 years from the date of its issuance (which date may be stated at the end of this Order, near the Commission's seal), or 20 years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) in federal court alleging any violation of this Order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Provision in this Order that terminates in less than 20 years;
- B. This Order's application to any Respondent that is not named as a defendant in such complaint; and
- C. This Order if such complaint is filed after the Order has terminated pursuant to this Provision.

Provided, further, that if such complaint is dismissed or a federal court rules that the Respondent did not violate any Provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Provision as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

April J. Tabor
Acting Secretary

SEAL:

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ISSUED:

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ATTACHMENT A

[To be printed on Health Research Laboratories, LLC or Whole Body Supplements, LLC
letterhead and sent via First Class mail]

[Date]

Subject: [Black Garlic Botanicals, BG18, The Ultimate Heart Formula, or Neupathic]

[Name of customer]

[Mailing address of customer]

Including zip code]

Dear [Name of customer]:

Our records show that you bought [Black Garlic Botanicals, The Ultimate Heart Formula, or Neupathic from Health Research Laboratories] [BG18 from Whole Body Supplements].

We made claims that our products could prevent, reduce the risk of, treat or cure serious diseases and health conditions such as cardiovascular disease, high blood pressure, and diabetic nerve pain. The Federal Trade Commission has found that we made these claims without having the scientific evidence to support them.

The enclosed FTC order requires us to stop selling dietary supplements and claiming that our products cure, treat, mitigate, prevent, or reduce the risk of any disease.

Furthermore, taking our products could interfere with effective treatments recommended by your doctor.

Learn more about the lawsuit against Health Research Laboratories and Whole Body Supplements at <https://www.ftc.gov/news-events/press-releases/2020/11/ftc-approves-administrative-complaint-against-supplement-marketer>.

Sincerely,

Kramer Duhon
Health Research Laboratories, LLC
Whole Body Supplements, LLC

Enclosure [Enclosed Order]

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ATTACHMENT B

The envelope for the notification letter must be in the following form, with the underlined text completed as directed:

*[HEALTH RESEARCH LABORATORIES, LLC OR
WHOLE BODY SUPPLEMENTS, LLC*

Street Address

City, State and Zip Code]

FORWARDING AND RETURN POSTAGE GUARANTEED ADDRESS CORRECTION
SERVICE REQUESTED

[name and
mailing address of customer,
including zip code]

**ABOUT YOUR PURCHASE OF [BLACK GARLIC BOTANICALS/BG18/THE
ULTIMATE HEART FORMULA, OR NEUPATHIC]**

**UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION**

COMMISSIONERS: **Lina Khan, Chair**
 Noah Joshua Phillips
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 and WHOLE BODY SUPPLEMENTS, LLC.

DOCKET NO. 9397

COMPLAINT COUNSEL'S BRIEF IN ADVANCE OF FINAL DECISION

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POM Wonderful, LLC v. FTC, 777 F.3d 378 (D.C. Cir. 2015) *passim*

Puerto Rico Tele-Com, Inc. v. Ocasio Rodriguez, 747 F. Supp. 836 (D.P.R. 1990) 25

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COMPLAINT COUNSEL’S BRIEF IN ADVANCE OF FINAL DECISION¹

The undisputed evidence, together with Respondents’ admissions, establish that Respondents Health Research Laboratories, LLC (“HRL”), Whole Body Supplements (“WBS”), and Kramer Duhon (“Duhon”) are liable for violating Sections 5 and 12 of the Federal Trade Commission Act (“FTC Act”). Specifically, Respondents’ admissions establish that they touted their supplements as miraculous medical products capable of reducing the risk of, curing, treating, or mitigating life-threatening diseases. Yet, Respondents admit they had no substantiation for these extraordinary claims. Additionally, because Respondents’ admitted violations are serious, deliberate, and readily transferable, affirmative relief and robust fencing-in relief including bans are needed to protect the public. Finally, none of Respondents’ defenses are meritorious.

I. Liability

Summary decision is appropriate in this case. Rule 3.24 provides summary decision “shall be rendered ... if the pleadings and any depositions, answers to interrogatories, admission on file, and affidavits show that there is no genuine issue as to any material fact and that the moving party is entitled to such decision as a matter of law.” 16 C.F.R. § 3.24(a)(2). Rule 3.24(a)(2) is applied consistently with case law interpreting the summary judgment standard set forth in Fed. R. Civ. P. 56. *See Jerk, LLC*, 159 F.T.C. 885, 2015 WL 13021976, *3-4 (Mar. 13, 2015).

¹ Consistent with the Commission’s Order, Complaint Counsel submits this brief addressing liability, Respondents’ defenses, and appropriate relief. All of these issues are appropriate for summary decision. Order Directing Parties to Submit Proposed Findings of Fact and Conclusions of Law and Providing for Summary Decision Proceeding (July 30, 2021), at 4 (“July 30 Order”) (requiring any party relying on facts outside the Complaint to state whether summary decision or partial summary decision is appropriate).

For the reasons explained below, there is no genuine issue regarding any material fact necessary to prove liability. Therefore, summary decision on all issues is appropriate at this time.

A. Legal Standards Under Sections 5 and 12 of the FTC Act.

Section 5(a) prohibits “unfair or deceptive acts or practices in or affecting commerce[.]” 15 U.S.C. § 45(a)(1). An advertisement is deceptive under Section 5 if it contains a representation or omission of fact that is likely to mislead consumers acting reasonably under the circumstances, in a material respect. *POM Wonderful, LLC*, 155 F.T.C. 1, 2013 WL 8364895, *6 (2013); *Cliffdale Assocs., Inc.*, 103 F.T.C. 110, 164-66, 1984 WL 565319, *37 (1984); *see also* Letter from James C. Miller, III, Chairman, Federal Trade Commission to Hon. John T. Dingell, Chairman, Committee on Energy and Commerce (Oct. 14, 1983) (“*Deception Statement*”), *reprinted in* 103 F.T.C. 174, 175 (Mar. 24, 1984). In deceptive advertising cases, the Commission engages in a three-part inquiry evaluating: “(i) what claims are conveyed in the ad, (ii) whether those claims are false, misleading, or unsubstantiated, and (iii) whether the claims are material to prospective consumers.” *POM Wonderful, LLC v. FTC*, 777 F.3d 478, 490 (D.C. Cir. 2015); *see also Kraft, Inc. v. FTC*, 970 F.2d 311, 314 (7th Cir. 1992).

Section 12 of the FTC Act prohibits the dissemination of any false advertisement that is likely to induce the purchase of food, drugs, devices, or cosmetics. 15 U.S.C. § 52. A “false advertisement” is any advertisement that is “misleading in a material respect.” 15 U.S.C. § 55; *see also FTC v. Pantron I Corp.*, 33 F.3d 1088, 1095 (9th Cir. 1994). If an advertiser lacks a reasonable basis for asserting a challenged objective claim was true, it is a false advertisement within the meaning of Section 12 and a deceptive act or practice under Section 5. *Pantron I*, 33 F.3d at 1096 (citing *Thompson Med. Co., Inc.*, 104 F.T.C. 648, 818-19 (1984)). The FTC Act

further provides violations of Section 12 are unfair or deceptive acts and practices under Section 5. 15 U.S.C. § 52(b).

As an initial matter, Respondents have admitted the obvious, that their activities were “in or affecting commerce” for the purposes of Section 5 and are advertisements for “food or drugs” for the purposes of Section 12. Complaint ¶¶ 4, 5, and 22; Amended Answer (Mar. 30, 2021). Thus, we turn to the three substantive elements.

B. Respondents’ Advertising Claims Are Deceptive Under Sections 5 and 12.

There is no factual dispute about whether Respondents’ mailers for each of the Challenged Products convey the disease-related efficacy claims alleged in the Complaint. First, Respondents admit their mailers convey the alleged representations. CCFOF, ¶¶ 23, 34, 43, 59. Second, the primary evidence of the claims an advertisement conveys to reasonable consumers is the advertisement itself. *Novartis Corp*, 127 F.T.C. 580, 680 (1999). When claims are express, or when language or depictions in an ad are clear enough to permit the Commission to conclude with confidence that an implied claim is conveyed, no extrinsic evidence related to ad interpretation is necessary. *Kraft*, 114 F.T.C. 40, 121 (1991).² When claims are implied, the Commission evaluates the overall net impression of advertisements, which includes examining the interaction of all elements including, but not limited to, language and visual components. *Telebrands Corp.*, 140 F.T.C. 278, 290 (2005); *Novartis*, 127 F.T.C. at 679; *Stouffer Foods Corp.*, 118 F.T.C. 746, 798-99 (1994).

² “Extrinsic evidence is unnecessary to establish the impression that consumers take away from an ad if the claims are reasonably clear from the face of the advertisement.” *POM Wonderful*, 2013 WL 8364895 at *9; see also *FTC v. Nat’l Urological Grp.*, 645 F. Supp. 2d 1167, 1189 (N.D. Ga. 2008) (“If the advertisement explicitly states or clearly and conspicuously implies a claim, the court need not look to extrinsic evidence to ascertain whether the advertisement made the claim.”).

Respondents' mailers contained numerous statements that together with physician endorsements and medical illustrations and imagery expressly state and strongly imply the alleged disease-related efficacy claims. Specifically, the net impression the Black Garlic Botanicals, BG18, and Neupathic mailers convey to consumers is that the products will effectively prevent, reduce the risk of, or treat cardiovascular disease and atherosclerosis as well as cure, treat, or mitigate hypertension. For example, one mailer states "Heart Attack is the #1 killer of men and women. If you want to AVOID it, I have good news about a revolutionary NEW and NATURAL treatment that can help keep your arteries clear and your mind at ease." The Neupathic mailer's net impression clearly conveys the product will effectively cure, treat, or mitigate diabetic neuropathy.³ For example, the mailer states "This "Perfect" Nerve Pain easing pill combines special nutrients to restore circulation and soothe nerve pain associated with diabetes!" CCFOF, ¶ 44.

Second, there is no factual dispute that the disease-related efficacy claims challenged in the Complaint were unsubstantiated. Specifically, Respondents have admitted they had no substantiation for the claims. CCFOF, ¶ 33, 42, 50, 67. Where, as here, a complaint challenges efficacy claims under Sections 5 and 12, the Commission evaluates whether the respondents had a reasonable basis for their claims in the form of appropriate substantiation. In determining the appropriate level of substantiation, the Commission normally weighs multiple factors first set forth in *Pfizer, Inc.*, 81 F.T.C. 23, 1972 WL 127465, *30 (1972). However, in this matter, the analysis is unnecessary because Respondents have conceded their representations were not substantiated at the time they were made.

³ Disclaimers that appear infrequently in small font and inconspicuous locations in the lengthy mailers are inadequate to offset the overall messages conveyed by the advertisements. CCFOF, ¶¶ 27, 41, 46, 65; *Deception Policy Statement*, 103 F.T.C. at 180-81.

Unsubstantiated efficacy claims are false or misleading because an objective claim for a product carries an implied representation the advertiser possessed and relied upon a reasonable basis at the time the claim was disseminated. *FTC Policy Statement Regarding Advertising Substantiation Statement*, appended to *Thompson Med.*, 104 F.T.C. 648, 1984 WL 565377, *105 (1984) (“*Substantiation Statement*”) (“Objective claims for products or services represent explicitly or by implication that the advertiser has a reasonable basis supporting these claims.”).

In order to have a reasonable basis for health efficacy claims, advertisers must possess substantiation in the form of “competent and reliable scientific evidence” at the time of dissemination. *POM Wonderful*, 777 F.3d at 495-97 (affirming Commission’s competent and reliable scientific evidence standard for disease-related claims about food products); *FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285, 300 (D. Mass. 2008), *aff’d*, 624 F.3d 1 (1st Cir. 2010); *Nat’l Urological*, 645 F. Supp. 2d at 1190 (applying same standard to weight loss and erectile dysfunction claims for dietary supplements). This standard, at a minimum, generally requires tests, analyses, research, or studies that (1) have been conducted and evaluated in an objective manner by qualified persons; and (2) using procedures generally accepted in the profession to yield accurate and reliable results. *POM Wonderful*, 2013 WL 8364895 at *37; *Telebrands*, 140 F.T.C. at 347 (2005), *aff’d*, 457 F.3d 354 (4th Cir. 2006). Further, competent and reliable evidence for certain types of health-related efficacy claims must include randomized, controlled clinical trials of the product. *POM Wonderful*, 2013 WL 8364895 at *23 (finding randomized, controlled clinical trials required to substantiate prevention and treatment claims related to heart disease, prostate cancer, and erectile dysfunction); *Daniel Chapter One*, 2009 WL 2584873, *89 (F.T.C. Aug. 5, 2009) (initial decision) (competent and reliable evidence to substantiate cancer treatment claims requires controlled, clinical studies); *Thompson Med.*, 1984 WL 565377 at *68 (requiring two well-controlled clinical trials); *Direct Mktg. Concepts*,

Inc., 569 F. Supp. 2d at 303; *Nat’l Urological Grp.*, 645 F. Supp. 2d at 1202-03.⁴ Here, no such evidence exists. Therefore, Respondents’ implied claim that they could substantiate their miraculous disease cure and treatment claims is false.

Finally, there is also no genuine factual dispute about whether the challenged advertising representations were material to consumers. A representation is material if it “is one which is likely to affect a consumer’s choice of or conduct regarding a product.” *Deception Statement*, 103 F.T.C. at 182; *see also Kraft*, 114 F.T.C. at 70. Materiality is presumed when advertising claims are express, intentionally implied, or involve health, safety, or a central characteristic of the product such as purpose or efficacy. *Jerk*, 2015 WL 13021976 at *13; *Novartis Corp. v. FTC*, 223 F.3d 783, 786 (D.C. Cir. 2000); *Deception Statement*, 103 F.T.C. at 182. Because all of the challenged representations in Respondents’ mailers relate to health as well as central characteristics of the Challenged Products⁵ (*i.e.*, purpose, performance, and efficacy), they are presumptively material. *Kraft*, 970 F.2d at 322. Moreover, Respondents have not introduced any contrary evidence to rebut the presumption of materiality.⁶ *Id.* at 323; *Novartis Corp.*, 127 F.T.C. at 686.

For these reasons, Respondents’ admissions and the uncontroverted evidence establish HRL’s and WBS’s unsubstantiated advertising representations challenged in the Complaint were

⁴ Section III of the Stipulated Order establishes a substantiation standard for Respondents’ representations about health benefits, performance, or efficacy that is consistent with FTC case law. CCFOF, ¶¶ 79-80.

⁵ This term is used to collectively refer to Black Garlic Botanicals, BG18, The Ultimate Heart Formula, and Neupathic.

⁶ The Commission’s May 14, 2021 Order required both parties to “identify any additional material facts that they intend to assert and state whether those facts are in dispute. Commission Order for Further Proceedings Before the Commission (May 14, 2021) at 2. Respondents identified no additional facts or evidence in their Response. *See* Respondents’ Response to Complaint Counsel’s Statement of Additional Material Facts (June 1, 2021).

likely to mislead consumers and constitute unfair and deceptive acts or practices, and false advertisements, in or affecting commerce in violation of Sections 5 and 12 of the FTC Act.

Further, Duhon is individually liable because Respondents admit he controlled or had the authority to control the unlawful acts of the corporate Respondents. CCFOF, ¶ 6. Courts and the Commission consistently have held that to find an individual liable for deceptive acts or practices, “the individual must either have participated directly in or had the authority to control the acts or practices at issue; both participation and control are not required.” *POM Wonderful*, 2013 WL 8364895 at *56 (citing cases); *see also FTC v. Bay Area Bus. Council, Inc.*, 423 F.3d 627, 636 (7th Cir. 2005).

II. Relief

The proposed relief is both appropriate and necessary to protect the public. The Commission’s authority “is not limited to prohibiting the illegal practice in the precise form in which it is found to have existed in the past.” *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 395 (1965) (quotation omitted). Once Respondents have “been caught violating the [FTC] Act”—as Respondents have here—they ““must expect some fencing in.”” *Id.* at 395 (quoting *FTC v. National Lead Co.*, 352 U.S. 419, 431 (1957)). As one court explained, “[f]encing-in’ relief refers to provisions in a final [FTC] order that are broader than the conduct that is declared unlawful. Fencing-in remedies are designed to prevent future unlawful conduct.” *Telebrands*, 457 F.3d at 357 n.5 (quotation omitted); *see also FTC v. Ruberoid Co.*, 343 U.S. 470, 473 (1952) (explaining the Commission “cannot be required to confine its road block to the narrow lane the transgressor has traveled; it must be allowed effectively to close all roads to the prohibited goal, so that its order may not be by-passed with impunity”).

Fencing-in relief is appropriate unless it has “no reasonable relation to the unlawful practices found to exist.” *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 612-13 (1946); *see also*

Colgate-Palmolive, 380 U.S. at 394-95 (“The propriety of a broad order depends upon the specific circumstances of the case, but the courts will not interfere except where the remedy selected has no reasonable relation to the unlawful practices found to exist.”) (citations omitted). Given its responsibility to protect the public and its substantial discretion in doing so, the Commission frequently orders relief that goes beyond merely requiring that respondents cease the precise practice at issue. *See, e.g., Telebrands*, 457 F.3d at 357 (affirming order prohibiting misrepresentations related to any product); *Kraft*, 970 F.2d at 324 (affirming order that “extends not only to the product contained in the deceptive advertisements,” but to related products); *see also Warner-Lambert Co. v. FTC*, 562 F.2d 749, 762 (D.C. Cir. 1977) (“[T]he Commission [has] the power to order corrective advertising in appropriate cases.”); *Brake Guard Prod., Inc.*, 125 F.T.C. 138, 216 (1998) (ordering respondents to excise deceptive acronym from registered trademark); *see also Telebrands*, 140 F.T.C. at 344 (holding that “fencing-in relief may include a performance bond requirement,” but declining to impose the requirement).

A. Proposed Relief Is Appropriate If It Is Clear and Reasonably Related To Respondents’ Wrongdoing.

Proposed relief is appropriate as long as it is sufficiently “clear and precise,” *Colgate-Palmolive*, 380 U.S. at 392 (quoting *FTC v. Cement Inst.*, 333 U.S. 683, 726 (1948)), and, as discussed above, “reasonabl[y] relat[ed] to the unlawful practices,” *National Lead*, 352 U.S. at 428 (quotation omitted). Both the Commission and courts consider three factors to determine whether a reasonable relationship exists: “(1) the seriousness and deliberateness of the violation; (2) the ease with which the violative claim may be transferred to other products; and (3) whether the respondent has a history of prior violations.” *Stouffer*, 118 F.T.C. at 811 (quotation omitted); *see also Telebrands*, 457 F.3d at 358-59.

Importantly, the Commission considers “the circumstances as a whole” rather than “the presence or absence of any single factor.” *Sears, Roebuck & Co. v. FTC*, 676 F.2d 385, 392 (9th Cir. 1982); *Telebrands*, 457 F.3d at 358-59 (“All three factors need not be present for a reasonable relationship to exist.”) (citation omitted). Stated another way, “[t]he reasonable relationship analysis operates on a sliding scale—any one factor’s importance varies depending on the extent to which the others are found.” *Telebrands*, 457 F.3d at 358-59. For example, “the more serious a violation, the less important transferability and prior history become.” *Id.* (citation omitted). Thus, “[t]he more egregious the facts with respect to a particular element, the less important it is that another negative factor be present.” *Sears*, 676 F.2d at 392. Here all three factors require strong relief.

1. Respondents’ Violations Were Serious and Deliberate.

Admitted facts and uncontroverted evidence establish that Respondents’ violations were serious and deliberate. Respondents’ marketing included express or strongly implied claims that their supplements could cure or treat, among other things, cardiovascular disease, atherosclerosis, and diabetic neuropathy. CCFOF ¶¶ 23-49, 59-66. Peddling phony disease treatments is an especially pernicious form of deceptive advertising because it can divert consumers from effective treatments. *See United States v. Rutherford*, 442 U.S. 544, 556 (1979) (“If an individual suffering from a potentially fatal disease rejects conventional therapy in favor of a drug with no demonstrable curative properties, the consequences can be irreversible.”); *Daniel Chapter One*, 2009 WL 2584873 at *104 (“There is a potential harm if a cancer patient foregoes potentially beneficial therapy and replaces it with one or more of the [supplements].”) (initial opinion). The nature of health claims makes them serious. *See, e.g., Stouffer*, 118 F.T.C. at 812 (finding that deceptive “low sodium” claim was serious due to “the overall health ramifications of any sodium claim”); *Daniel Chapter One*, 2009 WL 2584873 at *104 (noting

the fact “that the representations are health-related claims” helps establish their seriousness) (initial opinion); *cf. American Home Prod. Corp. v. FTC*, 695 F.2d 681, 706 (3d Cir. 1982) (“When drug advertising is at issue, the potential health hazards may well justify a more sweeping order than would be proper were the Commission dealing with a less consequential area.”).

Respondents’ advertisements included frightening images of heart attack victims clutching their chests or collapsed on the ground. CCFOF ¶¶ 28, 37. They also include purported physician endorsements, *id.* ¶¶ 30, 38, 47, 60, 63, medical imagery (flat-lining electrocardiogram graphs, clogged arteries, and diseased hearts, *id.* at ¶¶ 29, 63), and consumer testimonials claiming improved health, *id.* at ¶¶ 26-27, 41, 45-46, 62, 65. This is not a case where a marketer acting in good faith inadvertently stepped slightly over the line.

Additionally, the fact that consumers are not experts in cardiology or diabetic neuropathy and cannot easily evaluate the veracity of Respondents’ claims further demonstrates the violations’ seriousness. *Stouffer*, 118 F.T.C. at 812 (“The seriousness of the violations here is enhanced by the fact that consumers cannot readily judge for themselves the truth or falsity of a low sodium claim.”); *see also ECM Biofilms, Inc.*, 160 F.T.C. 652, 2015 WL 13879743, *60 (2015) (noting that customers’ inability to “readily judge for themselves the truth or falsity” of claims “enhanced” their seriousness) (citing *Stouffer*, 118 F.T.C. at 812); *Thompson Med.*, 1984 WL 565377 at *94 (“The seriousness of the violations also is affected by the fact that consumers could not readily judge the truth or falsity of the claims Thompson was making.”).

Moreover, the fact that Respondents did not confine their wrongdoing to a particular product further demonstrates the deliberateness of Respondents’ deceptive representations. *Cf. Colgate-Palmolive*, 380 U.S. at 395 (explaining that presence of deceptive practice in three different commercials favored strong relief); *DOJ v. Daniel Chapter One*, 89 F. Supp. 3d 132,

145 (D.D.C. 2015) (noting “multitude of products”). Specifically, Respondents aggressively presented express or strongly implied disease claims to promote four distinct products. CCFOF ¶¶ 23-49, 59-66.

The fact that Respondents disseminated more than 1.6 million deceptive ads further demonstrates the deliberateness of their violations. *See id.* at ¶¶ 51-54, 68-69; *see also Stouffer*, 118 F.T.C. at 812-13 (identifying “extensiveness of [an] ad campaign” as “relevant in assessing the seriousness and deliberateness of a violation”).

Additionally, Respondents’ deceptive claims constitute essentially their entire campaign for the four challenged products, demonstrating these claims “were no accident or isolated instance.” *Thompson Med.*, 1984 WL 565377 at *95. Furthermore, the prior Stipulated Order delineates Respondents’ obligations, including the obligation not to make health benefit or efficacy claims for supplements without supporting competent and reliable scientific evidence, CCFOF ¶¶ 78-80—which Respondents admittedly lack for the four supplements at issue, CCFOF ¶¶ 33, 42, 50, 67. The fact that Respondents “were well aware of what they were required to do to comply” further establishes that they acted deliberately. *See Daniel Chapter One*, 89 F. Supp. 3d at 144.

Finally, Respondents ignored advice from a consultant, Curtis Walcker. When Respondents told Walcker other consultants or attorneys raised no issues with their claims, he responded: “I am a bit in shock, as my view would be that they are pretty egregious in terms of blatantly explicit disease claims being made. . . . I do not know many companies that are still going out this aggressively.” CCFOF ¶ 94. Accordingly, Respondents knew their claims were problematic, yet they disseminated the mailer anyway unchanged—which further underscores that Respondents acted deliberately. *See Stouffer*, 118 F.T.C. at 813 (fact that marketer “was well aware that a [claim] was inappropriate” suggests deliberateness).

Collectively, these undisputed facts demonstrate beyond serious question that Respondents' violations were extremely serious and deliberate.

2. Respondents' Violations Are Highly Transferable.

A "violation is transferrable where other products could be sold utilizing similar techniques." *Daniel Chapter One*, 2009 WL 2584873 at *104 (citations omitted). Misrepresentations regarding supplements are highly transferable. Unlike situations involving products that are difficult to manufacture or claims unlikely to appeal in other contexts, Respondents can simply assert that any supplement treats any disease. *See id.* ("In this case, the claims that the [supplements] prevent, treat, or cure cancer, and the use of testimonials by doctors and consumers to make such claims, could readily be employed for any dietary supplement."); *see also Daniel Chapter One*, 89 F. Supp. 3d at 145 ("[T]he defendants' dietary supplement marketing involves deliberate, deceptive strategies that are easily adaptable or transferable to other products[.]"). As with any supplement case involving unsubstantiated disease-related claims, ease of transferability weighs heavily in favor of broad relief.

3. Respondents Have a History of Prior Violations.

Respondents have a history of prior violations. The Commission and the State of Maine sued the Respondents in Federal Court for making false and unsubstantiated health claims.

CCFOF ¶¶ 73-74. Respondents settled that matter without a finding of liability;⁷ however, they

⁷ The Commission has concluded that one consent order (standing alone) does not establish a history of past violations, *see Telebrands*, 140 F.T.C. at 340. However, the existence of—and violation of—a prior consent order still suggests that this factor weighs against Respondents. In *Telebrands*, the Commission noted only that "one prior consent agreement may say little about the appropriate scope of relief," not that it could never have weight regardless of the context. *See Telebrands*, 140 F.T.C. at 340 (emphasis added). The Commission explained that a consent order is not "a legal admission of wrongdoing," *id.* (quoting *Thompson Med.*, 104 F.T.C. at 833 n.78), which is markedly distinct from the current situation, in which Respondents' admissions establish not only a violation of the FTC Act, but a violation of the prior Stipulated Order. Although the mere existence of a prior consent order is potentially irrelevant under *Telebrands*, the violation of such an order is extremely significant. Nothing in *Telebrands* forecloses the Commission from considering the violation of the prior Stipulated Order when

then violated that order by making the admittedly unsubstantiated health claims for the challenged products. CCFOF ¶¶ 33, 42, 50, 67.

However, even if the Commission were to conclude Respondents’ have a clean “prior history”—which they do not—“[a]ll three factors need not be present” to issue broad relief. *Sears*, 676 F.2d at 392; *see also Telebrands*, 457 F.3d at 362 (affirming Commission conclusion that two factors, seriousness and deliberateness, and transferability, were “sufficient, without more” to justify order); *Kraft*, 970 F.2d at 327 (same).

B. The Commission Has the Authority to, and Should Issue, the Proposed Relief.

The Commission has the authority to, and based on the analysis above should, issue the following relief proposed in the Proposed Order: (1) bans on dietary supplements and on disease claims (Proposed Order §§ I and II); (2) additional fencing-in for products other than supplements (Proposed Order §§ III and IV), and consumer information (Proposed Order § VII); (3) corrective notice to consumers (Proposed Order § VI) and cancellation of any negative option subscription agreements (Proposed Order § VIII); and (4) standard compliance monitoring and recordkeeping provisions (Proposed Order §§ V, IX, X, XI, and XII).

1. The Commission Has the Authority To Issue the Proposed Bans and Should Issue Them Here Because They Are Appropriate and Necessary to the Public Interest.

The Commission has broad discretion to issue appropriate remedial relief, including the power to issue industry bans. Here, the proposed supplement and disease bans are appropriate and necessary to protect the public interest because they are clear and reasonably related to Respondents’ serious, deliberate, and highly transferable wrongdoing.

determining the proper scope of relief. At absolute minimum, the violation of a prior order means that the “history of prior violations” factor does not counsel against broad relief.

a. The Commission Has the Authority to Ban Respondents from Otherwise Legal Activity.

District courts have used their equitable authority under the FTC Act to issue industry-wide bans when appropriate. *See, e.g., DOJ v. Daniel Chapter One*, 650 F. App'x 20, 22-24 (D.C. Cir. 2016) (affirming injunction that “permanently enjoined the defendants from advertising or selling any dietary supplement”); *In re Sanctuary Belize Litig.*, 482 F. Supp. 3d 373, 467 (D. Md. 2020) (“[A] permanent injunction that includes a blanket prohibition against engaging in any kind of real estate activity is warranted, given the cognizable danger of recurring violation and the need for fencing-in to prevent repeat violations and to monitor [the defendant’s] compliance with the law.”) (quotation omitted); *FTC v. Five-Star Auto Club, Inc.*, 97 F. Supp. 2d 502, 536 (S.D.N.Y. 2000) (“In this case, broad injunctive relief . . . including a prohibition on all multi-level marketing is appropriate.”); *see also FTC v. Gill*, 265 F.3d 944, 957 (9th Cir. 2001) (affirming credit repair industry ban); *FTC v. Think Achievement Corp.*, 144 F. Supp. 2d 1013, 1018 (N.D. Ind. 2000) (career advisory goods and services), *aff’d*, 312 F.3d 259 (7th Cir. 2002); *FTC v. Check Investors, Inc.*, No. 03-cv-2115, 2005 U.S. Dist. LEXIS 37199, *8 (D.N.J. July 18, 2005) (banning defendants from debt collection). Such injunctions are permissible because “the law allows for broad discretion in fashioning a remedy for deceptive advertising[.]” *FTC v. Direct Mktg. Concepts, Inc.*, 624 F.3d 1, 14 (1st Cir. 2010); *see also Pantron I*, 33 F.3d at 1102 (9th Cir. 1994) (explaining that 15 U.S.C. § 53(b) “gives the federal courts broad authority to fashion appropriate remedies for violations of the [FTC] Act”).

The Commission’s discretion to fashion cease-and-desist orders is similarly broad. *See, e.g., Colgate-Palmolive*, 380 U.S. at 392 (“It has been repeatedly held that the Commission has wide discretion in determining the type of order that is necessary to cope with the unfair practices found.”); *Jacob Siegel*, 327 U.S. at 611 (“The Commission has wide discretion in its

choice of a remedy deemed adequate to cope with the unlawful practices in this area of trade and commerce.”). Indeed, district courts and the Commission use identical standards to evaluate the proper scope of injunctive relief (in district courts) and cease-and-desist relief (by the Commission). *Compare Kraft*, 970 F.2d at 326 (stating the elements the Commission considers when evaluating fencing-in relief in a cease-and-desist order), *and Telebrands*, 140 F.T.C. at 334 (same), *with Sanctuary Belize*, 482 F. Supp. 3d at 467 (identifying the same three elements as considerations the court weighs when evaluating fencing-in relief in an injunction), *and FTC v. Direct Mktg. Concepts*, 648 F. Supp. 2d at 213 (same), *aff’d*, 624 F.3d 1 (1st Cir. 2010). There is no reason why the district courts can use their discretion to issue an industry ban, but the Commission can only use its equally broad discretion to restrict a respondent’s business within an industry yet not ban it.

b. The Proposed Supplement and Disease Bans Are Appropriate and Necessary to the Public Interest.

The factors discussed above establish a basis for comprehensive relief, including a dietary supplement ban (Proposed Order § I) and a ban on disease claims (Proposed Order § II). These proposed bans are clear and reasonably related to Respondents’ serious, deliberate, and highly transferable wrongdoing. *Stouffer*, 118 F.T.C. at 811. Allowing Respondents to continue marketing supplements or making disease claims threatens further injury to consumers: both financial and physical. In response to the admitted facts establishing serious, deliberate, and readily transferable violations, Respondents offer no mitigating evidence.

With respect to the proposed ban language itself, *see* Proposed Order §§ I-II, it is clear, precise, and plainly sufficient to “be understood by” Respondents. *Cement Inst.*, 333 U.S. at 726. Viewing the admitted and undisputed “circumstances as a whole,” *Stouffer*, 118 F.T.C. at

811-12, the proposed supplement ban is precise and reasonably related to Respondents' wrongdoing.

2. The Commission Can, and Should, Issue the Proposed Additional Fencing-In Relief Because It Is Clear and Reasonably Related to Respondents' Wrongdoing.

To protect the public, the Proposed Order includes additional fencing-in relief beyond the supplement ban. These clear and precise supplemental proscriptions address products other than supplements by preventing unsubstantiated claims with respect to food or drugs, *id.* at § III, and false establishment claims with respect to food or drugs, *id.* at § IV.⁸ As discussed above, disease claims are particularly serious and readily transferable, making an "all disease" prohibition appropriate. Such fencing-in also makes it more difficult for Respondents to evade the order by selling something that technically fails to qualify as a "dietary supplement."

Prohibiting unsubstantiated claims and misrepresented establishment claims with respect to foods and drugs serves a similar end. Respondents' aggressive unsubstantiated advertising includes purported physician endorsements, CCFOF ¶¶ 30, 38, 47, 60, 63, medical imagery, *id.* ¶¶ 29, 63, and consumer testimonials claiming improved health, *id.* at ¶¶ 26-27, 41, 45-46, 62, 65, all of which imply that their actually unsubstantiated claims are established. Given the seriousness of disease claims generally, and the ease with which Respondents could transfer unsubstantiated claims or baseless establishment claims from supplements to similar products such as foods or drugs, the proposed additional fencing-in relief reasonably relates to Respondents' wrongful practices. *See, e.g., Colgate-Palmolive*, 380 U.S. at 395.

Part VII prohibits Respondents from using or disclosing identifying information that consumers wrongfully induced to purchase supplements provided Respondents. This provision

⁸ An "establishment claim . . . suggests that a product's effectiveness or superiority has been scientifically established." *POM Wonderful*, 777 F.3d at 490 (citations omitted).

reasonably relates to Respondents' wrongdoing because Respondents would not have this information but for their material misrepresentations. Part VII is also clear, with simple but detailed requirements regarding what information it covers.

3. The Commission Has the Authority To Issue the Proposed Affirmative Relief and Should Issue It Here Because it is Appropriate and Necessary to the Public Interest.

a. The Commission Has the Authority To Issue the Proposed Affirmative Relief.

The FTC Act authorizes the Commission to issue affirmative relief.⁹ Specifically, 15 U.S.C. § 45(b) empowers the Commission to order respondents to “cease and desist from using such [unlawful] method of competition or such act or practice.” In the same paragraph, § 45(b) specifies that the Commission “shall reopen any such order” under certain circumstances “to consider whether such order (including *any affirmative relief provision* contained in such order) should be altered[.]” (emphasis added). Notably, legislative history associated with the quoted provision contemplates that the Commission may require a respondent “to make certain affirmative disclosures,” and then, should circumstances change, the Commission must “reexamine the original *affirmative relief provision*.” S. REP. NO. 500, 96TH CONG., 1ST SESS. 34 (1979), *reprinted in* 1980 U.S.C.C.A.N. 1102, 1111 (emphasis added).

Unsurprisingly given the statutory language and legislative history, case law analyzing the Commission's authority holds that “the Commission may order affirmative acts.” *Heater v. FTC*, 503 F.2d 321, 324 n.7 (9th Cir. 1974); *see also Warner-Lambert*, 562 F.2d at 756-57 (“[I]t is clear that the Commission has the power to shape remedies which go beyond the simple cease and desist order.”).

Additionally, courts routinely approve corrective notice to consumers, which is a form of affirmative relief. *See, e.g., Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1500 (1st Cir. 1989) (holding that “[t]he requirement that notice be sent to all past purchasers . . . ensures full compliance with the spirit of the Commission’s order”); *AMREP Corp. v. FTC*, 768 F.2d 1171, 1180 (10th Cir. 1985) (explaining that “affirmative disclosures designed to dissipate any misrepresentations that purchasers might have had” due to the respondent’s unlawful conduct are permissible as long as they are “reasonably related” to the “past violations and practices”). Thus, the Commission’s authority unquestionably includes both the power to issue relief beyond the particular practices at issue, and the power to issue affirmative relief.

b. The Commission Should Issue the Proposed Affirmative Relief Because It Is Appropriate and Necessary to the Public Interest.

Pursuant to the Commission’s broad authority to issue affirmative relief, the Proposed Order (Part §VI) requires Respondents to notify consumers who purchased the Challenged Products: (1) the serious disease claims for these products have no scientific basis; and (2) taking these products could interfere with effective treatments. Because Respondents falsely marketed their supplements as treatments for serious diseases, it is critical that they explain their claims are unsubstantiated so that consumers do not continue taking the products and thereby forego efficacious alternatives. This corrective notice is designed to mitigate the risk of injury to consumers and therefore reasonably relates to Respondents’ misrepresentations.

Additionally, because the Proposed Order contains detailed instructions regarding the corrective notice, including attachments illustrating the form of the notice and envelope, the proposed notice is clear. *See* Proposed Order §VI, Atts. A-B.

Also pursuant to the Commission’s broad authority to issue affirmative relief, Part VIII of the Proposed Order requires Respondents to cancel any negative option subscription plan related

to the Challenged Products. This provision reasonably relates to Respondents' wrongdoing because it stops sales that derive from admittedly unsubstantiated representations.¹⁰

4. The Proposed Monitoring and Recordkeeping Provisions Are Clear and Reasonably Related to Respondents' Wrongdoing.

The Proposed Order includes standard compliance monitoring and recordkeeping provisions requiring Respondents to maintain records associated with studies they rely upon to substantiate future claims concerning food or drugs, *see* Proposed Order § V, acknowledge receipt of the order and provide it to principals and personnel, *see id.* at § IX, create and maintain records related to the order, *see id.* at § XI, make basic periodic reports to the Commission, *see id.* at § X, and respond to requests for information from the Commission, *see id.* at § XII. These standard and clear provisions help prevent the wrongful practices at issue from recurring. *See, e.g., Fanning v. FTC*, 821 F.3d 164, 177 (1st Cir. 2016) (finding Commission order acknowledgment and recordkeeping provisions were "permissible fencing-in," but remanding monitoring provisions for additional justification).

III. RESPONDENTS' DEFENSES¹¹

Respondents' legal defenses do not raise any factual questions and are appropriately resolved at this time. Respondents contend: (1) the FTC's administrative process violates the Fifth Amendment of the U.S. Constitution because it denies Respondents due process; and (2) provisions limiting the removal of Commissioners and Administrative Law Judges violate Article II and the Constitution's separation of powers. Neither argument has any merit. Finally,

¹⁰ Those sales should halt under the supplement ban, but the negative option cancellation requirement provides additional protection.

¹¹ Respondents originally asserted nine legal defenses in this matter, but later narrowed their defenses to two constitutional arguments. *See* Answer (Dec. 4, 2020), ¶¶ 23-31; Amended Answer (Mar. 30, 2021), ¶ 1.

while Respondents have not explicitly made First Amendment arguments, we address them here so that they can be fully vetted.

A. Under Clear Supreme Court Precedent, the Commission’s Adjudicative Procedure Complies With Due Process.

Respondents first contend the FTC’s administrative process violates the Fifth Amendment right to due process because “the FTC’s combined role of prosecutor, trial judge, jury, and appellate court in the administrative proceedings” deprives them of a neutral decision-maker.¹² Respondents’ Response to Complaint Counsel’s Statement of Additional Material Facts, at 15 (June 1, 2021) (“Response”). This argument fails in light of the Supreme Court’s decision in *Withrow v. Larkin*, 421 U.S. 35 (1975). In *Withrow*, the Supreme Court held “the combination of investigative and adjudicative functions does not, without more, constitute a due process violation[.]” *Id.* at 58. “The combination of investigative and judicial functions within an agency has been upheld against due process challenges, both in the context of the FTC and other agencies.” *Gibson v. FTC*, 682 F.2d 554, 560 (5th Cir. 1982) (citations omitted). Consequently, “[i]t is uniformly accepted that many agencies properly combine the functions of prosecutor, judge and jury,” *Touche Ross & Co. v. SEC*, 609 F.2d 570, 581 (2d Cir. 1979), and Respondents’ argument is contrary to well-established principles of administrative law.

B. Under Clear Supreme Court Precedent, the Commission’s Independent Structure is Consistent with Article II and the Separation of Powers.

Respondents also contend this proceeding is unlawful because the FTC’s adjudicative process violates the Constitution’s Article II/separation of powers requirement. Specifically, Respondents assert that the “Constitution did not authorize Congress to create the FTC as a ‘quasi-legislative’ or ‘quasi-judicial’ body whose leadership is not subject to at-will removal by

¹² The Commission previously rejected this argument. *See* July 30 Order. However, Complaint Counsel reiterate our arguments to ensure the record is complete.

any branch of government.” *See* 15 U.S.C. § 41; Response at 8-9, 12. However, the Supreme Court squarely rejected this argument in *Humphrey’s Executor*, 295 U.S. 602 (1935), holding the for-cause removal provisions applicable to FTC Commissioners did not violate the Constitution’s vesting of executive authority in the President or the separation of powers. *Id.* at 629-32. In that case, the Court reasoned the FTC’s duties as an administrative agency were “quasi-legislative and quasi-judicial” rather than purely “executive,” *id.* at 624, and, therefore, Congressional authority to prohibit the removal of FTC Commissioners except for cause “cannot well be doubted,” *id.* at 629.

Faced with this clear authority, Respondents contend the Supreme Court “wrongly decided” *Humphrey’s Executor*, and therefore, is likely to overturn this long-standing precedent. Response at 8-9. Notwithstanding Respondents’ speculation about what the Supreme Court should, or will do, even recent decisions invalidating removal-protection provisions for single executives (not members of commissions) have reinforced the fact that *Humphrey’s Executor* remains good law, at least with respect to independent commissions. *See Seila Law, LLC v. CFPB*, 140 S. Ct. 2183, 2192 (2020) (explaining that *Humphrey’s Executor* establishes an “exception[] to the President’s unrestricted removal power” that allows Congress to “create expert agencies led by a *group* of principal officers removable by the President only for good cause”) (Supreme Court’s emphasis); *Free Enter. Fund v. Public Co. Accounting Oversight Bd.*, 561 U.S. 477, 483 (2010) (discussing, but not altering, the principle from *Humphrey’s Executor* that Congress can, “under certain circumstances, create independent agencies run by principal officers appointed by the President, whom the President may not remove at will but only for good cause”).

Consequently, *Humphrey’s Executor* disposes of Respondents’ Article II/separation of powers argument.

C. The Proposed Supplement and Disease-Claim Bans Do Not Violate the First Amendment.

1. The Proposed Bans Satisfy the *Central Hudson* Test.

The Supreme Court distinguishes between misleading commercial speech, potentially misleading commercial speech, and truthful commercial speech. *See, e.g., In re R.M.J.*, 455 U.S. 191, 203 (1982). Misleading speech receives no First Amendment protection. *See id.* However, the government also may prohibit potentially misleading speech, and even truthful speech, if the proposed regulation satisfies the *Central Hudson* test. *See id.*; *see also Bellion Spirits, LLC v. United States*, 393 F. Supp. 3d 5, 24 (D.D.C. 2019) (applying *Central Hudson* to “potentially misleading” speech), *aff’d*, No. 19-5252, 2021 WL 3438533 (D.C. Cir. Aug. 6, 2021); *Novartis Corp.*, 127 F.T.C. at 715 (applying *Central Hudson* to “[n]onmisleading commercial speech”). Under *Central Hudson*, the commercial speech prohibition must: (1) involve a substantial government interest; (2) directly advance that interest; and (3) not involve restrictions more extensive than necessary to serve that interest. *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 566 (1980). As discussed below, the proposed supplement industry and disease-claim bans easily meet this standard.

First, the Commission’s interest in consumer protection is substantial. *See, e.g., Edenfield v. Fane*, 507 U.S. 761, 769 (1993) (explaining that the governmental “interest in ensuring the accuracy of commercial information in the marketplace is substantial”); *Heffner v. Murphy*, 745 F.3d 56, 92 (3d Cir. 2014) (noting that the “interest in consumer protection is undoubtedly substantial”); *Mainstream Mktg. Servs., Inc. v. FTC*, 358 F.3d 1228, 1246 (10th Cir. 2004) (characterizing the interest in “consumer protection” as “substantial”). Accordingly, the supplement ban meets the first *Central Hudson* prong. *See POM Wonderful*, 777 F.3d at 501 (holding that Commission “remedial order” satisfied “*Central Hudson*’s first prong”).

Second, to satisfy *Central Hudson*'s requirement that the bans "directly advance[] the governmental interest" in consumer protection, *see Central Hudson*, 447 U.S. at 566, the bans need only "alleviate" the potential that Respondents would otherwise deceive consumers "to a material degree," *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 626 (1995) (citation omitted). *See also Edenfield*, 507 U.S. at 771 ("alleviate . . . to a material degree") (citations omitted). Because the proposed bans directly halt Respondents' representations, and therefore misrepresentations, concerning supplements and their alleged medical properties entirely, they directly advance the Commission's interest in protecting consumers from pernicious, false claims. Thus, the bans more than satisfy *Central Hudson*'s second prong.

Third, the final *Central Hudson* prong—that the regulation is not more extensive than necessary, *see* 447 U.S. at 566—is considerably less stringent than the least-restrictive-means standard. *Board of Trustees of the State University of New York v. Fox*, 492 U.S. 469, 478 (1989). Requiring that the Commission employ only the "least restrictive means" would not reflect the government's "ample scope of regulatory authority" concerning commercial speech, which receives only "a limited measure of protection, commensurate with its subordinate position in the scale of First Amendment values[.]" *Id.* at 477.

Instead, the Constitution requires only "a fit" between the government's "ends and the means chosen to accomplish those ends, a fit that is not necessarily perfect, but reasonable." *Id.* at 480 (quotations omitted).¹³ The proposed supplement ban "fits" because it covers only a

¹³ Courts have upheld Commission orders that prohibit nondeceptive or potentially truthful speech as part of more general prohibitions designed to prevent deception. *See Litton Indus., Inc. v. FTC*, 676 F.2d 364, 373-74 (9th Cir. 1982) (affirming order with modification; noting that "[e]ven truthful commercial speech can be regulated if the government's interest in regulation is substantial and if the regulation directly advances that interest and is not more extensive than necessary"); *United States v. Reader's Digest Ass'n*, 662 F.2d 955, 965 (3d Cir. 1981) (affirming order that prohibited certain speech without requiring proof of actual deception; "Any remedy formulated by the FTC that is reasonably necessary to the prevention of future violations does not impinge upon constitutionally protected commercial speech."). Likewise, District Courts approve orders that substantially restrict lawful speech when the orders satisfy *Central Hudson*. *See, e.g., FTC v. Trudeau*, 662 F.3d 947, 953 (7th Cir. 2011) (rejecting

precisely-defined product category (dietary supplements), *see* Proposed Order at 3. Likewise, the ban covers only commercial transactions—Respondents may promote supplements for non-economic reasons unencumbered by the Proposed Order. Furthermore, the proposed ban does not prevent other supplement manufacturers from making truthful claims, so truthful information about supplements can still pervade the marketplace.

Finally, with respect to both bans, Respondents’ serious and deliberate violations establish their potential to deceive consumers in the future. As a result, *Central Hudson*’s third prong is satisfied because there is a reasonable fit between the bans (covering Respondents’ potential future marketing of supplements and disease claims) and the goals (preventing Respondents’ potential future deceptive marketing of supplements and deceptive disease claims). Put another way, banning Respondents from supplement sales and disease claims is constitutional because the record establishes that further supplement marketing or disease claims Respondents make likely would constitute “communication more likely to deceive the public than inform it[.]” *Central Hudson*, 447 U.S. at 563.

2. The Proposed Bans Are Not Unlawful Prior Restraints.

Although the proposed bans prohibit Respondents from making future truthful claims about supplements or diseases, they do not constitute an unlawful prior restraint. The Supreme Court has “observed that commercial speech is such a sturdy brand of expression that traditional prior restraint doctrine may not apply to it.” *Central Hudson*, 447 U.S. at 571 n.13 (citations omitted); *see also Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Coun., Inc.*, 425

First Amendment challenge to “the requirement that [the defendant] post a bond before he participate in any infomercial, *misleading or not.*”) (Court’s emphasis). Finally, the Supreme Court recognizes “[t]he constitutional equivalence of compelled speech and compelled silence[.]” *Riley v. Nat’l Fed’n of the Blind of N. Carolina, Inc.*, 487 U.S. 781, 796-97 (1988). Put differently, there is no constitutional difference between “compelled silence”—a ban—and notice requirements (compelled speech) that, as discussed above, courts have routinely affirmed the Commission’s authority to impose.

U.S. 748, 772 n.24 (1976) (explaining that the unique attributes of commercial speech “may also make inapplicable the prohibitions against prior restraints”). Noting the Supreme Court’s reservations, lower courts have generally declined to use the rules governing prior restraints to evaluate commercial speech restrictions. *See, e.g., Bosley v. Wildwett.com*, 310 F. Supp. 2d 914, 930 (N.D. Ohio 2004) (“The vast majority of circuits . . . do not apply the doctrine of prior restraints to commercial speech.”) (citations omitted); *Puerto Rico Tele-Com, Inc. v. Ocasio Rodriguez*, 747 F. Supp. 836, 842 (D.P.R. 1990) (“[I]t seems clear at this point that the strong presumption against the validity of prior restraints does not apply in the commercial speech context.”) (citations omitted).

Additionally, regardless of whether the regulation at issue involves commercial speech, the Supreme Court distinguishes between “prior restraints,” which typically involve governmental pre-approval of speech and can raise constitutional questions, and “subsequent punishments,” or responses to speech already made. *See, e.g., Alexander v. United States*, 509 U.S. 544, 550 (1993) (noting the distinction, “solidly grounded in our cases, between prior restraints and subsequent punishments”). For example, in a First Amendment challenge to the Telemarketing Sales Rule (“TSR”), nonprofit organizations that used telemarketing to fundraise alleged “that the TSR is an unconstitutional prior restraint because it ‘silences’ the speech of nonprofit organizations that use professional telemarketers.” *National Fed’n of Blind v. FTC*, 303 F. Supp. 2d 707, 723 (D. Md. 2004), *aff’d sub nom. Nat’l Fed’n of the Blind v. FTC*, 420 F.3d 331 (4th Cir. 2005). From the challengers’ perspective, “any regulation that inhibits or chills protected speech in some way is a prior restraint[.]” *Id.*

However, as the court explained, this view “misunderstands the meaning of ‘prior restraint’ and ignores the long-held distinction between prior restraints and subsequent punishments. While it is presumptively unlawful to bar speech before it occurs, First

Amendment law fully accepts the ability to penalize speech that occurred in the *past*, after it has been challenged and the speaker has had the opportunity for appellate review.” *Id.* at 723 (Court’s emphasis) (citations omitted); *see also Alexander*, 509 U.S. at 550; *cf. Southeastern Promotions, Ltd. v. Conrad*, 420 U.S. 546, 559 (1975) (“[A] free society prefers to punish the few who abuse rights of speech after they break the law than to throttle them and all others beforehand.”). In the TSR context, “it is only after the speech is uttered that, if the telemarketer has violated the TSR, he may be brought into court by the state or a private individual.”¹⁴ *National Fed’n*, 303 F. Supp. 2d at 723 (citations omitted). As a result, the TSR prohibition at issue qualified as a “typical subsequent punishment.” *Id.*

This reasoning applies equally to Commission orders, including the one at issue. *See, e.g., Jay Norris, Inc. v. FTC*, 598 F.2d 1244, 1252 (2d Cir. 1979) (“[B]ecause the FTC here imposes the requirement of prior substantiation as a reasonable remedy for past violations of the Act, there is no unconstitutional prior restraint of petitioners’ protected speech.”); *Sears*, 676 F.2d at 399 (“[T]he Commission may require prior reasonable substantiation of product performance claims after finding violations of the Act, without offending the [F]irst [A]mendment.”) (citation omitted). The proposed cease-and-desist order does not enjoin Respondents from anything—the Commission cannot issue injunctions—but provides a basis for a subsequent punishment should Respondents disseminate certain speech after the Commission issues the order. *See* 15 U.S.C. § 45(l) (permitting Department of Justice to seek penalties for violations and authorizing, in a subsequent action seeking penalties, district courts to “grant

¹⁴ *See also Nat’l Fed’n*, 420 F.3d at 350 (“Traditionally, unconstitutional prior restraints are found in the context of judicial injunctions or a licensing scheme that places ‘unbridled discretion in the hands of a government official or agency.’ Here, by contrast, it is only after the speech is uttered that a violation of the TSR can occur and sanctions can be imposed.”) (quoting *FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 225-26 (1990)).

mandatory injunctions”); *see also Gibson v. Texas Dep’t of Ins.–Div. of Workers’ Comp.*, 700 F.3d 227, 234-35 (5th Cir. 2012) (finding that statute limiting use of words “Texas” and “Workers’ Comp” in certain contexts was not a prior restraint; “Because the instant regulation . . . penalizes past speech, as opposed to barring speech in the future, it is not a prior restraint[.]”) (quotations omitted); *Shelton v. Newberry Cty. Sch. Dist.*, No. 8:16-cv-3728, 2018 WL 4573094, *11 (D.S.C. May 17, 2018) (finding that prior restraint doctrine did not apply to school district staff conduct policy regulating speech “as under that policy it is only after the speech is uttered that violation of the policy can occur”) (citation omitted) (mag. op.), *report and recommendation adopted*, No. 8:16-cv-3728, 2018 WL 3490908 (D.S.C. July 20, 2018). For this reason as well, the proposed supplement bans are not a potentially unlawful prior restraint.

IV. CONCLUSION

For the above reasons, Complaint Counsel respectfully requests that the Commission issue its final decision finding Respondents liable for violations of Sections 5 and 12 of the FTC Act based on the false and deceptive representations in their mailers for each of the Challenged Products disseminated after January 16, 2018. Complaint Counsel also requests that the Commission enter the attached proposed cease and desist order.

Respectfully submitted,
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CERTIFICATE OF SERVICE

I certify that I served a copy of Complaint Counsel's Brief and the attached Proposed Order via electronic mail today.

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I also served one electronic copy via the Administrative E-Filing System and one electronic courtesy copy to the **Office of the Secretary** via email to ElectronicFilings@ftc.gov.

I served one electronic courtesy copy via email to the **Office of the Administrative Law Judge**:

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