

---

SUPPLEMENT TO ASSIGNMENT

The attached document is assigned to  
Commissioner  
Slaughter  
for review and presentation to the Commission.

---

Supplement to Assignment Date: 09/10/2021  
Original Assignment Date: 08/25/2021

Document Number: 602392

Matter Name: HEALTH RESEARCH LABORATORIES LLC ET AL

Matter Number: D09397 Issue Number: 4

Staff Contact: TABOR, APRIL

Document Title: ASSIGNMENT OF RESPONDENTS' OPPOSITION TO SUMMARY  
DISPOSITION AND REPLY FINDINGS OF FACT,  
CONCLUSIONS OF LAW, AND BRIEF

In the transfer of information from this sheet to a Commission circulation form, please note that the document number shown above should be entered on the Commission circulation form as the RELATED DOCUMENT NUMBER. In addition, please note that the document title shown above should NOT be identical to the document title on the circulation form. Instead, the document title on the circulation form should begin with one of the following three phrases:

"Motion to"

"For Information Circulation of" OR

April J. Tabor

---

Target Motion Date: 10/12/2021

PUBLIC

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

**RESPONDENTS' OPPOSITION TO SUMMARY DISPOSITION AND REPLY  
FINDINGS OF FACT, CONCLUSIONS OF LAW, AND BRIEF**

Pursuant to the Commission's July 30, 2021 Order,<sup>1</sup> Respondents Health Research Laboratories, LLC ("HRL"), Whole Body Supplements, LLC ("WBS"), and Kramer Duhon (collective "Respondents") provide the following Opposition to Summary Disposition and Reply Findings of Fact, Conclusions of Law, and Brief.

---

<sup>1</sup> The Commission's July 30, 2021 Order authorized Respondents to file their opposition to summary judgment and their reply findings of fact, conclusions of law, and brief in one document. This filing is intended to respond to all motions, briefs, affidavits, and proposed orders filed by Complaint Counsel on August 20, 2021.

PUBLIC

TABLE OF CONTENTS

I. INTRODUCTION ..... 1

II. FACTS..... 1

    A. Respondents’ Compliance with 2015 Civil Investigative Demand ..... 1

    B. Respondents’ Compliance with Consent Judgment..... 2

    C. FTC Searches for Another Dispute..... 3

    D. The “Aged Garlic Extract” Dispute. .... 4

    E. FTC’s Motion for Contempt..... 5

    F. FTC’s Administrative Complaint..... 7

    G. Reasons Why Respondents Elected Not to Contest the Facts Alleged in the Complaint. .... 9

        1. The FTC’s Unfair and Biased Administrative Process..... 10

        2. The Financial Toll of Fighting a Government Agency. .... 12

III. ARGUMENT AND OBJECTIONS..... 12

    A. No Evidence or Argument that the Challenged Practices Are Likely to Reoccur..... 12

    B. Respondents’ Statement of Disputed Facts. .... 13

    C. Objections to Proposed Conclusions of Law. .... 16

        1. No Statutory Authority for Conclusions of Law. .... 16

        2. Disguised Findings of Fact Within Purported Conclusions of Law. .... 17

        3. Relitigation of Maine Contempt Motion is Barred. .... 18

    D. Objections to Relief Requested by Complaint Counsel. .... 19

        1. Even if the Commission Could Issue the Requested Relief, Complaint Counsel’s Proposed Order Is Impermissibly Vague, Overbroad, and Unconstitutional. .... 20

**PUBLIC**

- 2. Sections I and II: The FTC Death Penalty Cease and Desist.....20
- 3. Sections III, IV and V: FTC’s Request for Unnecessary and Unreasonable Additional Prohibitions on the Sale of Food and Drugs..... 23
- 4. Section VI through XII: Statutorily Unauthorized Obligations. .... 24
- E. Other Objections to this Part 3 Administrative Process. ....28
  - 1. Violation of Article II of the United States Constitution and the Constitution’s Separation of Powers. ....28
  - 2. The FTC’s request for a mandatory injunction is beyond the permissible scope of relief provided by 15 U.S.C. § 45(b).....29
  - 3. Violation of Respondents’ Due Process Rights. ....29
  - 4. Violation of the FTC’s Rules and Respondents’ Constitutional Rights. 30
- IV. CONCLUSION AND PRAYER..... 31

PUBLIC

## I. INTRODUCTION

Respondents have repeatedly argued that, pursuant to 16 C.F.R. § 3.12(b) as previously interpreted by the FTC (74 Fed. Reg. 1804, 1808 (Jan. 13, 2009)), the Complaint and the Answer provide the record on which the Commissions “shall issue” a decision. On July 30, 2021, the Commission ruled that Complaint Counsel may present facts “beyond the Complaint” and authorized Complaint Counsel to file a motion for summary disposition under 16 C.F.R. § 3.24. In response to the Commission’s Order, Complaint Counsel filed numerous affidavits and 27-page brief. Respondents file this opposition pursuant to 16 C.F.R. § 3.24(a)(2).

## II. FACTS

As set forth in the Declaration of Kramer Duhon,<sup>1</sup> which is incorporated herein by reference, Respondents have worked diligently for more than six years to comply with the FTC’s never-ending requests for information and documents. Complaint counsel’s argument that the alleged violations of the FTC Act were committed deliberately and intentionally is contradicted by Respondents’ long history of compliance with the FTC’s numerous requests.

### A. Respondents’ Compliance with 2015 Civil Investigative Demand.

The current dispute with the FTC traces its origins to a Civil Investigative Demand served by the FTC on January 7, 2015. *See* RX 1. For almost three years, Respondents

---

<sup>1</sup> *See* RX 1 (Declaration of Kramer Duhon).

**PUBLIC**

repeatedly complied with the FTC's changing requests for information and documents. *See* RX 1. Respondents spent hundreds of hours and hundreds of thousands of dollars diligently answering the FTC's interrogatories and providing documents requested by the FTC. *See* RX 1. As explained in more detail below, Respondents provided names, addresses, and telephone numbers for their suppliers and vendors so that the FTC could verify the information provided was accurate and complete. *See id.* Respondents provided multi-year spreadsheets that included detailed product and financial information. *See id.* Over the course of several years, Respondents provided thousands of pages of documents and answered hundreds of written interrogatories. *See id.* Providing the information and documents requested by the FTC was all-consuming because the requests constantly changed and evolved over time. *See id.*

**B. Respondents' Compliance with Consent Judgment.**

By November 2017, Respondents thought that the issues with the FTC would be finally resolved through an agreed order submitted to a federal court in Maine. *See* RX 1. On November 30, 2017, the FTC and the State of Maine filed their Complaint against Respondents in the United States District Court for the District of Maine, along with a Joint Motion to Enter Final Judgment. On January 15, 2018, the Court signed a Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief (the "Consent Judgment"). *See* RX 1.

The Respondents actively tried to comply with the requirements of the Consent Judgment. Examples include the following:

**PUBLIC**

a. The Consent Judgment banned Respondents from making any representations regarding weight loss in connection with the sale of any Dietary Supplement, Food, or Drug. Respondents stopped selling all weight-loss products before the Consent Judgment was signed and, after the date of the Consent Judgment, Respondents have not made any of the “banned weight-loss claims” referenced in paragraph I of the Order.

b. The Consent Judgment banned Respondents from making any representations regarding joint-related disease claims and Alzheimer’s disease, memory, and cognitive performance claims in connection with the sale of any Dietary Supplement, Food, or Drug. Respondents stopped selling all such products before the Consent Judgment was signed and, after the date of the Consent Judgment, Respondents have not made any of the “prohibited representations” regarding “other weight-loss claims, joint-related disease claims, and Alzheimer’s Disease, memory, or cognitive performance claims” referenced in paragraph II of the Order.<sup>2</sup>

Respondents took many other actions to comply with the Consent Judgment, including preserving records, making required disclosures to customers and the FTC, obtaining informed consent for billing, honoring refunds, providing a simple mechanism for consumers to stop recurring charges, providing periodic compliance reports, and numerous other activities. *See* RX 1.

**C. FTC Searches for Another Dispute.**

Respondents’ hope of a final resolution with the FTC soon faded. In April 2018, three months after the entry of the Consent Judgment, the FTC started another round of interrogatories and document requests. *See* RX 1. For the next 18 months, Respondents responded to request after request for information and documents. *See* RX 1. Respondents again provided thousands of pages of documents and answered dozens of interrogatories.

---

<sup>2</sup> *See* RX 1.

PUBLIC

*See* RX 1. After scouring the Respondents' records for 18 months, the FTC eventually found another area of dispute.

**D. The “Aged Garlic Extract” Dispute.**

The FTC's current complaint, which originated shortly before the filing of the Contempt Motion (as defined below), is primarily about black garlic. Two of the four products at issue, Black Garlic Botanicals and BG18 (“**Black Garlic Products**”), are the same product under different labels and account for roughly 70 percent of the revenue at issue. *See* RX 1.

The Black Garlic Products contain 1,200 mg of black garlic. *See* RX 1. Black garlic is made by treating garlic cloves at high temperature and humidity for a period of time. *See* RX 1. The process turns the garlic cloves to purple or black and eliminates the smell and taste of fresh garlic. *See* RX 1. Because all black garlic is aged, black garlic is frequently referred to as “aged black garlic.” *See* RX 1.

The FTC never contended that the Black Garlic Products did not contain the represented amounts of black garlic or that the products contained any substance that is harmful to humans. *See* RX 1. In other words, this is not a case of Respondents selling supplements that did not contain black garlic or a case where Respondents sold supplements that contained harmful compounds. *See* RX 1. FTC also did not dispute the existence of valid and reputable scientific studies that substantiated the health benefits of aged garlic.<sup>3</sup>

---

<sup>3</sup> In fact, in connection with the Motion for Contempt, the FTC submitted the Expert Report of Frank M. Sacks, M.D., a Professor of Medicine at Harvard Medical School, who acknowledged that the studies supplied by Respondents of aged garlic extract “reported favorable effects on coronary calcium scores” and that one



**PUBLIC**

The FTC's complaints regarding the Black Garlic Products were more technical and nuanced. The FTC's argument was the "aged garlic extract" and "aged black garlic" were not identical, so Respondents' scientific studies—showing the health effects of aged garlic—were not substantiation for any statements about aged black garlic. *See* RX 1.

There is no material difference in aged black garlic vs aged garlic extract. However, out of an abundance of caution, Respondents did not send any mailers or advisements regarding Black Garlic Products the FTC first raised this issue. *See* RX 1. All of the advertisements at issue in this proceeding were sent prior to September 2019. *See* RX 1. In other words, immediately after the FTC first raised its aged garlic extract argument, the Respondents ceased selling the Black Garlic Products.

**E. FTC's Motion for Contempt.**

On December 17, 2019, the FTC and the State of Maine filed a Motion for 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 ("**Contempt Motion**") in the United States District Court for the District Court of Maine, alleging a violation of only one particular subsection of the 31-page Consent Judgment. *See* RX 1. At the same time, the FTC requested that the Court

---

study "showed a favorable effect of aged garlic extract on systolic blood pressure." *See* RX 2 (Contempt Motion in *FTC, et al. v. Health Research Laboratories, LLC, et al.*, Case No. 2:17-cv-00467-JDL (D. Maine) Dkt. No. 21, PageId# 366-67).

PUBLIC

modify the Consent Judgment to include additional prohibitions that were *not* in the original Consent Judgment. *See* RX 1.<sup>4</sup>

After extensive briefing over several months and a hearing, on August 12, 2020, the Court denied the FTC's Motion for an Order to Show Cause. The Court found that Section II.H of the FTC's Consent Judgment was "facially ambiguous" and, therefore, the allegations in the FTC's Contempt Motion "fail to support a finding of civil contempt" under Section II.H of the Consent Judgment.<sup>5</sup>

Pursuant to the FTC's request, the Court granted the FTC until October 31, 2020, to seek leave to file an amended motion for Order to Show Cause. *See* RX 1. The FTC did not seek leave to amend its motion. *See* RX 1. Instead, on November 13, 2020, the FTC filed an Administrative Complaint with the FTC, seeking a cease and desist order to prevent Respondents from "disseminat[ing] or caus[ing] to be disseminated advertising and promotional materials"<sup>6</sup> for four supplements that the Commission contends were "not substantiated at the time the representations were made."<sup>7</sup> The Administrative Complaint concerned the exact same alleged acts and practices regarding the same four supplements that were the subject of the Contempt Motion.

---

<sup>4</sup> *FTC, et al. v. Health Research Laboratories, LLC, et al.*, Case No. 2:17-cv-00467-JDL (D. Maine), Dkt. No. 22, PageId# 587.

<sup>5</sup> RX 3 (Order).

<sup>6</sup> *See* Complaint ¶¶ 7, 9, 11, and 13.

<sup>7</sup> *See* Complaint ¶¶ 15, 17, 19, and 21.

PUBLIC

**F. FTC's Administrative Complaint.**

The filing of the Administrative Complaint was unnecessary and not statutorily authorized. The alleged act or practice that was the subject of the Complaint had ceased more than a year prior to the filing of the Administrative Complaint.<sup>8</sup> Further, if the FTC wanted certain advertising and marketing to cease, the FTC could have accomplished this purpose through a simple written request. *See* RX 1. The long history of Respondents' compliance with the FTC's numerous requests demonstrates that Respondents would have ceased the advertisements if the FTC would have made the request before filing this proceeding. *See* RX 1.

Despite the FTC's stated policy to conduct these administrative proceedings "expeditiously,"<sup>9</sup> Complaint Counsel has had no interest in resolving this proceeding expeditiously and obtaining the statutorily-authorized cease and desist order. Consequently, Respondents were forced to try to expeditiously resolve this proceeding without Complaint Counsel's cooperation. *See* RX 1. On January 13, 2021, Respondents filed a Motion for Acceptance of Contested Cease-and-Desist Order, requesting that the FTC enter a binding cease and desist order that granted the following relief to the FTC:

Respondents shall "cease and desist" from disseminating or causing to be disseminated all advertising or promotional materials for all dietary supplement products referenced in the Complaint (i.e., Black Garlic

---

<sup>8</sup> As the FTC's own evidence shows, Respondents voluntarily ceased the advertising and marketing long before the Administrative Complaint was filed. *See* CCX2 – Averill Affidavit, Attachment F (showing that the last advertisement was sent on August 22, 2019). The Contempt Motion was filed on December 17, 2019. The Administrative Complaint was filed on November 13, 2020.

<sup>9</sup> *See* 16 C.F.R. 3.1 ("the Commission's policy is to conduct such proceedings expeditiously.").

## PUBLIC

Botanicals, BG18, The Ultimate Heart Formula, and Neupathic), as well as any substantially similar products.

Respondents shall cease and desist from selling or causing to be sold all dietary supplement products referenced in the Complaint (i.e., Black Garlic Botanicals, BG18, The Ultimate Heart Formula, and Neupathic), as well as any substantially similar products.

The terms “cease and desist” are intended to have the same meaning and scope as such terms are used in Sections 5(a) and 12 of the FTC Act, 15 U.S.C. § 45(a) and 52.<sup>10</sup>

To end this proceeding and avoid unnecessary costs, Respondents sought to have the Administrative Law Judge and the Commission enter a cease and desist order *against the Respondents*. Respondents made this request early in the case—only five weeks after they filed their Answer. Remarkably, Complaint Counsel *opposed* the entry of any cease-and-desist order and did not propose an alternative cease and desist order.<sup>11</sup>

On February 1, 2021, ALJ Chappell entered an Order Denying Respondents’ Motion for Acceptance of Contested Stipulated Cease and Desist Order. In response to this ruling, Respondents filed a motion for leave to elect not to contest the material allegations of fact in the Complaint, as permitted by 16 C.F.R. § 3.12(b)(2). The FTC opposed Respondents’ decision not to contest the material factual allegations *in the FTC’s own Complaint* and, in an effort to prevent the quick resolution of this administrative

---

<sup>10</sup> See Respondents’ Motion for Acceptance of Contested Stipulated Cease-and-Desist Order, filed January 13, 2021.

<sup>11</sup> See Complaint Counsel’s Opposition to Respondents’ Motion for Self-Imposed Cease-and-Desist Order, filed January 25, 2021; *see also* Certificate of Conference with Respondents’ Motion for Acceptance of Contested Stipulated Cease-and-Desist Order, filed January 13, 2021 (requesting that, if the FTC could not agree to the proposed cease and desist order, whether there was other language the FTC would propose for a cease and desist order).

PUBLIC

proceeding, Complaint Counsel sought to amend the Complaint to include numerous other allegations.<sup>12</sup>

On March 12, 2021, ALJ Chappell entered an Order Denying Complaint Counsel's Motion to Amend the Complaint. ALJ Chappell noted that "Complaint Counsel's seeking the proposed amendments, in reaction to Respondents' election under Rule 3.12(b)(2), appears to be more of a strategic effort to counter Respondents' effort to bring this case to a resolution, than an effort to facilitate a determination of this case on the merits."<sup>13</sup>

On March 30, 2021, Respondents filed their Amended Answer and, pursuant to 16 C.F.R. § 3.12(b), elected not to contest the material factual allegations in the Complaint.

**G. Reasons Why Respondents Elected Not to Contest the Facts Alleged in the Complaint.**

Complaint Counsel has argued that Respondents' election not to contest the facts alleged in the Complaint is evidence of the deliberateness of Respondents' conduct. Complaint Counsel is wrong. Respondents elected not to contest the material facts alleged in the Complaint because: (a) based on historical data, Respondents believed that this Part 3 Administrative Proceeding is not a fair and impartial process,<sup>14</sup> so Respondents had no hope of prevailing, regardless of the evidence presented; and (b) Respondents came to the

---

<sup>12</sup> See Complaint Counsel's Opposition to Motion to Amend Answer and Cross Motion to Amend Complaint, filed on February 24, 2021.

<sup>13</sup> See Order Denying Complaint Counsel's Motion to Amend the Complaint, filed on March 12, 2021.

<sup>14</sup> Respondents disclosed this reason when they elected not to contest the facts alleged in the Complaint. See Motion to Amend Answer, filed February 12, 2021 ("Respondents do not believe that the Part 3 administrative process is fair, impartial, or constitutional.").

PUBLIC

realization that Respondents could not afford to continue business operations while constantly responding to the FTC's endless, repetitive actions.

**1. The FTC's Unfair and Biased Administrative Process.**

According to information on the FTC's website, once the FTC Commissioners approve a complaint, the FTC Commissioners have historically used their veto appellate power to ensure that they have a 100 percent success rate on the approved Complaint.<sup>15</sup> In 2015, former FTC Commissioner Wright observed:

The FTC has voted out a number of complaints in administrative adjudication that have been tried by the administrative law judges in the past nearly twenty years. In each of those cases, after the administrative decision is appealed to the Commission, the Commission has ruled in favor of FTC staff and found liability. **In other words, in 100 percent of cases where the administrative law judge ruled in favor of the FTC staff, the Commission affirmed liability; and in 100 percent of the cases in which the administrative law judge [ ] found no liability, the Commission reversed. This is a strong sign of an unhealthy and biased institutional process.**<sup>16</sup>

Based on the comments on the FTC's website by former Commissioner Wright and information derived from the FTC's website, it was apparent to Respondents that no one had won a Part 3 administrative proceeding in 25 years. *See* RX 1. Consequently, it made no sense to continue paying hundreds of thousands of dollars to defend an administrative cease and desist action, particularly one that involved marketing and advertising that

---

<sup>15</sup> *See* RX 4 (Joshua D. Wright, *Section 5 Revisited: Time for the FTC to Define the Scope of its Unfair Competition Authority* at 6 (2015)) and RX 5 (Chart of post-2015 FTC administrative cases compiled by others from public information the FTC website).

<sup>16</sup> RX 4 (Joshua D. Wright, *Section 5 Revisited: Time for the FTC to Define the Scope of its Unfair Competition Authority* at 6 (2015) (emphasis added). The FTC's success rate post-2015 appears to have continued. *See* RX 5 (Chart prepared by others from publicly available data on the FTC's website).

PUBLIC

Respondents had ceased more than a year prior to the filing of the Administrative Complaint.

**2. The Financial Toll of Fighting a Government Agency.**

From January 2015 through January 2021 (when Respondents filed their Motion to Amend the Answer), Respondents paid an \$800,000 settlement, approximately \$235,000 in legal fees to Olshan for FTC-related issues and advertising review, \$71,000 to Olshan's medical researcher (Inna Yegorova), \$82,000 to other consultants, and roughly \$152,000 in legal fees for the defense of the Contempt Motion and this administrative proceeding. *See* RX 1. In addition, HRL and WBS's small staff spent vast amounts of time responding to the FTC's seemingly never-ending series of questions and document requests. *See* RX 1. Further, considering the experts necessary to defend the action and the extensive discovery sought by the FTC, Respondents could not continue to incur the financial burden of fighting the FTC. *See* RX 1. The expenses far exceeded the net profits from the four supplements in question.<sup>17</sup> Eventually, Respondents decided that the best course of action was for the Respondents to cease all business operations for all products. HRL and WBS have permanently ceased all operations and have no intention of continuing any future business operations.

---

<sup>17</sup> HRL and WBS

PUBLIC

### III. ARGUMENT AND OBJECTIONS

#### A. No Evidence or Argument that the Challenged Practices Are Likely to Reoccur.

The filing of the Administrative Complaint was unnecessary. Section 5 is a forward-looking provision concerned with remedying ongoing conduct that poses a current risk to consumers. *See New Std. Pub. Co. v. FTC*, 194 F.2d 181, 183 (4th Cir. 1952) (“The commission is not authorized to issue a cease and desist order as to practices long discontinued, and as to which there is no reason to apprehend renewal.” (citations omitted)). Thus, to be entitled to relief under Section 5, Complaint Counsel must prove that the challenged practices are likely to reoccur.<sup>18</sup> Complaint Counsel failed to do so, and for good reason.

The undisputed record makes plain that Respondent voluntarily ceased the challenged practices years ago.<sup>19</sup> Complaint Counsel has the burden of proof. Complaint Counsel has introduced no evidence that the alleged acts or practices that are the subject of the Complaint are likely to recur. Complaint Counsel has not even argued that the conduct is likely to recur.<sup>20</sup> Because of the lack of evidence of a likelihood of reoccurrence, “no

---

<sup>18</sup> *See, e.g., Oregon-Washington Plywood Co. v. FTC*, 194 F.2d 48, 51 (9th Cir. 1952); *see also Dejay Stores v. FTC*, 200 F.2d 865, 867 (2d Cir. 1952) (holding that Commission lacks authority to issue cease and desist order “when it appears that the practice has been ‘surely stopped’”).

<sup>19</sup> *See* CCX2 – Averill Affidavit, Attachment F (showing that the last advertisement was sent on August 22, 2019). The Contempt Motion was filed on December 17, 2019. The Administrative Complaint was filed on November 13, 2020.

<sup>20</sup> *See Oregon-Washington Plywood*, 194 F.2d at 51 (“The record here is silent as regards the existence of any special circumstances suggesting a likelihood that the petitioners will resume the practices discontinued so many years prior to the issuance of the complaints. It seems, indeed, doubtful that the orders in question would have been entered had not the Commission erroneously indulged the presumption that the activities continued. The discretion residing in the Commission is a reasoned discretion, not an arbitrary one, and we



PUBLIC

order is necessary, nor should one be entered.” *Oregon-Washington Plywood*, 194 F.2d at 51 (noting that “tackl[ing] this problem at the tomb instead of the womb” is inappropriate and subverts Section 5 because “the object of the proceeding is to stop the unfair practice”). For these reasons, Complaint Counsel is not entitled to, and the Commission cannot issue, the proposed relief.

### **B. Respondents’ Statement of Disputed Facts.**

Pursuant to Rule 3.12(b)(2), Respondents elected not to content the material factual allegations in the Complaint. Because Complaint Counsel seeks findings of fact beyond the facts alleged in the Complaint, Respondents assert the following objections to the proposed findings of fact requested by Complaint Counsel and aver that the facts below are disputed facts:<sup>21</sup>

Multiple Proposed Facts With No Record Support (23, 24, 31, 32, 33, 34, 35, 39, 40, 42, 43, 44, 48, 49, 50, 59, 61, 63, 64, 66, 67, 70, 71, and 82 through 90): The proposed facts in Complaint Counsel’s proposed Finding of Fact Nos. 23, 24, 31, 32, 33, 34, 35, 39, 40, 42, 43, 44, 48, 49, 50, 59, 61, 63, 64, 66, 67, 70, 71, and 82 through 90 were included in the legal counts, not the allegations of fact, of the Complaint and are contested by

---

are unable to see any substantial ground for inferring that the present public interest is served by the Commission's action.”).

<sup>21</sup> For ease of reference, the numbering of the objections corresponds to Complaint Counsel’s proposed findings of fact submitted on August 25, 2021. Rule 3.24 required that Complaint Counsel, as the movant, file a separate and concise statement of material facts. Complaint Counsel did not file a separate and concise statement of material facts. Pursuant to the Commission’s July 30, 2021 Order, the statement of disputed material facts are incorporated in this opposition, rather than a separate document.

## PUBLIC

Respondents.<sup>22</sup> Pursuant to 16 CFR § 3.12(b)(2), Respondents elected not to contest material allegations of facts. These statements are taken from Counts I through IV of the legal counts (not the factual allegations) of the Complaint and are hereby disputed. Complaint Counsel has the burden of proving all of these contested facts. *See In re Pfizer, Inc.*, 81 F.T.C. 23 (1972) (discussing expert testimony and evidence needed). Because there is no evidence in the record for these proposed findings, these findings should be denied.

Disclaimer Findings (27, 41, 46, and 65): Through proposed Finding of Fact Nos. 27, 41, 46, and 65, Complaint Counsel seeks findings regarding the sufficiency and efficacy of disclaimers included in the advertisements, but Complaint Counsel has offered no expert testimony, customer surveys, or other evidence to prove the requested facts. Because Complaint Counsel has submitted no evidence in the record for the requested findings and these specific facts regarding the sufficiency and efficacy of the disclaimers are disputed, these proposed findings of fact should be denied.

Maine Proceedings (73 through 92): Through proposed Findings of Fact Nos. 73 through 92, the FTC seeks to include findings of fact related to the FTC's failed attempt to seek contempt against Respondents in Maine. The FTC Rule of Practice governing administrative complaints states that a complaint must contain "[a] clear and concise factual statement sufficient to inform each respondent with reasonable definiteness of the

---

<sup>22</sup> Respondents are not contesting that the mailer included the statements and images referenced. Respondents are contesting the purported fact that the advertisements convey the claims that the referenced products cure, treat, or mitigate certain diseases. The FTC has presented no expert witness or other evidence in the record for these purported findings. *See In re Pfizer, Inc.*, 81 F.T.C. 23 (1972).

**PUBLIC**

type of acts or practices alleged to be in violation of the law.” 16 C.F.R. § 3.11. None of these proposed facts are included in the Complaint.

Complaint Counsel sought permission to include some of these proposed facts in the Complaint, but ALJ Chappell denied that request. *See* Order Denying Complaint Counsel’s Motion to Amend the Complaint (signed March 12, 2021). ALJ Chappell ruled that “allowing the proposed amendments risk injecting into this case the merits of whether Respondents’ conduct violated the Maine consent judgment, which would complicate resolution of the case on the merits.” *Id.* ALJ Chappell also found that, “[u]nder these circumstances, allowing the proposed amended complaint would not serve the purpose of Rule 3.15(a)(1) and would also unnecessarily frustrate the right to obtain expedited proceedings under Rule 3.12(b)(2).” Complaint Counsel elected not to appeal this ruling.

Respondents object to proposed Findings of Fact Nos. 73 through 92 because (a) the facts are not included in the live Complaint in this case and Respondents did not receive fair notice of these facts before Respondents elected not to contest the facts alleged in the Complaint; (b) these facts are not in the record created by the Complaint and the Answer, as set forth in Rule 3.12(b)(2); (c) these facts are irrelevant to this proceeding; (d) including these facts, and any later use of these facts by the FTC, would violate Respondents’ due process rights under the United States Constitution; and (e) as set forth below, relitigation of the issues decided in the Maine action is barred by the doctrines of quasi-estoppel, res judicata, and collateral estoppel.

**PUBLIC**

Curtis Walcker Hearsay Statements (93, 94, and 95). The statements attributed to Curtis Walcker are hearsay opinions of a witness who was not subject to cross examination. Complaint Counsel seeks to introduce the statements to prove that “Respondents did not make any changes to their Black Garlic Botanicals mailer after receiving” the purported feedback from Walcker. Complaint Counsel’s evidence does not prove this allegation, because there is no evidence regarding the dates of either mailer. Further, none of the requested findings regarding Curtis Walcker were included in the Complaint with “reasonable definiteness” or any “definiteness.” 16 C.F.R § 3.11. Pursuant to 16 C.F.R 3.12, ALJ Chappell found that Respondents had waived the right to hearing and that the parties could not engage in further discovery. Presenting these hearsay statements at the Eleventh hour when Respondents have to ability to cross-examine the witness violates Respondents’ due process rights and Respondents’ right to cross-examine adverse witnesses under the Sixth Amendment to the United States Constitution.

**C. Objections to Proposed Conclusions of Law.**

**1. No Statutory Authority for Conclusions of Law.**

Section 5 of the FTC Act authorizes the FTC to “make a report in writing in which it shall state its findings as to the facts,” but nothing in Section 5 of the FTC authorizes the FTC to state its findings as to the law. *See* 15 U.S.C. § 45(b). Respondents object to all conclusions of law by the Commission. Neither the FTC Act, nor the United States Constitution, authorize the FTC to decide or opine on matters of law.

PUBLIC

## 2. Disguised Findings of Fact Within Purported Conclusions of Law.

The Complaint does not include any allegations that the alleged conduct by Respondents was serious, deliberate, or intentional, or that Respondents disregarded the Stipulated Order. Yet, at this Eleventh hour, after Respondents exercised their right to not contest the facts alleged in the Complaint, Complaint Counsel now seeks to include numerous purported conclusions of law that are essentially unpled factual allegations regarding intent and deliberateness.

Respondent vigorously dispute that Respondents deliberately or intentionally violated any provision of the FTC Act. Pursuant to 16 C.F.R. § 3.24(b), Respondents submit the Declaration of Kramer Duhon which shows (a) extensive efforts by Respondents to comply with the FTC's never-ending requests over a multi-year period; (b) Respondents' compliance with the Consent Judgment; (c) the origin and nature of the dispute with the FTC regarding the advertisements related to Black Garlic; (d) the constant changing nature of the FTC's requests and demand; and (e) the valid reasons that Respondents elected not to contest the material allegations of fact in the Complaint. *See* RX 1. This declaration is incorporated by referenced in its entirety. This declaration counters the following proposed Conclusions of Law (i.e., factual allegations): Nos. 33, 34, 47, 48, 52, 56, 57, 58, 71, and 75. This declaration also counters the allegations in the following proposed Findings of Fact: Nos. 88-90, and 93-95.

Respondents object to all conclusions of law and findings of facts related to the allegation that the conduct of Respondents was deliberate or intentional (including any

PUBLIC

allegation that Respondents intentionally disregarded the Stipulated Order) on the following grounds: (a) the Complaint includes no allegations that any of the alleged violations were committed deliberately or intentionally; (b) injecting proposed findings on a standard of conduct at this stage of the case deprives Respondents of their due process rights under the United States Constitution; and (c) whether Respondents' conduct was deliberate and intentional is a disputed fact issue for which summary disposition is improper (*See* RX 1).

### 3. Relitigation of Maine Contempt Motion is Barred.

In Proposed Conclusions of Law Nos. 33, 34, 48, 51, and 52, Complaint Counsel seeks conclusions of law regarding an alleged violation of the Consent Judgment entered in the United States District Court for the District of Maine. None of these allegations regarding the Maine action are included in the Complaint. *See* 16 C.F.R. § 3.11. Further, due to the ruling in the Maine act, the FTC is estopped from now claiming that Respondents violated the Consent Judgment.

On December 17, 2019, the FTC filed its Motion for Contempt and alleged that Respondents “brazenly” ignored “the Court’s order barring them from making unsubstantiated claims for their dietary supplements.”<sup>23</sup> On August 12, 2020, U.S. District Judge Jon Levy of the United States District Court for the District of Maine found the following in his Order denying the Contempt Motion:

---

<sup>23</sup> *See* RX 1; *see also* RX 2 (Contempt Motion in *FTC v. Health Research Laboratories, LLC*, Case No. 2:17-CV-00467-JDL, Dkt. No. 21, PageID# 182).

PUBLIC

Because I have previously determined that Section II.H is facially ambiguous, and because the Plaintiffs do not seek a hearing at which to offer extrinsic evidence to cure the ambiguity, I conclude that Section II.H does not “clearly and unambiguously” prohibit the Contempt Defendants’ allegedly contumacious conduct. Accordingly, I conclude as a matter of law that the allegations in the Plaintiffs’ motion for an Order to Show Cause fail to support a finding of civil contempt under Section II.H, and the Plaintiffs’ motion for an Order to Show Cause is denied. Additionally, because the Plaintiffs have represented that their motion to modify the Judgment “is predicated on Defendants’ contempt” under Section II.H, ECF No. 42 at 2, their motion to modify the Judgment is denied.<sup>24</sup>

The issue of whether Respondents violated the Consent Judgment has been decided against the FTC. The FTC chose not to appeal that decision or to file an amended motion within the time period permitted by the Court. Under the doctrines of quasi-estoppel, res judicata, and collateral estoppel, Judge Levy’s August 12, 2020 decision bars any relitigation of the issue of whether Respondents violated the FTC’s ambiguous Consent Judgment, including any findings of fact or conclusions of law regarding the conduct that was the subject of the prior Contempt Motion. *See In re Paige*, 610 F.3d 865, 872 (5th Cir. 2010) (collecting authorities for the proposition that “it is beyond doubt that [an unappealed order] constitute[s] a final judgment on the merits” for res judicata purposes).

#### **D. Objections to Relief Requested by Complaint Counsel.**

As set forth in other sections of this Response, Complaint Counsel’s requested relief should be denied outright. But even if some relief were warranted—and it is not—only Section I of Complaint Counsel’s Proposed Order reasonably relates to Respondents’

---

<sup>24</sup> See RX 1; see also RX 3 (Order in *FTC v. Health Research Laboratories, LLC*, Case No. 2:17-CV-00467-JDL, Dkt. No. 52, PageID# 845).

PUBLIC

alleged misconduct. *FTC v. Nat'l Lead Co.*, 352 U.S. 419, 428 (1957) (holding that the Commission's cease and desist orders must have a "reasonable relation to the unlawful practices found to exist"). Imposing other obligations against Respondents is unreasonable, unnecessary, unconstitutional, and not statutorily permitted.

**1. Even if the Commission Could Issue the Requested Relief, Complaint Counsel's Proposed Order Is Impermissibly Vague, Overbroad, and Unconstitutional.**

If the Commission issues any relief—and it should not—that relief should be confined to Section I of Complaint Counsel's Proposed Order. Section I seeks to permanently ban Respondents from the supplements industry. This ban is effectively a cease and desist order that permanently prohibits Respondents from advertising, selling, and promoting all Dietary Supplements (not just the four supplements at issue) under all circumstances.

Section I's Dietary Supplements ban is the broadest "cease and desist" relief even possibly authorized by the FTC Act. Imposing other obligations against Respondents is unreasonable, unnecessary, unconstitutional, and not statutorily permitted.

**2. Sections I and II: The FTC Death Penalty Cease and Desist.**

For companies that have sold only supplements, Sections I and II of the Proposed Order are the business equivalent of the death penalty. Section I seeks to permanently ban Respondents from advertising, marketing, promoting, offering for sale *any Dietary Supplement* (not just the four supplements at issue) or assisting others in the advertising, marketing, promoting, or offering for sale *any Dietary Supplement*. Section II seeks to



**PUBLIC**

permanently ban Respondents from “advertising, marketing, promoting, or offering for sale” *any product* (not just Food, Drugs, or Dietary Supplements) that purportedly “cures, treats, mitigates, prevents, or reduces the risk of any disease.” These restrictions fail for several reasons.

First, “any product” that purportedly “cures, treats, mitigates, prevents, or reduces the risk of any disease” is facially overbroad and bears no reasonable relation to the four Dietary Supplements at issue. This restriction could apply to anything—from sneakers (which could be used for exercise and thus reduce the risk of disease) to toothbrushes (prevents gum disease) to keyboards (mitigates the risk of carpal tunnel). *E.g.*, *Chrysler Corp. v. FTC*, 561 F.3d 357, 365 (D.C. Cir. 1977) (deleting remedies with “potentially limitless” application as “lack[ing] a reasonable relationship to the violations found to exist”). The proposed prohibition also purports to apply regardless of the efficacy of the products in preventing disease.

Second, the relief in Section II is vague and unpled. Respondents have a due process right to fair notice of the contours of any cease and desist order issued by the Commission. *LabMD v. FTC*, 894 F.3d 1221, 1235 (11th Cir. 2018). This means that both the Complaint and Proposed Order must spell out with “clarity and precision” Complaint Counsel’s requested relief. *Id.* But Section II’s relief is neither contained in the Complaint nor specific. As discussed above, “*any product*” that purportedly “cures, treats, mitigates, prevents, or reduces the risk of *any disease*” is virtually limitless. Accordingly, and “given the severity of the civil penalties a district court may impose for the violation of a cease and

PUBLIC

desist order,” awarding the relief sought in Section II of the Proposed Order would violate Respondents’ due process rights. *Id.*

Third, Section II violates Respondents’ First Amendment rights. To start, Section II fails the test articulated by the Supreme Court in *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 566 (1980), which requires (i) an asserted governmental interest that is substantial; (ii) regulation that directly advance the governmental interest; and (iii) regulation that is not more extensive than is necessary to serve the governmental interest. Respondents voluntarily stopped the challenged practices *years ago*. So on its face, Section II does not involve a substantial government interest. Even if it did, its sweeping prohibitions do not directly advance that interest and are far broader than necessary to serve that interest.<sup>25</sup> Moreover, Section II amounts to an unlawful prior restraint on free speech by prohibiting Respondents from making “any representation, expressly or by implication, that a product cures, treats, mitigates, prevents, or reduces the risk of any disease.” As addressed above, this prohibition is so broad that it could reach every product in the marketplace. Complaint Counsel’s suggestion that this is not a true prior restraint disregards both Section II’s plain text and the stark penalties Respondents face for potential disobedience. Complaint Counsel’s argument that the prior restraint doctrine does not apply to commercial speech likewise falls flat. *See N.Y. Mag. v. Metr. Transp. Auth.*, 136 F.3d 123, 131–32 (2d Cir. 1998).

---

<sup>25</sup> *E.g., Ocheese Creamery LLC v. Putnam*, 851 F.3d 1228, 1240 (11th Cir. 2017) (“The State’s mandate was clearly more extensive than necessary to serve its interest in preventing deception and ensuring adequate nutritional standards.”).

PUBLIC

Banning Respondents from making any “disease” claims about “any product” is overly broad, unconstitutionally vague, and not reasonably related to the conduct that is the subject of the Complaint. For these reasons, Section II should be deleted.

**3. Sections III, IV, and V: FTC’s Request for Unnecessary and Unreasonable Additional Prohibitions on the Sale of Food and Drugs.**

Considering the broad and sweeping nature of Sections I and II, the other section of Complaint Counsel’s Proposed Order are unnecessary and unreasonable and will only lead to further confusion. Sections III and IV prohibit Respondents, their agents, and persons working in concert or participation with Respondents from making misleading representations or misrepresentations regarding any Food or Drug. Section V requires certain human clinical tests or studies if Respondents make any representations regarding any tests or studies related to any Food or Drug.

Sections III, IV, and V fail for the same reasons detailed above as to Section II—they are facially overbroad and bear no reasonable relation to the four Dietary Supplements at issue, are vague and unpled and thus violate Respondents’ due process rights, and violate Respondents’ First Amendment rights both under *Central Hudson* and as unlawful prior restraints on speech.

Simply put, there is no evidence that Respondents have ever made any representations regarding any products other than Dietary Supplements. Given that Respondents are banned from the supplements industry, it is neither reasonable nor necessary to ban Respondents from making representations regarding Food and Drugs.

PUBLIC

Banning Respondents and persons working in concert with Respondents from making any misrepresentations regarding any Food or Drug is overly broad, unconstitutionally vague, and not reasonably related to the conduct that is the subject of the Complaint.

**4. Section VI through XII: Statutorily Unauthorized Obligations.**

Sections VI through XII of Complaint Counsel’s Proposed Order seek to impose a series of obligations upon Respondents far beyond the statutorily authorized cease and desist order. Proposed Section VI would require Respondents to identify all Eligible Customers, mail FTC-drafted letters to all Eligible Customers, and submit reports and data to the FTC. Proposed Section VII would control Respondents’ customer data and, if requested by the FTC, require Respondents to destroy the data.<sup>26</sup>

Proposed Section IX is the FTC’s “scarlet letter” requirement. Section IX seeks to require *for twenty years* that Respondents provide a copy of the Order to every future business associate and employee and that Respondent obtain a “signed and dated acknowledgment of receipt” of the Order for all such persons.<sup>27</sup> Under Proposed Section X, the FTC seeks to require Respondents *for twenty years* to submit periodic compliance reports, under the penalty of perjury, that require Respondents to provide a host of information and data. For example, Proposed Section X seeks to require Respondents to

---

<sup>26</sup> Respondents do not challenge Proposed Section VIII because Respondents have already voluntarily canceled all subscription plans.

<sup>27</sup> This provision is one of the most offensive requested by Complaint Counsel. If a future business associate or employees decides that he or she does not want to sign the FTC’s Acknowledge Form (which is, of course, their right), Respondents could face massive civil penalties. *See LabMD*, 894 F.3d at 1234 (noting that “[t]he imposition of penalties upon a party for violating an imprecise cease and desist order—up to \$41,484 per violation or day in violation—may constitute a denial of due process.”).

## PUBLIC

(a) identify and describe all future businesses and all business activity (including businesses that have nothing to do with Dietary Supplements);<sup>28</sup> (b) describe in detail how Respondents are in compliance with the Order; and (c) identify all future employment, and all addresses and telephone numbers. Proposed Section XI seeks to require Respondents *for twenty years* to “create” and “retain” (a) accounting records showing revenue, costs, and profit from all good and services (not just Dietary Supplements); (b) personnel records for all employees; (c) consumer complaints and refund requests (regardless of the business); (d) “records necessary to demonstrate full compliance with each Provision of this Order, including all submissions to the Commission”; (e) advertising and marketing materials regarding any representations; and (f) other records. Respondents must also somehow create records “that tend to show any lack of compliance by Respondents with this Order.” *Cf. FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 392 (1965) (holding FTC cease and desist orders must be “clear and precise”)

Proposed Section XII would require Respondents *for the next twenty years* to submit additional compliance reports, produce whatever documents are requested by the FTC, answer interrogatories, and “sit for investigative hearings” within 30 days of a request. Proposed Section XII would require Respondents to “permit representatives of the Commission” to interview “anyone affiliated” with “any Respondent.” This imprecise and impermissible provision would arguably require the Respondents to compel their spouses,

---

<sup>28</sup> At least one Circuit has found that this exact provision was impermissible. *See Fanning v. FTC*, 821 F.3d 164, 177 (1st Cir. 2016).

PUBLIC

children, priests, or lawyers to testify before the FTC or face civil penalties of \$41,484 per violation.<sup>29</sup>

The relief requested by the FTC in Proposed Sections VI through XII of the Proposed Order is not authorized by the FTC Act. *See* 15 U.S.C. § 45(b). Sections VI through XII of the Proposed Order do not instruct Respondents to “cease and desist” from any act or practice. *See, e.g., LabMD*, 894 F.3d at 1237 (vacating cease and desist order that did “not enjoin a specific act or practice” but mandated broad affirmative relief). Instead, these provisions are the equivalent of a mandatory injunction that command Respondents to take numerous indefinite actions for a twenty-year period or else face severe penalties. The FTC Act only authorizes the Commission to enter “an order requiring” Respondents to “cease and desist from using such method of competition or such act or practice.” 15 U.S.C. § 45(b). Section 5 of the FTC does not authorize the FTC to enter a mandatory injunction that *commands* Respondents to take affirmative actions for twenty years.<sup>30</sup>

The relief requested by the FTC in Proposed Sections VI through XII of the Proposed Order violates Respondents’ due process rights because these commands were not identified with “reasonable definiteness” in the Complaint. *LabMD v. FTC*, 894 F.3d 1221, 1235 (11th Cir. 2018). The FTC Rules of Practice require that a complaint contain “[a] clear

---

<sup>29</sup> Sections 5(l) and 5(m)(1)(B) of the FTC Act set the maximum penalty at \$10,000, but the Commission may adjust this figure for inflation under 16 C.F.R. § 1.98. The current penalty of \$41,484 figure applies to penalties assessed after January 22, 2018. *Id*

<sup>30</sup> *Compare* 15 U.S.C. § 45(b) (defining the FTC’s power as the ability to enter a cease and desist order) *with* 15 U.S.C. § 53 (granting the district courts, not the FTC, the right provide equitable relief through a permanent injunction).

**PUBLIC**

and concise factual statement sufficient to inform each respondent with reasonable definiteness of the type of acts or practices alleged to be in violation of the law.” 16 C.F.R. § 3.11. As noted by the Eleventh Circuit, “the remedy the complaint seeks must comport with this requirement of reasonable definiteness.” *See id.* Injecting these burdensome, imprecise, and overly broad commands into the cease and desist order now, which would subject Respondents to severe penalties if the commands are not followed, violates Respondents’ due process rights. *Id.* At 1235–37; *see BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 574 & n.22, (1996) (“Elementary notions of fairness enshrined in our constitutional jurisprudence dictate that a person receive fair notice . . . of the conduct that will subject him to punishment . . . [T]he basic protection against judgments without notice afforded by the Due Process Clause is implicated by civil penalties.”) (cleaned up); *Sessions v. Dimaya*, 138 S. Ct. 1204, 1228–29 (2018) (Gorsuch, J., concurring) (suggesting that the severity of a civil penalty corresponds with the degree of fair notice of unlawful conduct that must be afforded to the defendant).

The overly broad and imprecise nature of the commands in Sections VI through XII of Complaint Counsel’s Proposed Order violates Respondents’ due process rights. Administrative cease and desist orders are required to be clear and precise to avoid raising questions as to their meaning and application. *See FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 392, 85 S.Ct. 1035, 1046, 13 L.Ed.2d 904 (1965). The commands in Proposed Sections VI through XII do not clearly and precisely state what conduct is prohibited, are statutorily unauthorized, and are not reasonably related to the challenged practices.

PUBLIC

**E. Other Objections to this Part 3 Administrative Process.**

Respondents object to this administrative process and the entry of a cease and desist order on the following grounds, and request a ruling on these objections:

**1. Violation of Article II of the United States Constitution and the Constitution's Separation of Powers.**

Respondents object to an administrative cease and desist order by this Commission because the FTC's administrative process and structure violates Article II of the United States Constitution. The Commissioners are not subject to Presidential control and cannot be removed by the President except for "inefficiency, neglect of duty, or malfeasance in office." 15 U.S.C. § 41. This structure violates Article II of the Constitution and the Constitution's separation of powers. *See Seila Law LLC v. Consumer Financial Prot. Bureau*, 140 S.Ct. 2183, 2193 (2020) ("The President's power to remove—and thus supervise—those who wield power on his behalf follows from the text of Article II, was settled by the First Congress, and was confirmed in the landmark decision *Myers v. United States*, 272 U.S. 52 (1926)."). To be clear, Respondents contend that the 1935 decision by the Supreme Court of the United States in *Humphrey's Executor v. U.S.*, 295 U.S. 602 (1935), which was "fundamental departure from our constitutional structure with nothing more than handwaving and obfuscating phrases such as 'quasi-legislative' and 'quasi-judicial,'"<sup>31</sup> was wrongly decided. The United States Constitution did not authorize

---

<sup>31</sup> *See Seila Law LLC v. Consumer Financial Prot. Bureau*, 140 S.Ct. 2183, 2216 (2020) (J. Thomas, concurring).



PUBLIC

Congress to create the FTC as a “quasi-legislative” or “quasi-judicial” body whose leadership is not subject to at-will removal by the Executive Branch.

**2. The FTC’s request for a mandatory injunction is beyond the permissible scope of relief provided by 15 U.S.C. § 45(b).**

As previously discussed, Section 5 of the FTC Act does not include a general grant of authority for the FTC to enter whatever relief it deems appropriate. *See* 15 U.S.C. § 45(b). Instead, the FTC’s authority under 15 U.S.C. § 45(b) is limited to entering an order against the Respondents “to cease and desist from using such method of competition or such act or practice” identified in the Complaint. 15 U.S.C. § 45(b). Nothing in language of Section 5 of the FTC Act grants the FTC authority to enter an order that grants equitable relief to the FTC or commands a party to take certain future actions or face severe civil penalties. The relief requested by Complaint Counsel in Sections IV through XII of Complaint Counsel’s Proposed Order is equitable relief, which the Commission is not authorized to grant under the FTC Act or the United States Constitution.

**3. Violation of the Respondents’ Due Process Rights.**

The FTC’s combined role of prosecutor, judge, and jury in the administrative proceedings violates the Due Process Clause of the Fifth Amendment to the United States Constitution. Due process requires “notice of the factual basis” of the Government’s assertions “and a fair opportunity to rebut the Government’s factual assertions before a neutral decisionmaker.” *Hamdi v. Rumsfeld*, 542 U.S. 507, 533 (2004). Any use of the findings of fact—which are decided without due process—to deprive Respondents of

**PUBLIC**

property in a later action under 15 U.S.C. § 57b violates the Due Process Clause of the Fifth Amendment. *See* 15 U.S.C. § 57b(c). In particular, Respondents contend the provisions of the FTC Act that require the Commission’s findings of fact, if supported by evidence, to be “conclusive” are unconstitutional and violate the Due Process Clause of the Fifth Amendment because (a) the Commissioners who decide the facts are not neutral decisionmakers; and (b) the process by which the Commissioners decide the facts is unconstitutional. *See* 15 U.S.C. § 45(c) and 57b(c).

**4. Violation of the FTC’s Rules and Respondents’ Constitutional Rights.**

Under 16 C.F.R. § 3.11, the Complaint is required to include “[a] clear and concise factual statement sufficient to inform each respondent with reasonable definiteness of the type of acts or practices alleged to be in violation of the law.” 16 C.F.R. § 3.11. Under 16 C.F.R. § 3.12(b)(2), the Complaint and the Amended Answer in this case provide “a record basis on which the Commission shall issue a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding.” 16 C.F.R. § 3.12(b)(2). Respondents’ Amended Answer had the effect of dispensing with a hearing in this case and removing the proceedings to the Commission for determination of a final order. *See* 16 C.F.R. § 3.12(b)(2). In 2009, the Commission changed its Rules of Practice to “eliminate the ALJ’s authority to render an initial decision when the allegations of the complaint are admitted or there is a default. In those cases, the Commission would issue a final decision

PUBLIC

on the basis of the facts alleged in the complaint.” 74 Fed. Reg. 1804, 1808 (Jan. 13, 2009) (interim final rules with request for comment).<sup>32</sup>

The Commission’s decision to issue findings of fact for facts that are not part of the record created by the Complaint and Answer violates the FTC’s regulations, the FTC’s prior rules, Respondents’ due process rights, and Respondents’ rights under the Fifth, Sixth, and Fourteenth Amendments to the United States Constitution.

#### IV. CONCLUSION AND PRAYER

For the reasons set forth herein, Respondents request that the Commission deny any requested summary disposition and dismiss the Complaint or, in the alternative and based on the record created by the Complaint and Answer, enter cease and desist order prohibits the acts or practices alleged in the Complaint without imposing additional mandatory obligations on the Respondents.

---

<sup>32</sup> In explaining the 2009 amendments to Rule 3.12(b)(2), the Commission stated that “the Commission would issue a final decision on the basis of the facts alleged in the complaint.” 74 Fed. Reg. at 1808. The Commission further noted that where the allegations are admitted pursuant to Rule 3.12(b), there would be no evidence to hear or “voluminous record” to review, and therefore, it would be more “efficient for the Commission to issue a final opinion and order without the intermediate step of an ALJ’s initial decision.” 73 Fed. Reg. 58832, 58836 (Oct. 7, 2008) (Proposed Rules). In explaining the 2009 amendments to Rule 3.12(b)(2), the Commission also stated that these “cases can be resolved more expeditiously ... the only issues in such cases are legal or policy ones.” 74 Fed. Reg. at 1808.

PUBLIC

Dated: September 10, 2021

Respectfully submitted,

**REESE MARKETOS LLP**

By: /s/ Joel W. Reese

Joel W. Reese  
Texas Bar No. 00788258  
joel.reese@rm-firm.com  
Joshua M. Russ  
Texas Bar No. 24074990  
josh.russ@rm-firm.com

750 N. Saint Paul St., Suite 600  
Dallas, TX 75201-3201  
Telephone: (214) 382-9810  
Facsimile: (214) 501-0731

**ATTORNEYS FOR RESPONDENTS**

**CERTIFICATE OF SERVICE**

I hereby certify that on September 10, 2021, I filed the foregoing document electronically using the FTC's E-Filing system, which will send notification to:

April J. Tabor  
Acting Secretary  
Federal Trade Commission  
600 Pennsylvania Ave., NW, Rm. H-113  
Washington, DC 20580  
ElectronicFilings@ftc.gov

The Honorable D. Michael Chappell  
Administrative Law Judge  
Federal Trade Commission  
600 Pennsylvania Ave., NW, Rm. H-110  
Washington, DC 20580  
email: [oyalj@ftc.com](mailto:oyalj@ftc.com)

**COMPLAINT COUNSEL**

Elizabeth Averill  
eaverill@ftc.gov  
Jonathan Cohen  
jcohen2@ftc.gov

/s/ Joel W. Reese  
Joel W. Reese

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**

**RESPONDENTS' EXHIBIT INDEX**

Exhibit No.	Title and Brief Description	In Camera / Public
RX 1	Declaration of Kramer Duhon	Public
RX 1 – Att. A	Andrew Lustigman's Online Resume	Public
RX 1 – Att. B	Ried 2016 Study	Public
RX 1 – Att. C	Budoff 2004 and 2006 Studies	Public
RX 1 – Att. D	Ried 2013 and 2010 Studies	Public
RX 2	Contempt Motion in <i>FTC, et al. v. Health Research Laboratories, LLC, et al.</i> , Case No. 2:17-cv-00467-JDL, Dkt. No. 21	Public
RX 3	Order Denying Motion for Contempt in <i>FTC, et al. v. Health Research Laboratories, LLC, et al.</i> , Case No. 2:17-cv-00467-JDL, Dkt. No. 52	Public
RX 4	Joshua D. Wright, <i>Section 5 Revisited: Time for the FTC to Define the Scope of its Unfair Competition Authority</i> at 6 (2015)	Public
RX 5	Post-2015 FTC cases chart	Public

# Exhibit RX 1

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

**DECLARATION OF KRAMER DUHON**

I, Kramer Duhon, hereby declare:

**I. Background Information.**

1. My name is Kramer Duhon. I am the CEO of Health Research Laboratories, LLC (“**HRL**”) and Whole Body Supplements, LLC (“**WBS**”). I, along with HRL and WBS, are collectively referred to as the “**Respondents**.”

2. I have owned and managed HRL since approximately 2007 and WBS since approximately 2015. HRL and WBS were extremely small companies. From the formation of each company until they ceased all marketing in 2019, HRL and WBS had between two and four shared employees, including me. At no time did HRL and WBS collectively have more than six shared employees, including me.

3. During the entire time of their existence and operation, there were no consumer lawsuits filed against HRL or WBS. In addition, during its entire existence, HRL

only had one federal regulatory warning letter which was resolved in approximately October 2014.<sup>1</sup>

4. At least a year prior to the FTC's filing of the Administrative Complaint in this action, HRL and WBS ceased all marketing of all products. Both companies are still in existence, but, due to the FTC's activities, the companies have no employees and have ceased all operations.

5. Although I did not know it at the time, HRL and WBS started their path towards closure when I received the FTC's Civil Investigative Demand in early 2015.

## II. The 2015 Civil Investigative Demand.

6. On or about January 7, 2015, I received a Civil Investigative Demand ("CID") from the FTC and immediately hired the law firm of Olshan Frome Wolosky LLP ("Olshan") to represent Respondents in connection with the CID and all other legal issues related to the FTC.<sup>2</sup> From January 7, 2015 until I terminated Olshan's representation on or about November 13, 2019, Olshan represented the Respondents.<sup>3</sup>

7. The CID was a shock and surprise to me when I received it. I had never received a CID before and I had no idea what a CID was. I remember the day distinctly because it was my last day of chemotherapy treatment for Hodgkin lymphoma.

8. The CID initiated a multi-year process through which Respondents provided information and documents requested by the FTC. As explained in detail below, Respondents spent hundreds of hours and hundreds of thousands of dollars providing the information and documents requested by the FTC. Respondents tried to diligently answer the FTC's interrogatories and to promptly provide documents requested by the FTC. As explained in more detail below, Respondents provided names, addresses, and telephone numbers for their suppliers and vendors so that the FTC could verify the information provided was accurate and complete. Respondents provided multi-year spreadsheets that included detailed product and financial information. Over the course of several years, Respondents provided thousands of pages of documents and answered hundreds of written interrogatories. Providing the information and documents requested by the FTC was all-

---

<sup>1</sup> The warning letter was from the U.S. Food and Drug Administration and was promptly resolved without any legal or administrative action.

<sup>2</sup> Based on information that we found on the Olshan website, I believed Mr. Lustigman to be a very experienced advertising lawyer with specific expertise and experience in the law and regulations related to the FTC. Attachment A is a copy of Mr. Lustigman's resume from the Olshan website.

<sup>3</sup> I am providing the information in this paragraph for background purposes because, as explained below, Olshan had numerous communications with the FTC over a period of several years. Most, if not all, of my communications with the FTC described in this declaration were through my counsel at Olshan.



consuming because the requests constantly changed and evolved over time. Examples of the many communications with the FTC include the following:<sup>4</sup>

- a. On January 30, 2015, Respondents answered more than a dozen of the FTC's interrogatories<sup>5</sup> regarding Respondents' corporate structure, ownership, officers, directors, affiliates, and business relationships.
- b. On January 30, 2015, the FTC sent a letter that provided a detailed schedule for three more rounds of discovery under which, over the course of months, Respondents were required to answer dozens of interrogatories and to provide thousands of documents.
- c. On February 24, 2015, pursuant to the FTC's request, Respondents provided a 19-page supplemental response to the FTC's CID, along with 2,918 pages of documents requested by the FTC. Respondents provided the names of the ingredients for their products, the names and contact information for their suppliers, detailed product and financial information,<sup>6</sup> the URL addresses for their websites, the educational background and work history of the individual Respondent, billing and refund information, copies of consumer complaints, and other information.
- d. On March 16, 2015, pursuant to the FTC's request, Respondents produced additional documents and responded to numerous additional interrogatories.
- e. On April 14, 2015, the FTC sent a letter claiming that there were deficiencies in the production submitted by HRL and requested that HRL provide additional information and documents in response to dozens of interrogatories and requests for documents.
- f. On May 12, 2015, The FTC sent an email, requesting dozens of additional items, including the substantiation for all of the products, documents related to the FDA warning letter, documents regarding customer service scripts, correspondence with numerous vendors, customer policies and training manuals, lists of upsold products, names of endorsers and testimonialists for products, names of all persons who created, evaluated, or approved all

---

<sup>4</sup> Respondents likely do not have a complete record of all communications between Olshan and the FTC because Respondents do not have access to Olshan's records.

<sup>5</sup> Many of the interrogatories served by the FTC had multiple subparts. For purposes of this declaration, I refer to each subpart as a separate interrogatory.

<sup>6</sup> Respondents provided the per unit wholesale price, per unit retail price, number of units sold, gross sales per year, gross sale revenue, total dollar amount provided in refunds, total dollar amount spent on marketing, advertising and promotion, and total dollar amount spent on research and development.

advertising, information on all web-based pop-up ads, banners or other internet content, inbound customer service voice records, names of all companies affiliated with Respondents, and other information.

- g. On June 30, 2015, pursuant to the FTC's request, Respondents sent the FTC audio recordings for approximately 133 inbound customer calls.
- h. On August 19, 2015, the FTC requested additional information regarding mailing lists and mail codes.
- i. On August 31, 2015, the FTC requested additional customer information and additional information regarding the recorded calls provided to the FTC.
- j. On September 9, 2015, Respondents provided the additional information and documents. The FTC immediately requested additional information regarding certain customer calls.
- k. On October 15, 2015, pursuant to the FTC's request, Respondents provided 12 additional customer recordings.
- l. On October 20, 2015, the FTC requested recordings for 12 inbound customer calls. Respondents immediately responded and advised the FTC that the inbound calls (with the exception of two recordings) were already sent to the FTC.
- m. On October 22, 2015, pursuant to the FTC's request, HRL provided two additional customer recordings.
- n. On April 7, 2016, after not hearing from the FTC for several months, the FTC requested that HRL update its responses to numerous interrogatories.
- o. On April 29, 2016, HRL advised the FTC that two of the products at issue had not been affirmatively marketed since prior to the receipt of the CID and that HRL had discontinued the alleged claims to which the FTC raised questions. HRL also provided supplemental sales and refund information and updated information regarding its vendor relationships.
- p. On October 17, 2016, after more than 20 months of investigating HRL, the FTC advised HRL's counsel that the FTC and the Maine Attorney General wanted to seek authority to engage in consent negotiations regarding certain advertising and marketing practices.

- q. On **November 29, 2016**, the FTC advised HRL's counsel that the FTC and the Maine Attorney General had approved a proposed federal complaint, but had authorized the FTC counsel to negotiate a resolution of the complaint charges. The FTC wanted "consumer redress," which it calculated as "gross sales (including from continuity sales) minus refunds." The FTC included a proposed Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief that the FTC had drafted, as well as a copy of the proposed Complaint that the FTC was threatening to file.
- r. On **December 2, 2016**, HRL's counsel advised the FTC that it was interested in pursuing a settlement with the FTC and Maine.
- s. On **January 6, 2017**, the FTC requested additional revenue and sales information and additional information regarding the marketing involving two products.
- t. On **January 13, 2017**, HRL's counsel provided the additional information requested by the FTC on January 6, 2017.
- u. On **January 18, 2017**, the FTC requested additional information regarding gross sales by HRL, the Duhons' tax payments, the income from other sources on the Duhons' tax returns, foreign bank accounts, foreign income, compensation paid to officers, balance sheets and income statements for other companies, payments for personal expenses, and QuickBooks reports for sales and refunds.
- v. On **February 10, 2017**, the FTC requested information and documents regarding Respondents' income, assets, bank account statements, and other documents. The FTC threatened that, if it did not receive the additional information quickly, the FTC would prepare a complaint against Respondents.
- w. On **February 21, 2017**, the Respondents provided additional financial documents requested by the FTC.
- x. On **February 23, 2017**, the FTC sent a letter to Respondents' counsel, requesting additional bank statements, documentation regarding investments, account statements from closed bank accounts, statements from several investments, and payment information on more than a dozen checks.
- y. On **March 8, 2017**, the FTC requested additional documents.

- z. On March 16, 2017, the FTC requested detailed information and documents regarding numerous financial transactions, accounts, and investments, including payments from my retirement account, names and contact information for the administrators of several investments, and additional statements for certain investments and bank accounts.
- aa. On April 7, 2017, at my request, I met with Thomas Pahl, the Acting Director of the FTC's Bureau of Consumer Protection, at the FTC's offices in Washington, D.C., in an attempt to resolve the FTC's threatened complaint against me. On April 6, 2017, the day prior to the meeting, FTC's Complaint Counsel sent me a list of 18 items (with multiple subparts each), seeking information and documents regarding various financial transactions over the previous five years. At the meeting, I provided some of the additional information requested by the FTC. After the meeting, the FTC's counsel requested additional bank statements for additional periods of time.
- bb. On April 7, 2017, the FTC contacted one of Respondents' vendors and requested detailed sales data for all products from 2013 to 2017.
- cc. On April 18, 2017, the FTC sent a revised offer to settle the monetary part of the proposed Complaint that the FTC had threatened to file. After assessing Respondents' financial information, the FTC apparently concluded that Respondents simply did not have the ability to pay the amounts demanded by the FTC.
- dd. On April 26, 2017, the FTC sent a request to one of Respondents' vendors to provide sales data for all HRL products from 2013 and all Client Relationship Management data for several years.
- ee. On May 17, 2017, the FTC requested additional information and documents from one of HRL's vendors, including information regarding amounts spent by customers, total returns by customers, customer complaints, and refunds.
- ff. On May 24, 2017, the FTC sent a letter to Respondents' counsel requesting detailed information regarding product advertising, websites, revisions to customer scripts, and changes to marketing.
- gg. On August 2, 2017, Respondents' counsel sent a seven page "White Paper," attempting to address the FTC's concerns regarding the products at issue and issues with the FTC's proposed Consent Judgment. Respondents provided information regarding studies on the products at issue and agreed to many of the prohibitions requested by the FTC in its proposed Consent Judgment.

- hh. On or about August 9 or 10, 2017, at my counsel's request, I met with Commissioner McSweeney, Acting Chairman Ohlhausen, and others at the FTC's offices in Washington D.C., in another attempt to resolve the FTC's complaints.
- ii. On September 7, 2017, the FTC sent the proposed Consent Judgment to Respondents' counsel with additional changes and prohibitions, which Respondents' counsel accepted on September 14, 2017.
- jj. On November 14, 2017, I received notice that the FTC had approved the settlement. At that time, I thought all issues with the FTC had been resolved.

The above list is not intended to be an exhaustive list of all communications with the FTC or all requests from the FTC. I am certain that there were dozens of telephone calls and numerous other written communications over the almost three year period from the service of the CID to the filing of the Consent Judgment. During this entire time period, I tried to provide the FTC with the information and documents it requested and to resolve its concerns.

9. By November 2017, I thought that this issues with the FTC would be finally resolved through an agreed order submitted to a federal court in Maine.

### III. The Consent Judgment.

10. On November 30, 2017, the FTC and the State of Maine filed their Complaint against Respondents in the United States District Court for the District of Maine, along with a Joint Motion to Enter Final Judgment. On January 15, 2018, the Court signed a Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief (the "Consent Judgment").

11. The Respondents actively tried to comply with the requirements of the Consent Judgment. Examples include the following:

- a. The Consent Judgment banned Respondents from making any representations regarding weight loss in connection with the sale of any Dietary Supplement, Food, or Drug. Respondents stopped selling all weight loss products before the Consent Judgment was signed and, after the date of the Consent Judgment, Respondents have not made any of the "banned weight-loss claims" referenced in paragraph I of the Order.
- b. The Consent Judgment banned Respondents from making any representations regarding joint-related disease claims and Alzheimer's disease, memory, and cognitive performance claims in connection with the sale of any Dietary Supplement, Food, or Drug. Respondents stopped selling

all of such products before the Consent Judgment was signed and, after the date of the Consent Judgment, Respondents have not made any of the “prohibited representations” regarding “other weight-loss claims, joint-related disease claims, and Alzheimer’s Disease, memory, or cognitive performance claims” referenced in paragraph II of the Order.

12. Respondents took many other actions to comply with the Consent Judgment, including preserving records, making required disclosures to customers and the FTC, obtaining informed consent for billing, honoring refunds, providing a simple mechanism for consumers to stop recurring charges, providing periodic compliance reports, and numerous other activities.

13. After the Respondents settled with the FTC and I had paid the FTC \$800,000, I assumed that all matters in dispute with the FTC had been resolved. Consequently, on March 29, 2018, pursuant to the Consent Judgment, Respondents’ counsel submitted the required Compliance Report and the required acknowledgment forms from seven vendors and business associates. Unfortunately, soon thereafter, the FTC started another campaign of requests for documents and information. Examples of the communications with the FTC include the following:

- a. On **April 19, 2018**, the FTC sent a letter to Respondents’ counsel, requesting a list of all persons who received a copy of the Consent Judgment, information regarding entities that acknowledged receipt of the Consent Judgment, names of employees that provide the post-sale consumer support, and a list of goods and services that Respondents advertise or sell.
- b. On **May 11, 2018**, pursuant to the FTC’s request, Respondents’ counsel provided the FTC with a Supplemental Compliance Report that provided information regarding the persons and entities that had received a copy of the Consent Judgment, the name of the entity that provided post-sale customer support, and information regarding the goods and services sold since the date of the Consent Judgment.
- c. On **May 21, 2018**, the FTC sent a letter to Respondents’ counsel, requesting that Respondents provide detailed information regarding products being sold and that Respondents produce all advertisements, scripts, direct mail pieces, website pages, and other documents for all products sold since April 19, 2017.
- d. On **December 19, 2018**, the FTC requested additional information and documents regarding total revenue for Respondents’ products, refunds and chargebacks for products, complaints received, testimonials, and scientific studies or other documentation regarding Respondents’ products.

- e. On **January 30, 2019**, pursuant to the FTC's request, Respondents' counsel provided the FTC with information regarding consumer complaints, scientific studies regarding various products, and additional information.
- f. On **March 28, 2019**, the FTC requested the quantity of each ingredient in one of Respondent's products, additional information regarding chargebacks and refunds, and additional information regarding any complaints from consumers regarding refunds.
- g. On **June 6, 2019**, the FTC sent another letter to Respondents' counsel. The FTC contended that it had reviewed the purported substantiation submitted by Respondents in response to the FTC's December 2018 letter and it did not identify any "human clinical testing of Black Garlic Botanicals, BG-18, Ultimate Heart Formula, or any essentially equivalent product as defined in the Order, showing that the three products cure, mitigate, or treat heart disease, atherosclerosis, or hypertension." The FTC also claimed that it was necessary to have human clinical testing on Neupathic. The FTC also requested information regarding the total revenue from these products since the entry of the Order.
- h. On **June 20, 2019**, Respondents' counsel responded to the FTC's June 6, 2019 letter and provided information regarding human clinical testing on what Respondents believed were essentially equivalent products to the products at issue, as well as additional financial information regarding the products at issue.
- i. On **July 1, 2019**, the FTC sent a letter to Respondents' counsel, requesting additional information and documents. The FTC wanted additional information regarding the products at issue in this proceeding, including studies involving "human clinical testing" of Black Garlic Botanicals, BG-18, Ultimate Heart Formula, Neupathic. The FTC also requested information regarding chargeback, return and refund volume, and information regarding revenue for these products.
- j. On **September 4, 2019**, the FTC sent a letter to Respondents' counsel, stating that the FTC intended to file a motion for contempt related to Section II.H of the Consent Judgment with regard to Black Garlic Botanicals, BG-18, Ultimate Heart Formula, and Neupathic. The FTC sought to enter into a modified Consent Judgment (that prohibited additional conduct) and sought additional monetary payments.
- k. On **September 27, 2019**, pursuant to the FTC's request, the Respondents produced additional documents.

1. On **September 29, 2019**, Respondents' counsel provided the FTC with updated revenue figures and claims substantiation for the Black Garlic Botanicals and BG-18 products, including numerous scientific studies. Respondents also advised the FTC that Respondents had stopped actively marketing the four products at issue (Black Garlic Botanicals, BG-18, Ultimate Heart Formula, and Neupathic). **In other words, the FTC was advised that the alleged deceptive act or practice that was the subject of the later Administrative Complaint had ceased more than a year prior to filing of the Administrative Complaint.**<sup>7</sup>

#### IV. The Aged Garlic Extract Dispute.

14. The current dispute with the FTC, which started shortly before the filing of the Contempt Motion (as defined below), is primarily about black garlic. Two of the four products at issue, Black Garlic Botanicals and BG18 ("**Black Garlic Products**"), are the same product under different labels and account for roughly 70 percent of the revenue at issue.

15. The Black Garlic Products contain 1,200 mg of black garlic. Black garlic is made by treating garlic cloves at high temperature and humidity for a period of time. The process turns the garlic cloves to purple or black and eliminates the smell and taste of fresh garlic. Because all black garlic is aged, black garlic is frequently referred to as "aged black garlic."

16. To my knowledge, the FTC has never contended that the Black Garlic Products did not contain the represented amounts of black garlic or that the products contained any substance that is harmful to humans.<sup>8</sup> In other words, this is not a case of Respondents selling supplements that did not contain black garlic or a case where Respondents sold supplements that contained harmful compounds. Further, to my knowledge, FTC did not dispute the existence of valid and reputable scientific studies that substantiated the health benefits of aged garlic.<sup>9</sup> The FTC's complaints regarding the Black Garlic Products were more technical and nuanced. The FTC's complaints regarding the Black Garlic Products centered around what I refer to as the FTC's "aged garlic extract"

---

<sup>7</sup> Through the Consent Judgment, the FTC had the legal ability to obtain records and contact vendors to verify that this fact.

<sup>8</sup> Pursuant to the FTC's request, I provided samples of the Black Garlic Products, as well as the other products, to the FTC for testing. I presume that the FTC has tested the products.

<sup>9</sup> In fact, in connection with the Motion for Contempt, the FTC submitted the Expert Report of Frank M. Sacks, M.D., a Professor of Medicine at Harvard Medical School, who acknowledged that the studies supplied by Respondents of aged garlic extract "reported favorable effects on coronary calcium scores" and that one study "showed a favorable effect of aged garlic extract on systolic blood pressure." See RX 2 (Contempt Motion in *FTC, et al. v. Health Research Laboratories, LLC, et al.*, Case No. 2:17-cv-00467-JDL, filed December 17, 2019, Dkt. No. 21, PageId# 366-67).



argument. In an October 21, 2019 email to Respondents' counsel, FTC Complaint Counsel Elizabeth Averill explained this issue:

One point that we might want to discuss during the call is that our information suggests that aged garlic extract and aged black garlic are not essentially equivalent products. They are prepared in different ways and have different chemical components, and therefore are not identical ingredients or the same form of the ingredients. The Budoff and Ried studies you have highlighted in your submissions tested aged garlic extract.

17. The Budoff and Ried studies referenced by Complaint Counsel in her October 21, 2019 email are studies that confirm the beneficial health effects of 1200 mg of aged garlic powder:

Ried K., Travica N., Sali A. 2016 (PMID 26869811), *The effect of aged garlic extract on blood pressure and other cardiovascular risk factors in uncontrolled hypertensives: the AGE at Heart trial*. The Ried study determined that a daily intake of 1200 mg of aged garlic powder significantly reduced blood pressure and had beneficial effects on total cholesterol and low-density lipid cholesterol. With respect to hypertension, the Ried study concluded that aged garlic extract is effective in reducing blood pressure “in a large proportion of patients with uncontrolled hypertension.” The study found that aged garlic extract was superior to a placebo in lowering blood pressure in patients with uncontrolled hypertension. **A copy of the Ried 2016 Study is attached as Attachment B.**

Budoff M. 2006 (PMID 16484554), *Aged Garlic Extract Retards Progression of Coronary Artery Calcification*; Budoff M. et al. 2004 (PMID 15475033), *Inhibiting progression of coronary calcification using Aged Garlic Extract in patients receiving statin therapy: a preliminary study*. With respect to arterial plaque calcification, the Budoff studies found that patients given AGE demonstrated a significant slowing of the accumulation of coronary artery calcification during this randomized, placebo-controlled trial. The difference in progression was significant, whether measured by absolute plaque volume or percent change. According to the Budoff 2004 study, “Aged Garlic Extract (AGE) reduces multiple cardiovascular risk factors, including blood pressure, cholesterol, platelet aggregation and adhesion, while stimulating nitric oxide generation in endothelial cells.” **Copies of the Budoff 2004 and 2006 Studies are attached as Attachment C.**

Ried K., Frank O., Stocks N. 2013 (PMID 23169470) Title: Aged garlic extract reduces blood pressure in hypertensives: a dose–response trial. The Ried 2013 study had a relatively large sample size and concluded that even a lower amount of aged garlic extract [compared to HRL's 1200 mg products] yielded a reduction in systolic blood pressure that was “comparable to that

achieved with commonly prescribed antihypertensive medicines, and is of clinical significance.”

Ried K., Frank O., Stocks N. 2010 (PMID: 20594781) Title: Aged garlic extract lowers blood pressure in patients with treated but uncontrolled hypertension: A randomized controlled trial. Copies of the Ried 2013 and 2010 studies are attached as Attachment D.

18. The FTC’s aged garlic extract argument shocked me.<sup>10</sup> Prior to the FTC’s raising this issue, I do not recall anyone ever asserting that there was a difference in the chemical composition or health benefits of “aged black garlic” vs “aged garlic extract.” I do not believe that there is a material difference in the health benefits of aged black garlic versus aged black garlic extract. However, out of an abundance of caution, Respondents did not send any mailers or advisements regarding Black Garlic Products after September 2019. All of the advertisements at issue in this proceeding were sent prior to September 2019.

#### V. FTC’s Motion for Contempt.

19. On December 17, 2019, the FTC and the State of Maine filed their Motion for 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 (“**Contempt Motion**”) in the United States District Court for the District Court of Maine, alleging a violation of only one particular subsection of the 31-page Consent Judgment.<sup>11</sup> In its Motion for Contempt, the FTC alleged that Respondents “brazenly” ignored “the Court’s order barring them from making unsubstantiated claims for their dietary supplements.”<sup>12</sup> At the same time, the FTC requested that the Court modify the Consent Judgment to include additional prohibitions that were *not* in the original Consent Judgment. In other words, the FTC was claiming that the Consent Judgment clearly prohibited the conduct for which the FTC was seeking contempt, but, at the same time, the FTC argued that the Consent Judgment needed to be modified to “accomplish the Order’s original purpose.”<sup>13</sup>

20. As part of the FTC’s efforts to obtain a contempt order, the FTC told the district court that there were records proving the FTC’s interpretation was the parties’ intended interpretation:

---

<sup>10</sup> I believe that FTC first raised the “aged black garlic” issue on or about October 21, 2019, as reflected in Ms. Averill’s email, but it is possible that it was raised in late September 2019.

<sup>11</sup> RX 3 (Contempt Motion in *FTC, et al. v. Health Research Laboratories, LLC, et al.*, Case No. 2:17-cv-00467-JDL, Dkt. No. 21).

<sup>12</sup> *Id.*

<sup>13</sup> *FTC, et al. v. Health Research Laboratories, LLC, et al.*, Case No. 2:17-cv-00467-JDL, Dkt. No. 22, PageId# 587.

Even if the Court were to determine the phrase “cures, mitigates, or treats any disease” is ambiguous, which it plainly is not, and looked beyond the four corners of the Stipulated Order for clarification, **there is substantial evidence in the record demonstrating that the parties intended Section II.H to mean precisely what it says.**<sup>14</sup>

21. The FTC later admitted that *there was no material evidence* that could be presented that would support the FTC’s interpretation of Section II.H.<sup>15</sup>

22. After extensive briefing over several months and a hearing, on August 12, 2020, the Court denied the FTC’s Motion for an Order to Show Cause. Judge Levy stated the following in his Order:

Because I have previously determined that Section II.H is facially ambiguous, and because the Plaintiffs do not seek a hearing at which to offer extrinsic evidence to cure the ambiguity, I conclude that Section II.H does not “clearly and unambiguously” prohibit the Contempt Defendants’ allegedly contumacious conduct. Accordingly, I conclude as a matter of law that the allegations in the Plaintiffs’ motion for an Order to Show Cause fail to support a finding of civil contempt under Section II.H, and the Plaintiffs’ motion for an Order to Show Cause is denied. Additionally, because the Plaintiffs have represented that their motion to modify the Judgment “is predicated on Defendants’ contempt” under Section II.H, ECF No. 42 at 2, their motion to modify the Judgment is denied.

23. Pursuant to the FTC’s request, the Court granted the FTC until October 31, 2020, to seek leave to file an amended motion for Order to Show Cause. The FTC did not seek leave to amend its motion. Instead, on November 13, 2020, the FTC filed an Administrative Complaint with the FTC, seeking a cease and desist order to prevent Respondents from “disseminat[ing] or caus[ing] to be disseminated advertising and promotional materials”<sup>16</sup> for four supplements that the Commission contends were “not substantiated at the time the representations were made.”<sup>17</sup> The Administrative Complaint

<sup>14</sup> *FTC, et al. v. Health Research Laboratories, LLC, et al.*, Case No. 2:17-cv-00467-JDL, Dkt. No. 40, PageId# 771.

<sup>15</sup> See RX 3 (Order Denying Motion for Contempt in *FTC, et al. v. Health Research Laboratories, LLC, et al.*, Case No. 2:17-cv-00467-JDL, Dkt. No. 52, Order, p. 3) (“At the conference, the Plaintiffs maintained their position that extrinsic evidence is admissible for purposes of determining whether Section II.H is clear and unambiguous, but **indicated that in any event, they lacked sufficient extrinsic evidence to specifically prove that Section II.H clearly and unambiguously prohibits the conduct on which their contempt allegations are based.**”)(emphasis added).

<sup>16</sup> See Complaint, ¶¶ 7, 9, 11 and 13.

<sup>17</sup> See Complaint, ¶¶ 15, 17, 19, and 21.

concerned the exact same alleged acts and practices that were the subject of the Contempt Motion.

## VI. FTC's Administrative Complaint.

24. In my opinion, this administrative action has been an unnecessary waste of taxpayer resources. The FTC is seeking a cease and desist order for an alleged act or practice that, as the FTC knows, ceased more than a year prior to the filing of Administrative Complaint. If the FTC wanted the Respondents to cease using any specific advertisements or marketing, the FTC could have accomplished this purpose through a simple letter that directed the Respondents to “cease and desist” from sending out a specific advertisement.

25. Complaint Counsel might argue that Respondents would not have ceased the complained-of marketing practices based simply on a written request from the FTC. This, of course, would be speculation because, prior to filing the Contempt Motion and the Administrative Complaint, the FTC never sent a written request to Respondents to cease and desist from the alleged marketing acts or practices that were the subject of the Contempt Motion and the Administrative Complaint. Further, the long history of this dispute shows that the Respondents have repeatedly complied with the FTC's requests. As previously explained, Respondents have produced thousands of pages of documents to the FTC and answered hundreds of the FTC's questions. For example, based on the FTC's requests, Respondents produced databases of consumer records, multiple years of financial records, and contact information for all of Respondents' vendors and business associates. Respondents agreed to a Consent Judgment under which Respondents paid the FTC \$800,000 and agreed to extensive prohibitions on marketing and advertising. Additionally, as required, Respondents ceased marketing all weight loss products and all cognitive performance products. Further, as the FTC's own evidence shows,<sup>18</sup> Respondents *voluntarily ceased* the advertising and marketing at issue in the case prior to the filing of the Contempt Motion and the Administrative Complaint.

26. The history of this administrative proceeding demonstrates that the FTC's true purpose is not simply to obtain the statutory-authorized “cease and desist” order. Despite the FTC's stated policy to conduct these administrative proceedings “expeditiously,”<sup>19</sup> the FTC's actions, as set forth below, show that the FTC has had no interest in resolving this proceeding expeditiously.

---

<sup>18</sup> See CCX2 – Averill Affidavit, Attachment F (showing that the last advertisement was sent on August 22, 2019). The Contempt Motion was filed on December 17, 2019. The Administrative Complaint was filed on November 13, 2020.

<sup>19</sup> See 16 C.F.R. 3.1 (“the Commission's policy is to conduct such proceedings expeditiously.”).

27. On January 13, 2021, Respondents filed a Motion for Acceptance of Contested Cease-and-Desist Order, requesting that the FTC enter a binding cease and desist order that granted the following relief to the FTC:

Respondents shall “cease and desist” from disseminating or causing to be disseminated all advertising or promotional materials for all dietary supplement products referenced in the Complaint (i.e., Black Garlic Botanicals, BG18, The Ultimate Heart Formula, and Neupathic), as well as any substantially similar products.

Respondents shall cease and desist from selling or causing to be sold all dietary supplement products referenced in the Complaint (i.e., Black Garlic Botanicals, BG18, The Ultimate Heart Formula, and Neupathic), as well as any substantially similar products.

The terms “cease and desist” are intended to have the same meaning and scope as such terms are used in Sections 5(a) and 12 of the FTC Act, 15 U.S.C. § 45(a) and 52.<sup>20</sup>

28. To end this proceeding and avoid unnecessary costs, Respondents sought to have the Administrative Law Judge and the Commission enter a cease and desist order *against the Respondents*. Respondents made this request early in the case—only five weeks after they filed their Answer. Remarkably, the FTC *opposed* the entry of any cease-and-desist order and did not propose an alternative cease and desist order.<sup>21</sup>

29. On February 1, 2021, ALJ Chappell entered an Order Denying Respondents’ Motion for Acceptance of Contested Stipulated Cease and Desist Order. In response to this ruling, Respondents filed a Motion for Leave to Amend, seeking to amend the answer in order to elect not to contest the material allegations of fact in the Complaint, as permitted by 16 C.F.R. § 3.12(b)(2). The FTC opposed Respondents’ effort to not contest the material factual allegations *in the FTC’s own Complaint* and, in an effort to prevent the quick resolution of this administrative proceeding, Complaint Counsel requested leave to amend the Complaint to include numerous other allegations.<sup>22</sup>

---

<sup>20</sup> See Respondents’ Motion for Acceptance of Contested Stipulated Cease-and-Desist Order, filed January 13, 2021.

<sup>21</sup> See Complaint Counsel’s Opposition to Respondents’ Motion for Self-Imposed Cease-and-Desist Order, filed January 25, 2021; *see also* Certificate of Conference with Respondents’ Motion for Acceptance of Contested Stipulated Cease-and-Desist Order, filed January 13, 2021 (requesting that, if the FTC could not agree to the proposed cease and desist order, whether there was other language the FTC would propose for a cease and desist order).

<sup>22</sup> See Complaint Counsel’s Opposition to Motion to Amend Answer and Cross Motion to Amend Complaint, filed on February 24, 2021.

30. On March 10, 2021, ALJ Chappell entered an Order Granting Respondents' Motion for Leave to Amend Answer. ALJ Chappell found that Complaint Counsel had failed "to explain how amending the Answer is prejudicial to Complaint Counsel's case."

31. On March 12, 2021, ALJ Chappell entered an Order Denying Complaint Counsel's Motion to Amend the Complaint. ALJ Chappell noted that "Complaint Counsel's seeking the proposed amendments, in reaction to Respondents' election under Rule 3.12(b)(2), appears to be more of a strategic effort to counter Respondents' effort to bring this case to a resolution, than an effort to facilitate a determination of this case on the merits."<sup>23</sup>

32. On March 30, 2021, Respondents filed their Amended Answer and, pursuant to 16 C.F.R. § 3.12(b), Respondents elected not to contest the allegations set forth in the Complaint.

## VII. Why Respondents Elected Not to Contest the Facts Alleged in the Complaint.

33. The Commissioners may wonder why Respondents elected not to contest the material facts in the Complaint if Respondents believed that they had done nothing wrong. Respondents elected not to contest the material facts alleged in the Complaint because: (a) Respondents understood that this Part 3 Administrative Proceeding is not a fair and impartial process, so Respondents had no hope of prevailing, regardless of what evidence the Respondents presented; and (b) Respondents came to the realization that Respondents could not afford to continue business operations while constantly responding to the FTC's actions.

### A. The FTC's Unfair and Biased Administrative Process.

34. Soon after the FTC filed this Part 3 administrative action, I learned that the FTC's administrative process was not a fair or impartial process with a neutral factfinder.<sup>24</sup> First, based on the Complaint, I understood that the FTC was seeking a "cease and desist order" that prohibited "disseminat[ing] or caus[ing] to be disseminated advertising and promotional materials" for four supplements—advertising that had ceased long before the administrative complaint was filed. Second, as I understand the process, the FTC's Commissioners approve a complaint that is prosecuted by FTC lawyers before an Administrative Law Judge who is paid by the FTC, who renders a decision that is appealable to the FTC's Commissioners on a *de novo* basis. See 16 C.F.R. § 3.54. According to information on the FTC's website, once the FTC Commissioners approve a complaint, the FTC Commissioners use their veto appellate power to ensure that they have a 100 percent

<sup>23</sup> See Order Denying Complaint Counsel's Motion to Amend the Complaint, filed on March 12, 2021.

<sup>24</sup> Respondents disclosed this reason when they elected not to contest the facts alleged in the Complaint See Motion to Amend Answer, filed February 12, 2021 ("Respondents do not believe that the Part 3 administrative process is fair, impartial, or constitutional.").

success rate on the approved Complaint.<sup>25</sup> In 2015, former FTC Commissioner Wright observed:

The FTC has voted out a number of complaints in administrative adjudication that have been tried by the administrative law judges in the past nearly twenty years. In each of those cases, after the administrative decision is appealed to the Commission, the Commission has ruled in favor of FTC staff and found liability. **In other words, in 100 percent of cases where the administrative law judge ruled in favor of the FTC staff, the Commission affirmed liability; and in 100 percent of the cases in which the administrative law judge [ ] found no liability, the Commission reversed. This is a strong sign of an unhealthy and biased institutional process.**<sup>26</sup>

35. Based on the comments on the FTC's website by former Commissioner Wright and the review of the cases in the attached chart, it was apparent that no Respondent had won a Part 3 administrative proceeding in 25 years. Consequently, it made no sense to me to continue paying hundreds of thousands of dollars to defend an administrative cease and desist action, particularly one that involved marketing and advertising that Respondents had ceased more than a year prior to the filing of the Administrative Complaint.

#### **B. The Financial Toll of Fighting a Government Agency.**

36. As previously explained, the FTC's pursuit of claims against the Respondents started in approximately January 2015 with the issuance of the CID. From January 2015 through January 2021 (when Respondents filed their Motion to Amend), Respondents paid approximately an \$800,000 settlement, \$235,000 in legal fees to Olshan for FTC-related issues and advertising review, roughly \$71,000 to Olshan's medical researcher (Inna Yegorova), \$82,000 to other consultants, and roughly \$152,000 in legal fees for the defense of the Contempt Motion and this administrative proceeding. In addition, HRL and WBS's small staff spent vast amounts of time responding to the FTC's seemingly never-ending series of questions and document requests.

37. It appeared to me that, because of the manner in which the FTC was prosecuting this case, it would be extremely expensive to defend and, apparently, had no end. For example, in connection with the Contempt Motion, the FTC produced a detailed 22-page expert report from a Harvard Medical School Professor (Dr. Frank M. Sacks, M.D.) and a 25-page expert report from a Professor of Internal Medicine from the

---

<sup>25</sup> See RX 4 (Joshua D. Wright, *Section 5 Revisited: Time for the FTC to Define the Scope of its Unfair Competition Authority* at 6 (2015)) and RX 5 (Post-2015 FTC cases chart compiled by others from the FTC website).

<sup>26</sup> RX 4 (Joshua D. Wright, *Section 5 Revisited: Time for the FTC to Define the Scope of its Unfair Competition Authority* at 6 (2015) (emphasis added)). The FTC's success rate post-2015 appears to have continued. See RX 5 (Post-2015 cases chart).

University of Michigan (Dr. Charles F. Burant, M.D., PH.D.) According to their reports, the FTC was paying each professor \$350 an hour. Respondents simply did not have the resources to pay for medical experts and lawyers to defend advertising that had ceased long before the Administrative Complaint was filed.

38. In addition, in November 2020, Complaint Counsel served document requests and interrogatories. In early January 2021, the FTC served approximately 13 subpoenas on virtually every vendor and business partner connected to the Respondents, including Inna Yegorova, Kent Komae, Dietary Supplement Experts, Richard Cohen, Jennifer Osterhouse, Event Management Concepts, Stephen Kimball DM Copywriting, Page One Web Solutions, Direct Access Marketing, Impulse Media, Pure Source LLC, NexRep LLC, and Ship-Right Solutions.

39. The time and expense of this case far exceeded the net profits at issue. For the time period at issue, based on federal tax returns, I estimate that HRL and WBS collectively less than \$70,000 in net profits for *all products* from 2018 through 2020. Consequently, I eventually decided that the best course of action was for the Respondents to cease all business operations for all products. HRL and WBS have permanently ceased all operations and have no intention of continuing any future business operations.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct based on my personal knowledge, including documents for which I am a custodian.



KRAMER/DUHON



# Exhibit RX 1 Attachment A



## Andrew B. Lustigman

Partner

1325 Avenue of the Americas  
New York, NY 10019

T: 212.451.2258  
F: 212.451.2222  
alustigman@olshanlaw.com

### Practice Areas

Advertising, Marketing & Promotions

Brand Management & Protection

Intellectual Property Law

Litigation

White Collar Defense & Government Investigations

### Honors

Andy has been repeatedly ranked as a "Leading Lawyer" in Advertising: Transactional & Regulatory" by Chambers USA annually since 2008

Andy has been recognized as a "Recommended Lawyer" in *The Legal 500 U.S. in Media, technology and telecoms* – Advertising and Marketing annually since 2016

Andy has been selected by his peers for inclusion in *The Best Lawyers in America* in the field of Advertising Law, annually since 2016

Andy has been consistently named to the New York *Super Lawyers* list, a Thomson Reuters lawyer rating service, since 2008

Andy has been named to the Top 100: New York — Metro Super Lawyers list for 2019 and 2020

Andy is AV-rated ("Preeminent") by Martindale-Hubbell

### Education

J.D., *magna cum laude*, American University, Washington College of Law, 1991

**Andrew B. Lustigman represents marketers, advertisers, agencies and suppliers in connection with the legal aspects of their advertising and promotional marketing businesses. According to Chambers USA, Andrew was cited by clients as "pragmatic and always looking for solutions that meet a specific client's needs."**

Andy Lustigman is a member of the Olshan Executive Committee, Chair of the firm's Advertising, Marketing and Promotion's Group, and Co-Chair of Brand Management & Protection Group.

Leveraging his extensive experience in advertising, marketing and promotions, Andy counsels domestic and international clients regarding a broad range of matters, including the clearance of advertising and marketing materials, the structuring of sweepstakes, games of skill, and other contests, the development of social media programs and direct marketing campaigns from a compliance standpoint, and the resolution of regulatory, competitor, intellectual property and privacy matters. Having been recognized by Chambers USA for fourteen consecutive years, Chambers noted that, "*Andrew Lustigman provides clients with legal advice on a wide range of advertising concerns, from structuring sweepstakes to regulatory proceedings.*" The publication also notes that "*Andrew has always made himself available on short or no notice to provide comprehensive support as needed. He is well versed in all facets of advertising and marketing. he responds quickly with pragmatic analysis and is good at thinking outside the box.*"

### Advertising Clearance and Promotional Marketing Compliance

A significant portion of Andy's practice involves review of advertising and promotional campaigns to help ensure compliance with substantiation requirements and relevant legal standards. He provides advice for campaigns across all media channels — Internet, television, print, radio, direct mail, mobile, telemarketing, and other electronic media, as well as social media platforms.

### Regulatory Investigations and Litigation

Andy regularly represents clients in advertising-related investigations and litigation brought by federal and state regulatory agencies, including the Federal Trade Commission, the Food and Drug Administration, Federal Communications Commission, the United States Postal Service, the United States Senate, state attorneys general and other governmental organizations.

Managing Editor, *The American University Law Review*

B.A., University of Michigan, 1988

### Bar & Court Admissions

New York

New Jersey

U.S. District Court District of New Jersey

U.S. District Court District of Maryland

U.S. District Court of the District of Columbia

U.S. District Court District of Colorado

U.S. District Court, Eastern, Southern, and Western Districts of New York

U.S. Court of Appeals 2nd, 4th, 11th Circuits

U.S. Court of Appeals Federal Circuit

U.S. Supreme Court

### Consumer and Business Litigation

He also handles individual consumer, consumer class action, and related commercial litigation involving false and deceptive advertising issues, intellectual property, and corporate matters. He advises clients on strategies to address emerging threats and on creative and aggressive defense theories. In prosecuting and defending his clients' interests, he frequently appears in federal and state court and before the National Advertising Division of the Better Business Bureaus.

### Health Product Counseling and Defense

A core component of Andy's practice is advising clients on compliance with Federal Trade Commission and Food and Drug Administration requirements regarding advertising, labeling and distributing health-related products. These products include prescription drugs, OTC products, dietary supplements, medical devices, cosmetics, and medical foods. In addition, he frequently represents clients before these regulatory agencies in connection with investigations, warning letters, inspections, and litigation and in competitor disputes under the Lanham Act and state equivalents as well as in alternative dispute venues such as NAD and ERSP.

### Industry Expert

Andy regularly appears on television, radio, and in publications such as the *The Wall Street Journal*, *New York Post*, *National Law Journal*, *Inside Counsel*, *Bloomberg BNA*, *Law360*, *Mobile Marketer*, *Luxury Daily*, and *Response* discussing important new cases and trends that advertisers and marketers need to know. He also contributes to the Brand Activation Association/Promotion Marketing Association's Promotion Marketing Law treatise and various American Bar Association publications. He frequently speaks on advertising and promotional marketing law topics throughout the country.

### Ranked by Chambers USA, Legal 500 US and Best Lawyers

Each year since 2008, Andy has been selected as a Notable Practitioner in his practice area by Chambers USA, the leading legal directory that publishes annual rankings based on interviews with thousands of clients. According to Chambers USA, he was acclaimed by peers for his skill as an NAD practitioner and for his traditional advertising expertise, with Chambers noting, "He's the one guy in the industry I'd go to. Every single issue in advertising, compliance, litigation, whatever — he does it all, and he does it well." Chambers USA has also described Andy as a premier choice as he provides clients with legal advice on a wide range of advertising concerns, from structuring sweepstakes to regulatory proceedings. quoting clients who say "Andrew is amazing at what he does. He is very agreeable, social and has a winning personality." Legal 500 US has recognized Andy as a "Recommended Lawyer" in Advertising and Marketing since 2016. Clients praise Andy as 'an excellent name in the arena' and also notes that 'Lustigman is particularly focused on FTC regulation and compliance matters, with a solid record in the retail, e-commerce, and pharmaceutical sectors.' Additionally, Andy was selected by his peers for inclusion in The Best Lawyers in America for his distinguished work in Advertising.

Prior to joining Olshan, Andy was the principal of The Lustigman Firm, P.C.

## PROFESSIONAL & COMMUNITY AFFILIATIONS

LAWorld International Legal Network

New York State Bar Association

New Jersey Bar Association

Association of the Bar of the City of New York, Consumer Affairs Committee

Brand Activation Association/Promotion Marketing Association, Legal Affairs Committee

American Bar Association, Committee on Promotion and Marketing Law (past chair)

American Bar Association, Consumer Protection Committee

Direct Marketing Association

Federal Communications Bar Association

Fellows of the American Bar Foundation

## REPRESENTATIVE MATTERS

- Represented a global financial services firm in obtaining NAD decisions in connection with four multi-million dollar, wide-spread, national advertising campaigns. Prosecution of challenges resulted in decisions requiring competitors to significantly modify their wide-spread commercial advertising campaigns.
- Represented a nutritional supplement industry leader in its challenge of the false and unsubstantiated claims made by a competing supplement provider that one of its products was superior. NAD ruled in favor of our client on all challenged claims and determined that the competitor should modify its advertising.
- Provides ongoing advice to the leading consumer advocacy publisher in connection with Internet marketing promotions, mobile applications, review of direct mail subscription pieces, and contests and sweepstakes. Provides ongoing legal advice on regulatory and compliance matters.
- Represents leading interactive promotion agency in structuring contests, drafting rules, and reviewing advertising and promotional materials. Provides ongoing legal support throughout the contest period and winner selection process.
- Represents the largest subscription radio broadcaster in connection with advertising, marketing and business practices, ensuring compliance with a myriad of federal and state laws. Specifically provides guidance with respect to telemarketing, automatic renewal, billing disclosures, and collection issues.
- Represents two leading interactive promotional marketing agencies and their clients with respect to their contests and promotions. Helps structure sweepstakes, draft rules, review advertising and promotional materials, and provides ongoing legal support throughout the sweepstakes period and winner

selection process.

- Counsels mobile media and computing giant to ensure the marketing and business practices for its retail stores comply with a myriad of federal and state laws, specifically with respect to legal issues involving the retail marketing of the company's mobile phone products.
- Defended an Internet service provider in connection with a high-profile investigation brought by the New York Attorney General. Developed a strategy, assisted in responding to the investigation, and ultimately obtained a satisfactory resolution. The settlement was part of "Operation Clean Turf" which received national media attention. We continue to represent the company in ongoing matters.
- Represented a technology company that powers leading hybrid travel agencies in connection with a competitor's challenge to one of its agency's online airline price and savings claims made in a wide-spread, multi-channel advertising campaign. NAD recognized that our client offers consumers air fare savings, including discount airfares, a best price guarantee, and additional savings opportunities that may not be generally available to consumers. We continue to represent the company in ongoing matters.
- Represented telecommunications suppliers in litigation with the Vermont Attorney General, regarding marketing and billing practices of companies providing third-party services.
- Defending marketer of memorabilia in connection with an FTC and NY State investigation relating to its marketing practices, specifically providing proactive advice in terms of advertising review and responding to inquiries and media issues.
- Advised investment banking firm in connection with its proposed acquisition of a stake in one of the largest health and fitness companies in the United States. Services included review of advertising, privacy, and marketing practices.
- Successfully defeated a motion for class certification, reducing liability from \$20 million to \$500, for a provider of on-demand automated voice broadcasting and bulk text messaging technology, that was named as a defendant in a class action lawsuit under the Telephone Consumer Protection Act. Also won a summary judgment motion against a co-defendant for indemnification.

# Exhibit RX 1 Attachment B

# The effect of aged garlic extract on blood pressure and other cardiovascular risk factors in uncontrolled hypertensives: the AGE at Heart trial

This article was published in the following Dove Press journal:

Integrated Blood Pressure Control

27 January 2016

[Number of times this article has been viewed](#)

Karin Ried<sup>1-3</sup>  
Nikolaj Travica<sup>1</sup>  
Avni Sali<sup>1</sup>

<sup>1</sup>National Institute of Integrative Medicine, Melbourne, <sup>2</sup>Faculty of Health Science and Medicine, Bond University, Gold Coast, <sup>3</sup>Department of General Practice, University of Adelaide, Adelaide, Australia

**Background:** Hypertension affects 30% of adults worldwide. Garlic supplements have shown promise in the treatment of uncontrolled hypertension, and the mechanism of action is biologically plausible. Our trial is the first to assess the effect of aged garlic extract on central blood pressure and arterial stiffness, regarded as important risk factors for cardiovascular morbidity.

**Subjects and methods:** A total of 88 general practice patients and community members with uncontrolled hypertension completed a double-blind randomized placebo-controlled trial of 12 weeks investigating the effect of daily intake of aged garlic extract (1.2 g containing 1.2 mg *S*-allylcysteine) or placebo on blood pressure, and secondary outcome measures of central-hemodynamics and other cardiovascular markers, including cholesterol, homocysteine, platelet function, and inflammatory markers.

**Results:** Mean blood pressure was significantly reduced by  $5.0 \pm 2.1$  mmHg ( $P=0.016$ ) systolic, and in responders by  $11.5 \pm 1.9$  mmHg systolic and  $6.3 \pm 1.1$  mmHg diastolic compared to placebo ( $P<0.001$ ). Central hemodynamic-measures tended to improve in the garlic group more than in the placebo group, including central blood pressure, central pulse pressure, mean arterial pressure, augmentation pressure, pulse-wave velocity, and arterial stiffness. While changes in other cardiovascular markers did not reach significance due to small numbers in subgroups with elevated levels, trends in beneficial effects of garlic on the inflammatory markers TNF $\alpha$ , total cholesterol, low-density lipid cholesterol, and apolipoproteins were observed. Aged garlic extract was highly tolerable and acceptable, and did not increase the risk of bleeding in patients on blood-thinning medication.

**Conclusion:** Our trial suggests that aged garlic extract is effective in reducing peripheral and central blood pressure in a large proportion of patients with uncontrolled hypertension, and has the potential to improve arterial stiffness, inflammation, and other cardiovascular markers in patients with elevated levels. Aged garlic extract was highly tolerable with a high safety profile as a stand-alone or adjunctive antihypertensive treatment.

**Keywords:** hypertension, central blood pressure, arterial stiffness, cardiovascular risk factors, aged garlic extract

## Introduction

Hypertension affects 1 billion (one in four) adults worldwide, and attributes to about 40% of cardiovascular-related deaths.<sup>1-3</sup> Standard antihypertensive medication is not always effective, leaving about 24% (3 million) of the adult population uncontrolled hypertensive.<sup>4</sup> Garlic supplements have been associated with a blood pressure (BP)-lowering effect of clinical significance in hypertensive patients.<sup>5-8</sup> The mechanism of action is biologically plausible, whereby garlic's BP-lowering effect

Correspondence: Karin Ried  
National Institute of Integrative  
Medicine, 21 Burwood Road, Hawthorn,  
Melbourne, VIC 3122, Australia  
Tel +61 3 9912 9545  
Fax +61 3 9804 0513  
Email [karinried@niim.com.au](mailto:karinried@niim.com.au)

involves the hydrogen sulfide- and nitric oxide-signaling pathways.<sup>9</sup> Garlic in the form of Kyolic aged garlic extract is particularly effective and tolerable with a high safety profile, and standardized by dosage of the active ingredient *S*-allylcysteine (SAC).<sup>6,10</sup>

While previous research has shown aged garlic extract to reduce peripheral BP,<sup>5-8</sup> this study is the first to assess the effect of aged garlic extract on central hemodynamic measures, including central BP, central pulse pressure, pulse-wave velocity (PWV), and arterial stiffness.

Central hemodynamic measures and arterial stiffness are regarded as more important predictors or risk factors than peripheral BP for cardiovascular disease.<sup>11</sup> Furthermore, arterial stiffness, an indicator of the loss of flexibility or hardening of the arteries, increases with age through loss of intact elastin and collagen fibers in the arterial wall, leading to atherosclerosis and contributing to increased BP.<sup>12</sup> However, arterial stiffness is one of many other risk factors contributing to hypertension.

Here, we describe the effect and tolerability of aged garlic extract as an adjunct treatment on peripheral (office/clinical) BP, central hemodynamic measures, and cardiovascular markers in patients with uncontrolled hypertension.

## Subjects and methods

### Trial design and methods

This study was approved by the Human Research Ethics Committee at National Institute of Integrative Medicine, and the trial was registered with the Australian New Zealand Clinical Trial Registry (ACTRN12613000747729). Participants provided informed written consent.

Adults with uncontrolled hypertension (systolic BP [SBP]  $\geq 140$  mmHg and/or diastolic BP [DBP]  $\geq 90$  mmHg) were sought to participate in the double-blind randomized placebo-controlled parallel 12-week trial investigating the effect of aged garlic extract on BP and other cardiovascular markers/parameters. We recruited through seven general practices in metropolitan Melbourne, Australia, as well as by distribution locally of flyers, postcards, advertising in the local newspaper, our institute's website, and social media. We included patients with a mean SBP  $\geq 138$  mmHg or mean DBP  $\geq 85$  mmHg under clinical trial conditions who had been either on an established plan of prescription antihypertensive medication for at least 2 months or did not take any BP medication and their doctor did not plan to change their BP-medication regime during the trial. We excluded patients with unstable or serious conditions, including dementia, terminal illness, secondary hypertension, or pregnancy.

Patients were also excluded if they were not able to give informed consent or were taking daily supplements containing aged garlic extract.

### Allocation and treatment

Consenting eligible patients were randomly allocated to the garlic or placebo group using a computer-generated permuted random-number table provided by an independent consulting statistician. Patients were assigned either two capsules daily of Kyolic aged garlic extract (Reserve formula; Wakunaga of America Co Ltd, Mission Viejo, CA, USA)<sup>13</sup> containing 1.2 g of aged garlic extract powder and 1.2 mg SAC) or to two placebo capsules daily for 12 weeks.

Kyolic aged garlic extract powder is manufactured from organically grown garlic bulbs that have undergone a 20-month natural aging process at room temperature. During the aging process, volatile sulfur components found in raw garlic, such as allicin, are chemically converted into stable and standardizable components, including the main active component SAC.<sup>13,14</sup>

Placebo capsules were matched in appearance to the active capsules, and packaged in identical containers by independent staff not involved in the trial. Activated carbon sachets were added to each container to disguise any odor.

Patients, investigators, and research assistants were blinded to treatment allocation. Blinding success of patients was assessed at the end of the trial by questionnaire. Patients were instructed to take the trial capsules in the evening with food. Patients were reminded to take their usual prescription medication as instructed by their doctor. Compliance was assessed by daily entries in calendars provided. Baseline demographics, exercise, and stress levels were assessed at the first appointment by questionnaire.

## Assessments

### Blood pressure monitoring

#### Clinical blood pressure

Primary outcome measures were SBP and DBP at 4, 8, and 12 weeks compared with baseline. BP was measured by a trained research assistant using two independent devices: 1) a calibrated and validated digital sphygmomanometer (HEM-907; Omron Corporation, Kyoto, Japan), and 2) an oscillometric ambulatory BP monitor (Mobil-O-Graph; IEM GmbH, Stolberg, Germany), with appropriately sized brachial cuffs.

The displays of the BP monitors were positioned away from the patient to assure blinding to the BP readings. BP measurements were taken with the patient in a seated position



with the arm supported at heart level, after 5 minutes' rest, and after abstinence from food, caffeinated beverages, and smoking for a minimum of 2 hours prior to BP measurement at approximately the same time and day of the week. BP taken with the digital sphygmomanometer was recorded as three serial measurements at intervals of 30 seconds on both arms. Subsequently, BP was recorded with the Mobil-O-Graph device once on both arms, starting with the same arm as before. The mean of the BP measured with both devices on both arms was used in the analysis. If a BP reading deviated by more than 10 mmHg from the average reading, the BP reading on that arm was repeated.

#### Central blood pressure, arterial stiffness

With the Mobil-O-Graph device, we also assessed central hemodynamic measures, including central BP, PWV, pulse pressure, and arterial stiffness at baseline and 4, 8, and 12 weeks. The Mobil-O-Graph uses brachial oscillometric BP waves for a noninvasive estimation of central BP, by taking a 10-second snapshot of the radial arterial pressure wave and calculating the ascending aortic pressure wave with the ARCSolver algorithm, which in turn provides central BP, aortic augmentation index, ejection duration, and subendocardial viability ratio.<sup>15</sup> The Mobil-O-Graph has been validated for automated BP monitoring against invasive recordings using benchmark solid-state pressure sensor-tipped catheters (Millar Instruments, Houston, TX, USA) and against a validated US Food and Drug Administration-approved noninvasive system (SphygmoCor; AtCor Medical Inc., Sydney, Australia).<sup>16,17</sup>

Aortic PWV is considered the gold standard in the assessment of arterial stiffness,<sup>11</sup> and can be measured non-invasively by brachial oscillometry or radial tonometry using the Mobil-O-Graph monitor.<sup>18</sup> Measures of arterial stiffness, including augmentation pressure, augmentation index, and PWV, are strongly correlated with age and sex.<sup>19,20</sup>

#### Cardiovascular biomarkers

Fasted blood samples were taken by a research nurse at baseline and at 12 weeks to assess cardiovascular biomarkers, including serum cholesterol and triglycerides, lipoproteins, homocysteine, platelet function, and the inflammatory markers of ultrasensitive CRP, TNF $\alpha$ , and IL-1 $\beta$ . Platelet function was measured by clotting time on epinephrine/collagen and adenosine diphosphate/collagen using the PFA-100 platelet-function analyzer (Siemens AG, Munich, Germany), indicating platelet adhesion, activation, and aggregation. Principally, results indicate the longer

the closure time the thinner the blood, and the shorter the closure time the thicker or stickier the blood. Liver and kidney function and glucose levels were also assessed by standard pathology assays.

#### Tolerability and acceptability

The tolerability of trial supplements was monitored throughout the trial by questionnaire at the 4-weekly appointments, and long-term acceptability was assessed at 12 weeks using our previously developed questionnaire.<sup>5,6</sup> Patients were followed up by phone to assess reasons for withdrawal.

#### Sample size

A sample size of 100 patients was calculated based on the following assumptions: 1) to detect a difference of 10 mmHg SBP (standard deviation 10) or 6.5 mmHg DBP (standard deviation 10) in BP change between the active treatment (n=50) and control groups (n=50) with a power of  $\geq 80\%$  and 95% confidence; and 2) to account for 20% dropout or nonattendance at all appointments. Based on the experience of our previous trials,<sup>5,6</sup> assuming a response rate of 15% and 50% of patients meeting eligibility criteria under trial conditions, we aimed to invite 1,630 patients from seven general practices.

#### Statistical analysis

Analyses were performed using IBM SPSS version 22. Statistical significance was set at  $P < 0.05$ . Descriptive analysis was carried out for baseline characteristics. Differences between the groups were assessed by  $\chi^2$  test or Fisher's exact test for binominal variables, Mann-Whitney  $U$  test for ordinal variables, and one-way analysis of variance with Bonferroni adjustment for continuous variables. Potential confounding variables were included in the analysis using analysis of covariance (ANCOVA), eg, age and sex relevant for some central hemodynamic measures, and any baseline variables significantly different between groups. Primary outcome measures were clinical and central BP, and secondary outcome measures were other hemodynamic measures and cardiovascular markers.

Repeated-measure ANCOVA was used to assess the mean differences between groups for variables with multiple time points at 4, 8, and 12 weeks compared to baseline, including SBP and DBP and other central hemodynamic measures. Primary analysis was conducted with all participants following the protocol, excluding data points owing to BP-medication change and participant noncompliance of less than 50%.

Exploratory subgroup analysis using ANCOVA adjusted for baseline differences was performed by response to treatment for the primary outcome measure – BP. We defined responders to garlic treatment as mean reduction by more than 3% in SBP ( $\geq 5$  mmHg) or DBP ( $\geq 3$  mmHg) over time compared to baseline, which is clinically and statistically meaningful and similar to definitions by others.<sup>21</sup>

Exploratory subgroup analysis of secondary outcome measures using ANCOVA adjusted for age and sex was done by baseline levels (elevated versus normal) of selected central hemodynamic measures (eg, PWV, augmentation pressure, and augmentation index), and selected cardiovascular blood markers (total cholesterol, low-density lipoprotein [LDL], apolipoprotein A/B (ApoA/B), homocysteine, and platelet-function markers).

## Results

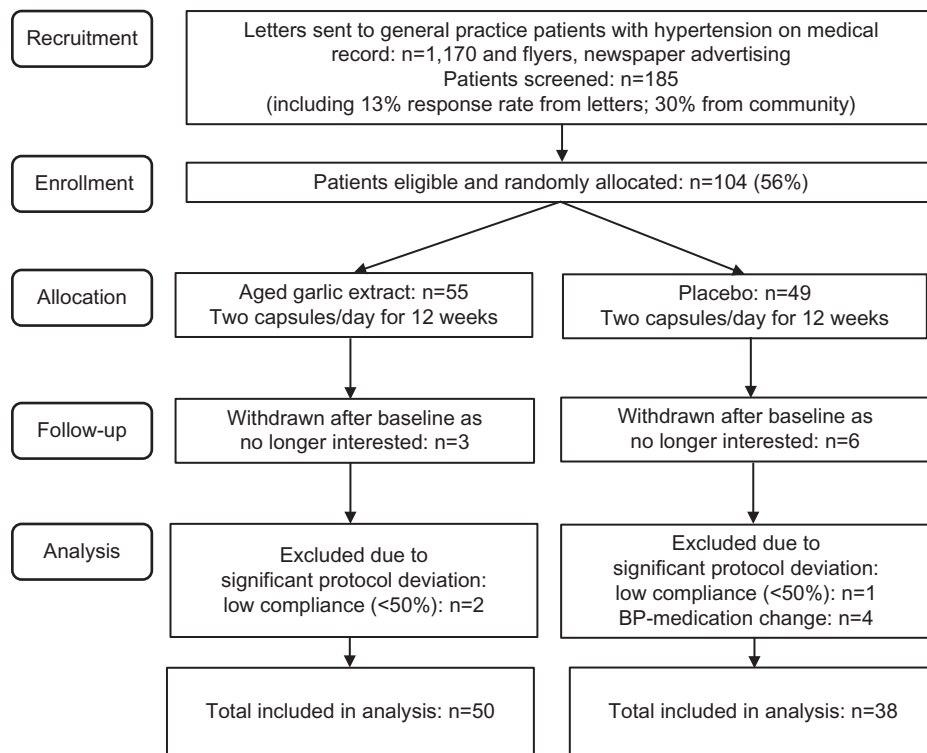
### Participants

The trial was conducted in Melbourne, Australia between September 2013 and August 2014. Two-thirds of the patients with uncontrolled hypertension on medical record were recruited from seven metropolitan general practices with the support of eleven doctors. A third of the patients were recruited by letterbox drop of flyers, postcard displays

at local pharmacies, advertising in the local newspaper, and through our institute’s website and social media. Of the 1,170 invitations sent through general practices, 13% responded. A total of 185 patients were screened for eligibility, and 104 patients (56%) were enrolled in the trial and randomly allocated to the garlic or the placebo group. Nine patients withdrew after their baseline assessment, due to personal reasons unrelated to the trial (Figure 1). After assessment of brachial BP and central hemodynamic measures using the digital sphygmomanometer and the ambulatory BP monitor (Mobil-O-Graph), eligible enrolled patients were asked to return to the clinic within the next few days for a fasted blood sample. On the day of the baseline blood-sample test, patients were provided with a month’s supply of the trial medication and a calendar, until the next appointment in 4 weeks’ time.

Baseline characteristics were not significantly different between groups, including BP medication and other prescription medication (eg, blood-thinning medication, lipid-lowering medication, hormone-replacement therapy), as well as physical activities and stress levels (Table 1).

Of the 95 participants who completed the trial, seven were excluded due to significant protocol deviation known to influence primary outcome measures, including BP-medication



**Figure 1** Trial flowchart.  
**Abbreviation:** BP, blood pressure.

**Table 1** Baseline characteristics

Demographics	All (n=88)	Placebo (n=38)	Garlic (n=50)	Garlic subgroup responders (n=29)	Garlic subgroup nonresponders (n=21)
	Mean ± SD				
<b>Age</b>					
Years	62.3±11.3	61.5±13.0	63.3±9.9	63.2±11.7	63.4±8.2
<b>BMI</b>					
kg/m <sup>2</sup>	27.7±4.9	28.3±4.9	27.3±4.9	26.7±5.0	28.1 ±4.8
<b>Vigorous exercise</b>					
Days/week	1.4±2.0	1.1±1.5	1.6±2.3	1.1±1.5	1.3±2.1
<b>Moderate exercise</b>					
Days/week	3.6±2.4	3.5±2.4	3.6±2.4	3.5±2.4	3.5±2.5
<b>Stress score (Cohen)</b>					
Range 0–40 points	10.1±6.6	12.0±6.5	13.9±6.6	13.8±6.5	13.9±6.7
<b>Other stressors</b>					
Range 0–4	0.4±0.8	0.4±0.6	0.5±0.9	0.5±0.9	0.5±0.9
	n (%)				
<b>Sex</b>					
Male/female	47/41 (53/47)	19/19 (50/50)	28/22 (56/44)	17/12 (59/41)	10/11 (48/52)
Current smoker	4 (5)	3 (8)	1 (2)	1 (3)	0
Family history of CVD	56 (64)	26 (68)	30 (60)	17 (59)	13 (62)
Heart attack	20 (23)	10 (26)	9 (18)	4 (14)	5 (23)
Stroke	13 (15)	5 (13)	7 (14)	4 (14)	3 (14)
CAD, bypass	13 (15)	3 (8)	10 (20)	5 (17)	5 (23)
Hypertension	13 (15)	8 (21)	5 (10)	3 (10)	2 (10)
<b>BP medication</b>					
Yes	63 (72)	26 (68)	37 (74)	23 (79)	14 (66)
<b>BP medications, n</b>					
0	25 (28)	12 (32)	13 (26)	6 (21)	7 (33)
1	35 (40)	12 (32)	23 (46)	15 (52)	8 (38)
2	21 (24)	11 (29)	10 (20)	5 (17)	5 (24)
3	6 (7)	2 (5)	4 (8)	3 (10)	1 (5)
4	1 (1)	1 (3)	0	0	0
<b>BP-medication type</b>					
ACEI	25 (28)	11 (29)	14 (28)	10 (34)	4 (19)
A2RA	34 (39)	15 (40)	19 (38)	12 (41)	7 (33)
CCB	22 (25)	10 (26)	12 (24)	7 (24)	5 (24)
BB	8 (9)	4 (11)	4 (8)	10 (34)	2 (9)
D	14 (16)	7 (18)	7 (14)	3 (10)	4 (19)
<b>Other medication</b>					
Yes	41 (47)	23 (60)	18 (36)	9 (31)	9 (39)
Blood-thinning medication	22 (25)	10 (20)	12 (32)	6 (21)	4 (19)
Lipid (statin)	15 (17)	7 (18)	8 (16)	2 (7)	6 (29)
Diabetes	6 (7)	1 (2)	5 (10)	2 (7)	3 (14)
Depression/SSRI	7 (8)	2 (5)	5 (10)	2 (7)	3 (14)
Reflux/PPI	7 (8)	4 (11)	3 (6)	1 (11)	2 (10)
Thyroid	3 (3)	3 (8)	0	0	0
HRT (% female)	3 (3)	2 (11)	1 (2)	0	1 (9)

**Note:** Garlic subgroup responders = reduction in systolic BP/diastolic BP ≥5/3 mmHg over time.

**Abbreviations:** ACEI, angiotensin II-converting enzyme inhibitor; A2RA, angiotensin II-receptor antagonist; BB, β-blocker; BP, blood pressure; BMI, body mass index; CAD, coronary artery disease; CCB, calcium-channel blocker; CVD, cardiovascular disease; D, diuretic; HRT, hormone-replacement therapy; PPI, proton-pump inhibitor; SD, standard deviation; SSRI, selective serotonin-reuptake inhibitor.

change during the trial (n=4) and low compliance (<50%, n=3), resulting in 88 participants for full analysis.

A total of 50 participants were allocated to the garlic group, and 38 participants to the placebo group, with a mean age of 62±12 years and almost even distribution of

sexes. The average body mass index in the trial participants was slightly overweight with a mean of 27.7±5 kg/m<sup>2</sup>. Participants exercised moderately an average of 3.5 days a week (eg, 30 minutes of brisk walking, dancing, gardening, or housework) and 1.5 days vigorously (30 minutes of running,

fast cycling, fast swimming, heavy shoveling, or carrying heavy loads). The average stress levels of participants assessed by the Cohen Stress score<sup>22</sup> were comparable to the population average in a similar age-group.

Family history of cardiovascular events was reported by two-thirds of the participants, including myocardial infarction by almost 25% and stroke by 15% (Table 1). Three-quarters of participants were taking standard BP medication, with the majority taking one to two different types, with angiotensin II-receptor antagonists and angiotensin-converting enzyme inhibitors the most often prescribed, followed by calcium-channel blockers, diuretics, and  $\beta$ -blockers. Almost half of the participants took other prescription medication, including blood thinners (25%) and lipid-lowering drugs (17%), and a few took medication for diabetes, depression, reflux, thyroid issues, or hormone-replacement therapy (Table 1).

## Blood pressure and central hemodynamic measures

Analysis of all participants ( $n=88$ ) revealed a significant reduction in SBP from baseline in the garlic group compared with placebo over 12 weeks (mean difference in SBP  $\pm$  standard error  $=-5.0\pm 2.1$  mmHg,  $P=0.016$ ), but not for DBP (mean difference in DBP  $\pm$  standard error  $=-1.9\pm 1.2$ ,  $P=0.12$ ; Table 2 and Figure 2).

About two-thirds of participants presented with high SBP or DBP at baseline, with about half of the participants having essential hypertension (SBP  $\geq 140$  and DBP  $\geq 90$ ). Subgroup analysis of participants with high SBP/DBP at baseline did not change results appreciably (Table 2).

However, closer evaluation of participants in the garlic group revealed that a proportion of participants (50%–60%) responded to treatment over time. We defined responders to garlic treatment as mean reduction by more than 3% in SBP ( $\geq 5$  mmHg) or DBP ( $\geq 3$  mmHg) over time compared to baseline, which is clinically and statistically meaningful and similar to definitions by others,<sup>21</sup> while mean BP, assessed by repeated-measure ANCOVA, did not change appreciably for nonresponders. Subgroup analysis of responders revealed an average reduction of  $11.5\pm 1.9$  mmHg SBP and  $6.3\pm 1.1$  DBP compared to placebo ( $P<0.001$ ; Table 2 and Figure 2).

A number of central hemodynamic measures tended to improve more in the garlic group compared to placebo, including central SBP (mean difference  $=-3.8\pm 1.9$  mmHg,  $P=0.05$ ), central pulse pressure (mean difference  $=-2.7\pm 1.5$  mmHg,  $P=0.08$ ), total vascular resistance (mean difference  $=-0.07\pm 0.03$  s  $\cdot$  mmHg/mL,  $P=0.06$ ), mean arterial pressure (mean difference  $=-3.1\pm 1.8$  mmHg,  $P=0.09$ ), augmentation pressure

if high at baseline (mean difference  $=-3.5\pm 1.8$  mmHg,  $P=0.06$ ), and PWV if high at baseline (mean difference  $=-0.33\pm 0.14$  m/s,  $P=0.02$ ) (Table 2). Trends were confirmed in ANCOVA analysis including age and sex as covariates.

## Blood tests

None of the blood markers tested changed significantly over time; however, lipid levels, including total cholesterol and LDL, tended to improve slightly more in the garlic group (Table 3). Subgroup analysis by lipid-lowering medication (eg, statins) intake did not change results appreciably. ApoA levels were highly correlated with high density lipoprotein (HDL) levels (Pearson  $r=0.588$ ,  $P<0.001$ ), and ApoB levels were highly correlated with LDL levels (Pearson  $r=0.767$ ,  $P<0.001$ ), as expected. Reduction of ApoB when above the reference range was greater in the garlic group compared to placebo, albeit not statistically significant due to small sample size (mean difference  $=-29.1\pm 46.3$  mg/dL,  $P=0.3$  [ $n=12$ ]). The average homocysteine level within participants in both groups was higher than the reference range (mean  $14.2\pm 3.6$   $\mu$ mol/L), indicating potential underlying vitamin B<sub>12</sub> or folate deficiencies.

Platelet-function analyses indicated a daily trial dosage of aged garlic extract to be safe, as platelet-aggregation times did not further increase in participants with slow platelet adhesion/aggression at baseline, often due to blood-thinning medication (eg, warfarin, aspirin). In contrast, platelet function tended to change more toward normal levels in the garlic group with high closure times (thin blood) at baseline for both agonists compared to the placebo group (Table 3).

The inflammatory marker TNF $\alpha$  was reduced in the garlic group compared to placebo with borderline significance ( $P=0.05$ ), while changes in IL-1 $\beta$  were not significant, but greater reduction was observed in the garlic group (Table 3). Subgroup analyses excluding patients with high inflammatory markers due to acute infection did not change results appreciably (data not shown). Neither glucose levels nor kidney-function and liver-function test variables changed noticeably over time within or between groups (Table 4).

## Tolerability, acceptability, and blinding

Compliance of included participants was high in both groups ( $96.6\pm 5.6\%$ ). About 40% of participants in both groups reported minor side effects, including reflux (8%), burping (5%), bloating (3%), and also improved digestion (7%) ( $P>0.05$ ; Table 5). Few participants found side effects bothersome, and usually experienced these only in the first week of the trial. All but four participants found it easy (95%) and acceptable (100%)

**Table 2** Blood pressure and central hemodynamic measures

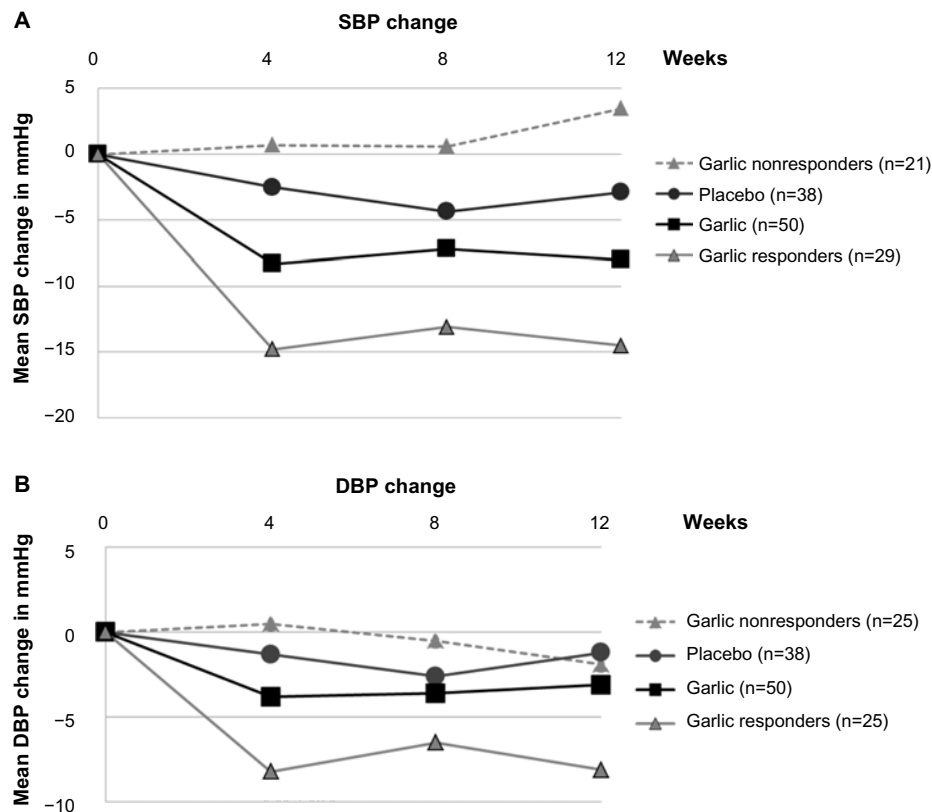
Measures			Group	n	Baseline		Baseline difference	12 weeks		Change		Mean difference between groups (garlic vs placebo)		
Office BP	Variable	Details			Mean	SD	P-value	Mean	SD	Mean	SD	Mean difference	SE	P-value
	SBP	mmHg	Placebo	38	142	9.4		140.3	18.2	-2.9	7.9			
			Garlic	50	148.7	15.3	0.02	141.7	15.3	-8	10.6	-5	2.1	0.02
	SBP >138 mmHg	68% high at baseline 76% high at baseline	Placebo	26	146.4	7.5		141.4	9.4	-4.9	7			
			Garlic	38	153.8	13.8	0.02	143.8	12.1	-10	10.8	-5.1	2.4	0.04
	SBP <138 mmHg		Placebo	12	132.4	4.5		133.8	7.7	1.4	8.1			
			Garlic	12	132.4	4.2	NS	130.9	7.1	-1.5	6.6	-2.9	3	0.34
	SBP placebo		Placebo	38	142	9.4		139.1	9.5	-2.9	7.9			
	SBP responders	58% >5 mm change	Garlic	29	153.2	15.4	0.001	138.8	11.4	-14.4	8.8	-11.5	1.9	<0.001
	SBP nonresponders		Garlic	21	142.3	12.9	NS	143.3	13.3	1	4.5	3.9	2.1	0.18
	DBP		Placebo	38	87.8	9.1		86	9	-1.8	5			
			Garlic	50	89.9	11.7	NS	86.1	11.3	-3.7	5.9	-1.9	1.2	0.12
	DBP >85 mmHg	63% high at baseline 64% high at baseline	Placebo	24	92.9	6.6		91.3	9.4	-2.3	5.7			
			Garlic	32	96.2	9	NS	92.4	9.9	-4.4	6.2	-2.1		0.19
	DBP <85 mmHg		Placebo	14	79.1	5.1		78.5	7.5	-1	3.5			
			Garlic	18	78.5	5.7	NS	76.7	7.7	-2.3	5	-1.3	1.6	0.40
	DBP placebo		Placebo	38	87.8	9.1		86	9	-1.8	5			
	DBP responders	50% >3 mm change	Garlic	25	93.2	11.4	NS	85.1	10.9	-1.8	3.8	-6.3	1.1	<0.001
	DBP nonresponders		Garlic	25	86.5	11.1	NS	88.4	12.7	0.8	4	2.5	1.1	0.08
	MAP	mmHg	Placebo	38	112.7	10.6		110.4	8.8	-2.3	7.2			
			Garlic	49	117.8	12.1	0.045	112.4	9.8	-5.4	9.3	-3.1	1.8	0.1
	HR	L/min	Placebo	38	70.4	9.6		70	8.5	-0.5	6			
			Garlic	48	68.7	11.2	NS	67.9	10.7	-0.7	6.6	-0.2	1.4	0.9
	PP	mmHg	Placebo	38	51	9.3		49.8	9.2	-1.3	9.5			
			Garlic	49	54.2	14.7	NS	50.2	10.1	-4	9.7	-2.7	2.1	0.2
Central BP	cSBP	mmHg	Placebo	38	129.3	9.3		126.8	9.9	-2.4	7.8			
			Garlic	48	134.8	14.2	0.04	128.5	10.3	-6.2	9.7	-3.8	1.9	0.05
	cDBP	mmHg	Placebo	38	90.8	9.7		88.6	8.8	-2.2	6.3			
			Garlic	48	95.1	12.3	0.08	90.4	10.7	-4.7	8	-2.6	1.6	0.11
	cPP	mmHg	Placebo	38	38.4	7.3		37.8	7.7	-0.5	6.4			
			Garlic	49	40.6	11.8	NS	37.5	8	-3.2	7.4	-2.7	1.5	0.08
	Cardiac output	L/min	Placebo	38	5.3	0.6		5	0.5	-0.3	0.5			
			Garlic	49	5.1	0.7	NS	5.1	0.7	-0.1	0.5	0.2	0.1	0.17
	TVR	s · mmHg/mL	Placebo	38	1.3	0.17		1.33	0.15	0.04	0.13			
			Garlic	49	1.41	0.21	NS	1.39	0.15	-0.03	0.17	-0.07	0.03	0.06
	Cardiac index	L/min × L/m <sup>2</sup>	Placebo	38	2.71	0.29		2.58	0.33	-0.13	0.25			
			Garlic	49	2.65	0.45	NS	2.57	0.35	-0.06	0.32	0.07	0.06	0.28
<b>Arterial stiffness</b>														
	AP	mmHg	Placebo	38	10.1	6.5		10.8	6.6	0.76	5			
			Garlic	49	13.2	8.9	0.07	11.6	4.9	-1	5.6	-1.9	1.2	0.12
	High AP*	mmHg	Placebo	14	15.4	6.9		14.4	8	-1	5.3			
			Garlic	23	20.6	7.5	NS	15.2	3	-4.6	5.1	-3.5	1.8	0.06
	High AP, male	mmHg	Placebo	2	10	2.8		7.5	0	0.3	3.3			
			Garlic	7	23.1	10.5	NS	15	7.1	-6.3	4.2	-6.6	2.7	0.04

(Continued)

**Table 2** (Continued)

Measures			Group	n	Baseline		Baseline difference P-value	12 weeks		Change		Mean difference between groups (garlic vs placebo)		
Office BP	Variable	Details			Mean	SD		Mean	SD	Mean	SD	Mean difference	SE	P-value
High AP, female	mmHg		Placebo	11	17.5	6.2	NS	19.5	11.5	-1.4	5.8	-2.3	2.3	0.32
			Garlic	14	19	4.6		18.4	6.4	-3.7	5.4			
Low AP	mmHg		Placebo	24	6.9	3.5	NS	8.7	4.6	1.8	4.6	-0.03	1.3	0.98
			Garlic	26	6.6	2.8		8.5	4.1	1.8	4.2			
RM	%		Placebo	38	65.1	6.6	NS	64.3	5.8	-0.82	5.2	-1.5	1.3	0.25
			Garlic	49	63.6	8.2		64.3	5.7	0.67	6.5			
AI	%		Placebo	35	21.7	11.6	NS	21.8	10	0.82	9.8	-0.97	3.1	NS
			Garlic	48	24	13.8		24.2	11.1	-0.15	9.4			
AI high*	%		Placebo	12	31.8	7.2	NS	26.4	8.3	-5	10.5	1.5	3.4	0.66
			Garlic	22	36.2	7.7		31.3	8.9	-4.6	7.9			
AI low	%		Placebo	23	16.4	9.7	NS	19.3	10.1	4.3	7.6	-0.5	2.5	0.85
			Garlic	25	13.8	8.3		18.1	9	3.6	9.1			
PWV	m/s		Placebo	38	9.3	1.8	NS	9.2	1.8	-0.071	0.33	-0.16	0.11	0.13
			Garlic	49	9.8	1.9		9.5	1.6	-0.28	0.58			
PWV high <sup>#</sup>	m/s		Placebo	25	9.6	1.9	NS	9.5	2	-0.15	0.35	-0.33	0.14	0.02
			Garlic	31	10.2	2.2		9.7	1.9	-0.49	0.62			
PWV normal	m/s		Placebo	13	8.5	1.2	NS	8.6	1.2	0.08	0.25	0.01	0.1	0.89
			Garlic	18	9	0.8		9.1	0.9	0.07	0.29			

**Notes:** \*Upper 50th percentile of population range adjusted for age and sex;<sup>19</sup> #above normal population range, adjusted for age and sex.<sup>20</sup> High AP/AI, upper 50% of population average; low AP/AI, lower 50% of population average; cardiac index, cardiac output from left ventricle in 1 minute per body surface area.  
**Abbreviations:** AI, augmentation index (at 75%); AP, augmentation pressure; BP, blood pressure; cSBP, central systolic BP; cDBP, central diastolic BP; cPP, central pulse pressure; HR, heart rate; MAP, mean arterial pressure; NS, not significant; PWV, pulse-wave velocity; RM, reflection magnitude; SD, standard deviation; SE, standard error; TVR, total vascular resistance.



**Figure 2** Effect of aged garlic extract on blood pressure.  
**Notes:** Mean change in SBP (A) and DBP (B) over 12 weeks in the placebo and garlic groups, and responder (SBP change  $\geq 5$  mmHg, DBP change  $\geq 3$  mmHg) and nonresponder subgroups.  
**Abbreviations:** SBP, systolic blood pressure; DBP, diastolic BP.

**Table 3** Cardiovascular markers by blood test

Blood tests	Reference range	Units	Group	n	Baseline		Baseline difference	12 weeks		Change from baseline		Change difference
					Mean	SD	P-value	Mean	SD	Mean	SD	P-value
<b>Lipids</b>												
TG		mmol/L	Placebo	38	1.6	0.9	NS	1.5	1	-0.07	0.66	0.07
			Garlic	50	1.2	0.6		1.3	0.8	0.15	0.45	
TC	<5.5	mmol/L	Placebo	38	5.3	1	NS	5.3	1.3	0.003	0.84	NS
			Garlic	50	5.5	1.3		5.5	1.2	-0.01	0.75	
TC subgroups	High	mmol/L	Placebo	17	6.1	0.6	NS	5.9	1.5	-0.16	1.1	NS
			Garlic	23	6.6	1		6.3	0.9	-0.27	0.79	
	Normal		Placebo	21	4.6	0.6	NS	4.7	0.7	0.13	0.54	NS
			Garlic	27	4.6	0.7		4.8	0.9	0.21	0.64	
LDL	<3.4	mmol/L	Placebo	37	3.1	0.9	NS	3.1	1	-0.028	0.52	NS
			Garlic	50	0.8	1.1		3.2	0.9	-0.12	0.7	
LDL subgroups	High	mmol/L	Placebo	13	4	0.6		3.8	1.2	-0.2	0.76	NS
			Garlic	18	4.4	1	NS	4	0.6	-0.46	0.91	
	Normal		Placebo	24	2.6	0.6		2.7	0.6	0.061	0.29	NS
			Garlic	32	2.7	0.6	NS	2.76	0.7	0.069	0.46	
HDL	0.9–2.2	mmol/L	Placebo	38	1.5	0.6	NS	1.4	0.5	-0.068	0.39	NS
			Garlic	50	1.7	0.6		1.7	0.6	-0.02	0.27	
TC/HDL			Placebo	38	3.9	1.2	NS	3.9	1.1	-0.0026	0.48	NS
			Garlic	50	3.5	1.1		3.5	1	-0.0034	0.47	
ApoA	105–185	mg/dL	Placebo	38	170.1	34.8	0.06	169.2	33.4	-0.92	21	NS
			Garlic	50	184.9	38		187.7	41.5	2.78	28.27	
ApoA subgroups	High	mg/dL	Placebo	8	219	34	NS	209.8	35.4	-9.25	27.28	NS
			Garlic	24	217	23.1		210.7	29.2	-6.25	23.81	
	Normal		Placebo	30	157.1	20.9	NS	158.4	23.3	1.3	18.94	NS
			Garlic	25	154.9	21.5		164.7	40	9.76	29.69	
ApoB	55–125	mg/dL	Placebo	38	101.5	25.5	NS	101.2	31	-0.26	16.38	NS
			Garlic	50	102	32.5		100.7	30.8	-1.34	28.4	
ApoB subgroups	High	mg/dL	Placebo	5	146.2	23.9	NS	148.2	51.1	2	32.57	NS
			Garlic	7	160.9	32.2		129.7	57.4	-31.14	64.34	
	Normal		Placebo	32	96.1	16.4	NS	94.9	19.4	-1.15	13.11	NS
			Garlic	42	92.4	20.6		95.5	21.8	3.14	13.17	
Homocysteine	3.7–13.9	µmol/L	Placebo	37	14.1	3.4	NS	13.5	4.3	-0.67	4.19	NS
			Garlic	50	14.2	3.7		14.9	4.5	0.67	3.88	
Homocysteine subgroups	High	µmol/L	Placebo	17	17	2.8	NS	15	5.4	-1.97	5.34	NS
			Garlic	26	17	2.6		16.9	4.6	-0.12	4.15	
	Normal		Placebo	20	11.8	1.3	NS	12.2	2.6	0.43	2.55	NS
			Garlic	24	11.2	1.7		12.8	3.2	1.57	3.44	
<b>Platelet function</b>												
Epi/Coll	120–150	s	Placebo	35	143.3	45.8	NS	142.7	55.4	-0.52	37.7	NS
			Garlic	46	142.3	47.2		138.6	54.5	-3.67	45.2	
Epi subgroups	Thick under 120	s	Placebo	12	101.7	15.7	NS	110.1	25.6	8.42	21.63	NS
			Garlic	18	102.5	10.4		107.9	32.7	5.4	32.9	
	Thin over 150		Placebo	13	188.8	40.4	NS	178.8	73	-10	56.7	NS
			Garlic	16	193.4	41.9		180	61.9	-13.34	63.5	
ADP/Coll	85–110	s	Placebo	34	95.4	21.6	NS	95.9	26.1	0.47	17.25	NS
			Garlic	41	92.8	21		89.6	16.3	-3.12	14.2	
	Thick under 85		Placebo	12	75.4	5.9	NS	79.6	12.4	4.17	10.9	NS
			Garlic	17	77.4	4.6		84.4	12.1	7.06	11.1	
Thin over 110	Placebo	6	132	15.1	NS	125.7	41.4	-6.33	26.8	NS		
	Garlic	5	137.4	25		117	19.3	-20.4	10			
<b>Inflammatory markers</b>												
CRP		mg/L	Placebo	38	3.2	4.6	NS	4	4.6	0.8	3.7	NS
			Garlic	50	2.7	3.7		3.1	4.2	0.4	3.8	
TNFα		fg/mL	Placebo	27	245.6	269.5	NS	448.7	550.8	203.1	475.9	0.05
			Garlic	31	238.9	310.6		227.8	196.6	-11.1	358.6	
IL-1β		fg/mL	Placebo	27	145.6	89.2	NS	139.8	104.2	-5.8	96.0	NS
			Garlic	31	211.7	439.0		114.3	48.3	-97.4	433.6	

**Abbreviations:** ADP, adenosine diphosphate; ApoA, Apolipoprotein A; ApoB, Apolipoprotein B; Coll, collagen; Epi, epinephrine; HDL, high-density lipoprotein; LDL, low-density lipoprotein; NS, not significant; SD, standard deviation; TC/HDL, total cholesterol:HDL ratio; TG, triglycerides.

**Table 4** Kidney- and liver-function test results

Blood tests	Reference range	Unit	Group	n	Baseline		Baseline difference	12 weeks		Change from baseline		Change difference
					Mean	SD	P-value	Mean	SD	Mean	SD	P-value
<b>Kidney function</b>												
Na		mmol/L	Placebo	38	139.8	2.7	NS	139.8	2.2	0.1	1.9	NS
			Garlic	49	140.1	2.3		139.9	2.3	-0.2	2.3	
K		mmol/L	Placebo	38	4.46	0.53	NS	4.3	0.4	-0.1	0.6	NS
			Garlic	49	4.55	0.47		4.4	0.4	-0.1	0.5	
Cl		mmol/L	Placebo	38	103.1	3.4	NS	103.3	2.9	0.3	2.8	NS
			Garlic	49	103.5	2.9		103.3	2.6	-0.1	2.5	
Bicarbonate		mmol/L	Placebo	38	28.3	2.8	NS	30.1	2.2	1.8	3.1	0.03
			Garlic	49	29.1	2.6		29.5	2.4	0.3	2.9	
Urea		mmol/L	Placebo	38	6.1	1.8	NS	6.2	1.6	0.1	1.5	NS
			Garlic	49	5.8	1.4		5.7	1.4	0.1	1.4	
eGFR		mL/min	Placebo	38	86.2	9.4	NS	84.9	9.6	-1.2	5.1	0.06
			Garlic	8	85.6	9.5		86.4	9.3	0.9	4.8	
Creatinine		µmol/L	Placebo	38	69.7	18.5	NS	70.63	17.34	1	7.8	0.05
			Garlic	49	69.8	15.4		67.18	16.42	-2.8	9.1	
Ca		mmol/L	Placebo	38	2.3	0.1	NS	2.33	0.096	-0.01	0.1	NS
			Garlic	50	2.3	0.1		2.33	0.07	-0.0012	0.1	
CorCa		mmol/L	Placebo	36	2.3	0.1	NS	2.23	0.07	-0.02	0.1	NS
			Garlic	50	2.3	0.1		2.24	0.07	-0.004	0.1	
Phosphate		mmol/L	Placebo	38	1.06	0.2	NS	1.02	0.2	-0.4	0.2	NS
			Garlic	50	1.04	0.2		1.05	0.1	0.01	0.2	
Urate		mmol/L	Placebo	38	0.37	0.1	NS	0.36	0.096	-0.01	0.06	
			Garlic	50	0.35	0.1		0.36	0.09	-0.01	0.06	NS
<b>Liver function</b>												
Bilirubin		µmol/L	Placebo	38	11.4	4.7	NS	12	4.22	0.6	3.5	NS
			Garlic	50	11.4	4.5		11.7	4.4	0.3	3.4	
ALT		U/L	Placebo	38	30.5	14.1	0.12	30.8	14.5	0.3	10.1	NS
			Garlic	50	25.7	13.8		25.5	14.1	-0.3	6.1	
AST		U/L	Placebo	38	26.2	6.8	NS	28.3	10.7	2.1	7.7	0.03
			Garlic	50	26.5	8.1		25.5	7.3	-1	5.7	
ALP		U/L	Placebo	38	67.4	14.4	0.005	71.2	18.1	3.8	10.9	NS
			Garlic	50	78.6	22		80.1	24.4	1.5	10.8	
GGT		U/L	Placebo	38	39.2	58	0.5	42.9	90.1	3.8	35.5	NS
			Garlic	50	32.7	30.3		34.8	34.8	2.1	12.2	
Total protein		g/L	Placebo	38	72.6	4.1	NS	73	4.3	0.3	3.8	NS
			Garlic	50	72.7	5.1		73	3.7	0.3	5.1	
Albumin		g/L	Placebo	38	44.3	3.3	NS	45	3.5	0.7	2.7	NS
			Garlic	50	44.2	2.9		44.4	2.5	0.2	3.1	
Globulin		g/L	Placebo	38	28.3	3	NS	28	3.3	-0.3	2.1	NS
			Garlic	50	28.5	3.4		28.5	3.1	0.1	2.5	
Glucose		mmol/L	Placebo	38	5.4	1.1		5.3	1	-0.1	0.5	0.19
			Garlic	49	5.3	1.2	NS	5.5	1.7	0.2	1.1	

**Abbreviations:** CorCa, corrected calcium for albumin; eGFR, estimated glomerular filtration rate; NS, not significant; SD, standard deviation.

to take two trial capsules a day for 12 weeks, and about 80% stated they would be willing to continue taking the capsules if they helped with BP control (Table 5). Blinding success was assessed at the end of the trial by questionnaire. While more participants in the garlic group (42%) than in the placebo group (21%) guessed their allocation correctly, a larger proportion in both groups were unsure or incorrect (garlic 58%, placebo 79%;  $P=0.023$ ; Table 5).

## Discussion

Our trial suggests that aged garlic extract is superior to placebo in lowering BP in patients with uncontrolled hypertension. A dosage of two capsules daily containing 1.2 g of aged garlic extract and 1.2 mg of SAC significantly lowered SBP by 5 mmHg compared with placebo over 12 weeks ( $P=0.016$ ), and was highly tolerated. BP changes were observed only in a proportion of participants, whereby 50%–58% responded



**Table 5** Tolerability, acceptability, and blinding

<b>Tolerability</b>	<b>All (n=88) n (%)</b>	<b>Garlic (n=50) n (%)</b>	<b>Placebo (n=38) n (%)</b>
<b>Side effects</b>			
Total	28 (32)	18 (36)	10 (26)
Reflux	7 (8)	5 (10)	2 (5)
Improved digestion	6 (7)	5 (10)	1 (2)
Garlic taste	3 (3)	3 (6)	0
Hot flushes	4 (5)	3 (6)	1 (2)
Burping	4 (5)	2 (4)	2 (5)
Bloating	3 (3)	1 (2)	2 (5)
Flatulence	3 (3)	1 (2)	2 (5)
Dizzy	1 (1)	1 (2)	0 (0)
Nosebleed	1 (1)	1 (2)	0
Diarrhea	2 (2)	1 (2)	1 (2)
Indigestion	2 (2)	1 (2)	1 (2)
Difficulty swallowing capsules	2 (2)	1 (2)	1 (2)
Nausea	1 (1)	0	1 (2)
Dry mouth	1 (1)	0	1 (2)
<b>Acceptability</b>			
Easy taking capsules			
Easy	84 (95)	48 (96)	36 (95)
Acceptable			
Acceptable	88 (100)	50 (100)	38 (100)
Willing to continue			
Agree	74 (84)	44 (88)	30 (79)
Unsure	11 (13)	4 (8)	7 (18)
Disagree	3 (3)	2 (4)	1 (3)
Willing to spend (AU\$0.3/capsule)			
Agree	70 (80)	42 (84)	28 (76)
Unsure	14 (16)	7 (14)	7 (19)
Disagree	3 (3)	1 (2)	2 (5)
<b>Blinding</b>			
Correct	29 (33)	21 (42)	8 (21)
Unsure	46 (52)	22 (44)	24 (63)
Incorrect	13 (15)	7 (14)	6 (16)

**Notes:** Acceptability was measured using 5-point Likert scales. The two highest categories were combined (eg, very easy/easy, very acceptable/acceptable, strongly agree/agree).

to treatment by a reduction in SBP of more than 5 mmHg (58%) or a reduction in DBP of more than 3 mmHg (50%). Subgroup analysis of responders revealed a significant average reduction of 11 mmHg SBP and 6 mmHg DBP compared to placebo ( $P < 0.001$ ).

Interindividual differences in BP response to garlic treatment are biologically plausible<sup>9</sup> and in line with our previous research, whereby SBP was reduced significantly in about 70% of participants.<sup>6</sup> Average BP reduction of responders in this trial is also consistent with meta-analyses of the effect of garlic on BP in hypertensives by 9–10 mmHg SBP and by 4–8 mmHg DBP ( $P < 0.001$ ).<sup>8,23</sup>

Garlic-derived polysulfides can influence BP via the nitric oxide- and hydrogen sulfide-signaling pathways.<sup>9</sup> Several

dietary and genetic factors influence the efficiency of these pathways, including vitamin B<sub>6</sub>, vitamin B<sub>12</sub>, and folate levels or genetic polymorphisms, eg, the transsulfuration gene *CBS*, and hence support or ameliorate the BP response to garlic intake.<sup>9</sup>

In our study, responders and nonresponders did not differ by age, sex, body mass index, or BP-medication intake. Therefore, we speculate that the variability in BP response to garlic in this study may be linked to underlying vitamin B<sub>6</sub>, vitamin B<sub>12</sub> or folate deficiency, or genetic polymorphisms.

Variation in vitamin B<sub>12</sub> levels prevalent in middle-aged populations is supported by the relatively high mean homocysteine levels found in our study sample, and the lack of effect of garlic on homocysteine levels, in line with the literature linking low vitamin B<sub>12</sub> levels and high homocysteine levels with hypertension and cardiovascular disease.<sup>24</sup>

Secondary outcome measures, including central hemodynamics, such as central SBP, central pulse pressure, mean arterial pressure, total vascular resistance, arterial stiffness, and PWV, were positively influenced by aged garlic extract. Central hemodynamic measures are regarded as more important predictors than peripheral BP for cardiovascular disease.<sup>11</sup> Our findings are in line with a previous trial showing a beneficial effect of aged garlic extract plus coenzyme Q<sub>10</sub> on PWV and endothelial function,<sup>25</sup> and provide new evidence that aged garlic extract has the potential to reduce central BP and arterial stiffness in individuals with uncontrolled hypertension.

While we did not find significant differences in other cardiovascular markers, favorable effects observed in the inflammatory marker TNF $\alpha$ , as well as total cholesterol, LDL cholesterol, and correlated ApoA and ApoB levels, were in line with previous research, whereby garlic was found to reduce the proinflammatory markers IL-1 $\beta$  and TNF $\alpha$ , subsequent activation of nuclear factor NF $\kappa$ B, and levels of oxidative LDL in vitro.<sup>26,27</sup> Furthermore, a previous meta-analysis of 39 trials suggested garlic was effective in reducing total cholesterol and LDL cholesterol by 10% in individuals with slightly elevated levels.<sup>28</sup>

Platelet-function testing provided evidence that Kyolic aged garlic extract was safe, even if taken in addition to blood-thinning medication, which is in line with previous research,<sup>10</sup> and in contrast to raw garlic intake.<sup>29</sup> In our sample, Kyolic aged garlic extract tended to normalize platelet function.

While our study was adequately powered and adjusted for confounding factors for the primary outcome measures – SBP and DBP – allowing also for exploration by subgroups of responders/nonresponders, our study has a few limitations.

The dropout rate in the placebo group (22%) was higher than in the garlic group (9%), which may have led to some biased results. Assessments of the effect of aged garlic extract on most secondary outcome measures, including arterial stiffness measures and cardiovascular blood markers, were limited by the smaller sample size in subgroups of participants with elevated levels of these markers at baseline. Intake of prescription medication, including medicines for BP, lipid-lowering agents, or hormone-replacement therapy were not matched between the groups, and numbers were too small in each category to undertake subgroup analyses. However, differences between the groups were not statistically significant, and did not change results appreciably when incorporated in the analyses as covariates.

Further larger studies are needed to assess the full potential of aged garlic extract on arterial stiffness measures, including PWV and augmentation pressure, as well as on cardiovascular biomarkers, such as inflammatory markers, lipids, and platelet function. Additionally, future research should test the hypothesis that individuals' responsiveness to aged garlic extract intake may be dependent on underlying dietary and genetic factors, such as vitamin B<sub>6</sub>, vitamin B<sub>12</sub>, folate levels, and CBS gene polymorphisms.

## Acknowledgments

We thank all patients, general practices, doctors, and staff for their participation in the trial. We are grateful to the research nurse Adela Cretoiu, who was instrumental in liaising with practices and patients. This trial was supported by a grant from Wakunaga of America Co Ltd, who supplied trial capsules and provided funding for costs of tests and research assistance. Wakunaga of America was not involved in study design, data collection, analysis, or preparation of the manuscript.

## Author contributions

KR and AS conceptualized the study, and KR acquired funding and oversaw data collection by NT. KR and NT undertook data analysis. All authors contributed toward drafting and critically revising the paper and agree to be accountable for all aspects of the work.

## Disclosure

The authors report no conflicts of interest in this work.

## References

1. World Heart Federation. Cardiovascular disease risk factors. 2012. Available from: <http://www.world-heart-federation.org/press/fact-sheets/cardiovascular-disease-risk-factors>. Accessed December 9, 2015.

2. Lawes CM, Vander Hoorn S, Rodgers A. Global burden of blood-pressure-related disease, 2001. *Lancet*. 2008;371(9623):1513–1518.
3. Martiniuk AL, Lee CM, Lawes CM, et al. Hypertension: its prevalence and population-attributable fraction for mortality from cardiovascular disease in the Asia-Pacific region. *J Hypertens*. 2007;25(1):73–79.
4. Briganti EM, Shaw JE, Chadban SJ, et al. Untreated hypertension among Australian adults: the 1999–2000 Australian Diabetes, Obesity and Lifestyle study (AusDiab). *Med J Aust*. 2003;179(3):135–139.
5. Ried K, Frank OR, Stocks NP. Aged garlic extract lowers blood pressure in patients with treated but uncontrolled hypertension: a randomised controlled trial. *Maturitas*. 2010;67(2):144–150.
6. Ried K, Frank OR, Stocks NP. Aged garlic extract reduces blood pressure in hypertensives: a dose-response trial. *Eur J Clin Nutr*. 2013;67(1):64–70.
7. Ried K, Frank OR, Stocks NP, Fakler P, Sullivan T. Effect of garlic on blood pressure: a systematic review and meta-analysis. *BMC Cardiovasc Disord*. 2008;8:13.
8. Ried K. Garlic lowers blood pressure in hypertensive individuals, regulates serum cholesterol, and stimulates immunity: an updated meta-analysis and review. *J Nutr*. 2016;146:1S–8S. In press.
9. Ried K, Fakler P. Potential of garlic (*Allium sativum*) in lowering high blood pressure: mechanisms of action and clinical relevance. *Integrat Blood Press Control*. 2014;7:71–82.
10. Macan H, Uykimpang R, Alconcel M, et al. Aged garlic extract may be safe for patients on warfarin therapy. *J Nutr*. 2006;136(3 Suppl):793S–795S.
11. Laurent S, Cockcroft J, Van Bortel L, et al. Expert consensus document on arterial stiffness: methodological issues and clinical applications. *Eur Heart J*. 2006;27(21):2588–2605.
12. O'Rourke M. Arterial stiffness, systolic blood pressure, and logical treatment of arterial hypertension. *Hypertension*. 1990;15(4):339–347.
13. Wakunaga. Kyolic Reserve. Available from: <http://www.kyolic.com/product/category/reserve>. Accessed December 9, 2015.
14. Amagase H. Clarifying the real bioactive constituents of garlic. *J Nutr*. 2006;136(3 Suppl):716S–725S.
15. Wassertheurer S, Kropf J, Weber T, et al. A new oscillometric method for pulse wave analysis: comparison with a common tonometric method. *J Hum Hypertens*. 2010;24(8):498–504.
16. Weber T, Wassertheurer S, Rammer M, et al. Validation of a brachial cuff-based method for estimating central systolic blood pressure. *Hypertension*. 2011;58(5):825–832.
17. Weiss W, Gohlisch C, Harsch-Gladisch C, Tölle M, Zidek W, van der Giet M. Oscillometric estimation of central blood pressure: validation of the Mobil-O-Graph in comparison with the SphygmoCor device. *Blood Press Monit*. 2012;17(3):128–131.
18. IEM. Mobil-O-Graph 24h PWA. Available from: <http://www.iem.de/en/products/mobil-o-graph.html>. Accessed December 9, 2015.
19. Nunan D, Wassertheurer S, Lasserson D, et al. Assessment of central haemodynamics from a brachial cuff in a community setting. *BMC Cardiovasc Disord*. 2012;12:48.
20. Nunan D, Fleming S, Hametner B, Wassertheurer S. Performance of pulse wave velocity measured using a brachial cuff in a community setting. *Blood Press Monit*. 2014;19(6):315–319.
21. Bulpitt C. Responders and non-responders to antihypertensive treatment. *Drugs*. 1988;35(6):142–146.
22. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *J Health Soc Behav*. 1983;24(4):385–396.
23. Rohner A, Ried K, Sobenin IA, Bucher HC, Nordmann AJ. A systematic review and metaanalysis on the effects of garlic preparations on blood pressure in individuals with hypertension. *Am J Hypertens*. 2015;28(3):414–423.
24. Catena C, Colussi G, Nait F, Capobianco F, Sechi LA. Elevated homocysteine levels are associated with the metabolic syndrome and cardiovascular events in hypertensive patients. *Am J Hypertens*. 2015;28(7):943–950.

25. Larijani VN, Ahmadi N, Zeb I, Khan F, Flores F, Budoff M. Beneficial effects of aged garlic extract and coenzyme Q10 on vascular elasticity and endothelial function: the FAITH randomized clinical trial. *Nutrition*. 2013;29(1):71–75.
26. Keiss HP, Dirsch VM, Hartung T, et al. Garlic (*Allium sativum* L) modulates cytokine expression in lipopolysaccharide-activated human blood thereby inhibiting NF-κB activity. *J Nutr*. 2003;133(7): 2171–2175.
27. Ide N, Lau BH. Garlic compounds minimize intracellular oxidative stress and inhibit nuclear factor-κB activation. *J Nutr*. 2001;131(3): 1020S–1026S.
28. Ried K, Toben C, Fakler P. Effect of garlic on serum lipids: an updated meta-analysis. *Nutr Rev*. 2013;71(5):282–299.
29. Harauma A, Moriguchi T. Aged garlic extract improves blood pressure in spontaneously hypertensive rats more safely than raw garlic. *J Nutr*. 2006;136(3 Suppl):769S–773S.

### Integrated Blood Pressure Control

Dovepress

### Publish your work in this journal

Integrated Blood Pressure Control is an international, peer-reviewed open-access journal focusing on the integrated approach to managing hypertension and risk reduction. Treating the patient and comorbidities together with diet and lifestyle modification and optimizing healthcare resources through a multidisciplinary team approach constitute key

features of the journal. This journal is indexed on American Chemical Society's Chemical Abstracts Service (CAS). The manuscript management system is completely online and includes a very quick and fair peer-review system, which is all easy to use. Visit <http://www.dovepress.com/testimonials.php> to read real quotes from published authors.

Submit your manuscript here: <http://www.dovepress.com/integrated-blood-pressure-control-journal>

# Exhibit RX 1 Attachment C

Format: Abstract ▾

Full text links



*Prev Med.* 2004 Nov;39(5):985-91.

# Inhibiting progression of coronary calcification using Aged Garlic Extract in patients receiving statin therapy: a preliminary study.

Budoff MJ<sup>1</sup>, Takasu J, Flores FR, Niihara Y, Lu B, Lau BH, Rosen RT, Amagase H.

## Author information

<sup>1</sup> Division of Cardiology, Harbor-UCLA Medical Center Research and Education Institute, Torrance, CA 90502, USA. Budoff@Flash.net

## Abstract

**BACKGROUND:** Aged **Garlic** Extract (AGE) reduces multiple cardiovascular risk factors, including blood pressure, cholesterol, platelet aggregation and adhesion, while stimulating nitric oxide generation in endothelial cells. However, no study has evaluated the ability of AGE to inhibit vascular calcification, a marker of plaque formation in human coronary arteries.

**OBJECTIVE:** To assess the efficacy of Aged **Garlic** Extract (AGE) on changing the rate of atherosclerosis progression as compared to placebo.

**DESIGN:** A placebo-controlled, double-blind, randomized pilot study to determine whether the atherosclerotic plaque burden detected by electron beam tomography (EBT) will change at a different rate under the influence of AGE as compared to placebo. Twenty-three patients were enrolled, and 19 patients completed the study protocol. AGE 4 ml or the equivalent amount of placebo was given to subjects. Duration of the study was 1 year. S-allylcysteine (SAC), one of the active compound of AGE, was measured in the blood as a compliance marker.

**RESULTS:** The mean change of the calcium score (volumetric method) for the AGE **group** (n = 9) was 7.5 +/- 9.4% over 1 year. The placebo **group** (n = 10) demonstrated an average increase in calcium scores of 22.2 +/- 18.5%, significantly greater than the treated cohort (P = 0.046). There were no significant differences in individual cholesterol parameters or C reactive protein between the groups. In patients randomized to AGE, there was a nonsignificant trend for improving cholesterol/high-density lipoprotein ratio (P = 0.07) and homocysteine level (P = 0.08).

**CONCLUSIONS:** This small pilot study indicates the potential ability of AGE to inhibit the rate of progression of coronary calcification, as compared to placebo over 1 year. Should these findings be extended and confirmed in larger studies, **garlic** may prove useful for patients who are at high risk of future cardiovascular events.



**Publication types, MeSH terms, Substances** +

**LinkOut - more resources** +

# Significance of Garlic and Its Constituents in Cancer and Cardiovascular Disease

## Aged Garlic Extract Retards Progression of Coronary Artery Calcification<sup>1,2</sup>

Matthew Budoff<sup>3</sup>

Division of Cardiology, Harbor-UCLA Medical Center, Torrance, CA

**ABSTRACT** Prospective epidemiologic studies have identified several risk factors for heart disease, and most can be the target of risk reduction interventions. The most widely recognized risk factors for atherosclerotic cardiovascular disease (ASCVD) include age, gender, cigarette smoking, sedentary lifestyle, elevated LDL, reduced HDL, hypertension, and diabetes. The consistency of associations between these factors and ASCVD risk across populations is substantial. Our understanding of the pathogenesis and etiology of coronary ASCVD, as well as its clinical implications, has grown tremendously over the past 20 y. The role garlic might play in treating ASCVD has been postulated for many years, but until recently no studies on garlic's ability to inhibit the atherosclerotic process have been reported. A pilot study evaluating coronary artery calcification and the effect of garlic therapy in a group of patients who were also on statin therapy suggested incremental benefits. The implications of this study must be put in context of the potential importance of early atherosclerosis detection and prevention. *J. Nutr.* 136: 741S–744S, 2006.

**KEY WORDS:** • aged garlic extract • atherosclerosis • cardiovascular • electron beam tomography • calcification

**Calcification and atherosclerosis.** Calcium deposition in the walls of coronary arteries is an active process, rather than a simple mineral precipitation in the atheromatous plaque (1). Calcification has been shown to be an early feature of atherosclerotic plaque formation, beginning with fatty-streak

<sup>1</sup> Published in a supplement to *The Journal of Nutrition*. Presented at the symposium "Significance of Garlic and Its Constituents in Cancer and Cardiovascular Disease" held April 9–11, 2005 at Georgetown University, Washington, DC. The symposium was sponsored by Strang Cancer Prevention Center, affiliated with Weill Medical College of Cornell University, and Harbor-UCLA Medical Center, and co-sponsored by American Botanical Council, American Institute for Cancer Research, American Society for Nutrition, Life Extension Foundation, General Nutrition Centers, National Nutritional Foods Association, Society of Atherosclerosis Imaging, Susan Samueli Center for Integrative Medicine at the University of California, Irvine. The symposium was supported by Alan James Group, LLC, Agencas Motta, S.A., Antistress AG, Amal, Birger Ledlin AB, Ecolandia International, Essential Sterol Products (PTY) Ltd., Grand Quality LLC, IC Vietnam, Intervac Ltd., Jenn Health, Kernpharm BV, Laboratori Mizar SAS, Magna Trade, Manavita B V B A, MaxiPharm AS, Nature's Farm, Naturkost S. Rui a.s., Niecha Company Limited, Nutra-Lite Health & Fitness Ltd., Oy Valio ravinto Ab, Panax, PT, Nutriprima Jayasakti, Purify Life Health Products Limited, Quest Vitamins, Ltd., Sabino S.A., The AIM Companies, Valosun Ltd., Wakunaga of America Co. Ltd., and Wakunaga Pharmaceutical Co., Ltd. Guest editors for the supplement publication were Richard Rivlin, Matthew Budoff, and Harunobu Amagase. *Guest Editor Disclosure:* R. Rivlin has been awarded research grants from Wakunaga of America, Ltd. and received an honorarium for serving as co-chair of the conference. M. Budoff has been awarded research grants from Wakunaga of America, Ltd. and received an honorarium for serving as co-chair of the conference, and Harunobu Amagase is employed by Wakunaga of America, Ltd.

<sup>2</sup> Author disclosure: M. Budoff has been awarded research grants from Wakunaga of America, Ltd. and received an honorarium for serving as co-chair of the conference.

<sup>3</sup> To whom correspondence should be addressed: E-mail: budoff@ucla.edu.

<sup>4</sup> Abbreviations used: AGE, aged garlic extract; ASCVD, atherosclerotic cardiovascular disease; CAD, coronary artery disease; CC, coronary calcification; EBCT, electron beam computed tomography.

0022-3166/06 \$8.00 © 2006 American Society for Nutrition.

formation and continuing throughout the natural history of the plaque (2). In 1959, Blankenhorn reported an association between coronary calcification (CC)<sup>4</sup> and atherosclerotic cardiovascular disease (ASCVD) at autopsy (3). Since then, at least 6 other autopsy studies involving >2500 hearts, have confirmed these initial findings. Several investigators have found a significant correlation between amount of coronary calcium and amount of atherosclerosis. These investigators used measurements of plaque volume rather than stenoses, and demonstrated, through the results of autopsies, that there was a consistent and direct relation between calcium and plaque volume (4–6). Similarly, in vivo studies have demonstrated a linear relationship between CC and ASCVD plaque burden (7,8).

Recently Mintz et al. (9) evaluated patients using intravascular ultrasound and electron beam tomography and found a strong relationship between calcification and plaque burden. **Electron beam computed tomography.** There has been great interest in the development of noninvasive imaging techniques to detect the presence or absence of atherosclerosis. One approach that has recently gained particular attention, and is being used in several NIH studies of subclinical atherosclerosis, is CC as measured by electron beam computed tomography (EBCT). As opposed to other noninvasive modalities to diagnose coronary artery disease (CAD) by focusing on physiologic consequences of coronary obstruction, coronary calcium represents an anatomic measure of plaque burden (10). There is general agreement that CC as measured by EBCT provides a useful measure of atherosclerosis for population studies. It is noninvasive and readily applicable for routine use; it demonstrates sufficient accuracy and reproducibility, and it correlates with angiographic or pathologic evidence of CAD.

The presence of CC is nearly 100% specific for atherosclerotic coronary plaque. Because both obstructive and nonobstructive lesions have calcification present in the intima, CC is not specific to obstructive disease (11). Studies have demonstrated a direct relationship between coronary-artery calcium as measured by EBCT and histologic (12,13) and in vivo intravascular ultrasound (14) measures of atherosclerotic plaque. In a multicenter study, it has been demonstrated that CC by EBCT correlates well with angiographic stenosis (15), with progressively higher scores found in nonobstructive, and 1-, 2- and 3-vessel obstructive CAD. Guerci et al. (16) demonstrated a strong correlation between the square root of the total EBCT calcium score and maximum percent luminal coronary stenoses in a small group of asymptomatic patients undergoing diagnostic coronary angiography. Rumberger (17) analyzed studies of symptomatic patients and demonstrated calcium scores with 90% specificities for variable degrees of angiographic stenosis. Thus, in both symptomatic and asymptomatic populations, correlative studies have demonstrated a relationship between the CC score and the severity of underlying disease.

The most powerful information regarding the utility of the EBCT calcium score relates to its prognostic ability regarding cardiovascular events. The greatest potential for coronary calcium detection is as a marker of coronary heart disease risk. A number of large studies have reported that the presence of CC is an independent predictor of coronary heart disease risk after controlling for coronary heart disease risk factors (18–21). In all studies to date, the extent of CC was an independent and incremental estimator of coronary events over and above age, gender, and traditional cardiovascular risk factors. These studies demonstrate that persons with significant CC (scores >100) have a 10- to 20-fold greater risk of future coronary events. Published guidelines state that “[t]he resulting calcium score is an important parameter to detect asymptomatic individuals at high risk for future CVD [cardiovascular disease] events, independent of the traditional risk factors” (22). Numerous professional organizations, including the National Cholesterol Education Panel, American Heart Association, American College of Cardiology, and European Society of Cardiology, in both guidelines and expert consensus documents, have extended the recommendation for its use in clinically selected intermediate coronary heart disease risk patients (e.g., those with a 10–20% Framingham 10-y risk estimate) to refine clinical risk prediction (23–27).

EBCT calcium scanning has achieved a substantial degree of standardization, allowing for use in randomized trials and across centers. It possesses an ease of implementation sufficient to make it applicable to population-based and multicenter studies of ASCVD. The reproducibility of calcium measurements is essential to assess progression or regression of disease and to conduct longitudinal studies. EBCT inter-scan, inter- and intra-observer variability has been extensively studied, with reproducibility varying from moderate (28) to excellent (29–31) ( $r = 0.96$ – $0.99$ ). With excellent inter- and intraobserver variability ( $\sim 1$ – $3\%$ ), this test can measure plaque burden and follow atherosclerosis over time. Using new gating algorithms, EBCT inter-scan variability has been shown to be  $\sim 11\%$  (32). Furthermore, with its ability to estimate total plaque burden, the tool has been demonstrated to be ideal for measuring the progression, stabilization, or regression of coronary plaque non-invasively.

Several studies have demonstrated a decrease in EBCT-measured calcium volume in patients treated with statin drugs (33). Callister enrolled 149 patients with hypercholesterolemia who underwent 2 EBCT scans after a minimum of 12 mo. Sixty percent of the subjects, having achieved LDL reductions to

$<120$  mg/dL, showed EBCT stabilization (regression or no increase) of coronary atherosclerosis compared with subjects whose LDL cholesterol was not reduced to  $<120$  mg/dL ( $P < 0.001$ ). A second study followed 274 patients with various cardiovascular risk factors who were scanned twice at least 1 y apart. Of 123 patients with hyperlipidemia, 61 were on statin therapy, and 62 reported no therapy. Those patients reporting use of a statin had an annual progression rate of 16%, compared with a 39% annual increase in the EBCT score for the untreated group ( $P < 0.01$ ) (34). In large studies of progression, annual changes in calcium scores measured by EBCT predict the progression of CAD; EBCT-measured progression of CC ( $> 115\%$  per year) is associated with a 13-fold greater risk of cardiac events (35,36).

**Garlic and atherosclerosis.** Several clinical reports, including meta-analyses, have revealed cholesterol-lowering effects of garlic supplementation in humans (37,38). Such reports have strongly affected public awareness of the cholesterol-lowering effect of garlic. Recent studies of aged garlic extract (AGE) have shown it to be a modulator of multiple cardiovascular risk factors (39), such as blood pressure, platelet aggregation and adhesion, total cholesterol, LDL, HDL, LDL oxidation, smoking-caused oxidative damages, and directly suppressed atherosclerosis (40–43). In addition, AGE has been demonstrated to improve endothelial function (44), inhibit endothelial cell damage, and transform smooth muscle cells (45). This suggests that AGE may have an effect on controlling arterial function through inhibiting the damage of nitric oxide synthesis (46). Thus, garlic and extracts have been postulated to impart cardiovascular benefits through multiple mechanisms.

We performed a placebo-controlled, double-blind, randomized pilot study to determine whether the atherosclerotic plaque burden detected by electron beam tomography will change at a different rate under the influence of AGE as compared with a placebo (47). Twenty-three high-risk patients were enrolled, and 19 (14 men, 5 women, with a mean age of  $59.9 \pm 10.5$  y) completed the 1-y study protocol. Subjects received 4 mL of AGE (1200 mg) or the equivalent amount of placebo. All patients were on, and maintained, a stable course of statin therapy and aspirin during the course of the study. Of the 19 patients who completed the study protocol, 9 were randomized to AGE, and 10 to placebo. S-allyl cysteine, one of the active compounds of AGE, was measured in the blood as a compliance marker. S-allyl cysteine serum measurement is currently the only reliable human compliance marker used for studies involving garlic consumption, since it is detectable and quantitatively increases in the blood after oral intake of garlic capsules (48).

The mean change and absolute difference in the calcium score (volumetric method) for the AGE group was  $7.5 \pm 9.4\%$  and  $45.2 \pm 57.2$  over the year, respectively. The placebo group exhibited a mean increase in calcium scores of  $22.2 \pm 18.5\%$  and  $129.0 \pm 102.1$ , significantly greater than the treated cohort ( $P = 0.046$  and  $0.045$ , respectively). All patients in this study were on statin therapy; thus the improvement seen under the influence of garlic suggests incremental benefit to statin therapy in this small study. The study shows that patients on placebo (with statin baseline therapy) progressed at a rate of  $22.2\%$  per y, while the addition of AGE reduced progression to  $7.5\%$ . Calcium scores did not correlate with measures of glutathione and lipid peroxidation at entry. Lipid peroxidation significantly decreased at follow-up period in both groups. Although the homocysteine changes did not achieve significance in this small study, there was a favorable trend.

Changes in baseline values over 1 y as observed under the influence of both AGE and placebo are shown in Table 1.



**TABLE 1**

*Changes in values over one year under the influence of therapies<sup>1</sup>*

	AGE (n = 9)	Placebo (n = 10)	P
Volume calcium score	45.2 ± 57.2	129.0 ± 102.1	0.0445
% Change (volume)	7.5 ± 9.4	22.2 ± 18.5	0.0464
Agatston calcium score	71.1 ± 95.8	151.6 ± 126.5	0.1401
% Change, Agatston	11.5 ± 16.8	21.1 ± 18.9	0.2628
Lipid peroxidase	-0.28 ± 0.20	-0.20 ± 0.10	0.2787
GSH, <sup>2</sup> micrograms/ 10 <sup>10</sup> RBC	-0.9 ± 108.0	-26.4 ± 102.7	0.6056
White blood count	-0.2 ± 1.90	-0.95 ± 1.85	0.3960
Hematocrit	-2.02 ± 3.02	-3.25 ± 2.58	0.3522
Platelet	3.2 ± 17.4	1.8 ± 42.6	0.9269
Sodium	3.33 ± 3.12	1.8 ± 6.65	0.5365
Potassium	-0.01 ± 1.15	-0.15 ± 0.64	0.7464
Glucose	14.3 ± 55.1	13.3 ± 50.8	0.9666
Creatinine	0.00 ± 0.00	0.01 ± 0.14	0.9152
AST <sup>3</sup>	1.89 ± 7.85	-4.6 ± 15.0	0.2620
Alkaline phosphatase	4.0 ± 12.1	-10.1 ± 25.2	0.1452
ALT <sup>4</sup>	0.11 ± 7.25	-2.6 ± 13.0	0.5876
Total cholesterol	7.0 ± 21.8	12.8 ± 25.9	0.6065
HDL	3.0 ± 10.6	-1.3 ± 13.8	0.4611
Cholesterol/HDL	-0.15 ± 1.04	0.79 ± 1.13	0.0763
LDL	-3.2 ± 16.2	21.9 ± 39.4	0.0932
Triglycerides	8.3 ± 42.6	29.5 ± 95.7	0.5500
Homocysteine	-1.77 ± 9.85	5.77 ± 7.75	0.0798
C-reactive protein	-0.10 ± 0.22	-0.13 ± 0.27	0.8464

<sup>1</sup> Values are means ± SD.  
<sup>2</sup> GSH, glutathione.  
<sup>3</sup> AST, aspartate aminotransferase.  
<sup>4</sup> ALT, alanine aminotransferase.

All patients were taking a stable dose of statin and aspirin throughout the study. There were no significant changes in cholesterol parameters, homocysteine or C-reactive protein between the groups, although there was a trend toward improvement of cholesterol parameters and homocysteine ( $P = 0.07-0.09$  for these measures, Table 1). There was also a trend (not significant) toward decreasing cholesterol/HDL ratios ( $P = 0.076$ ).

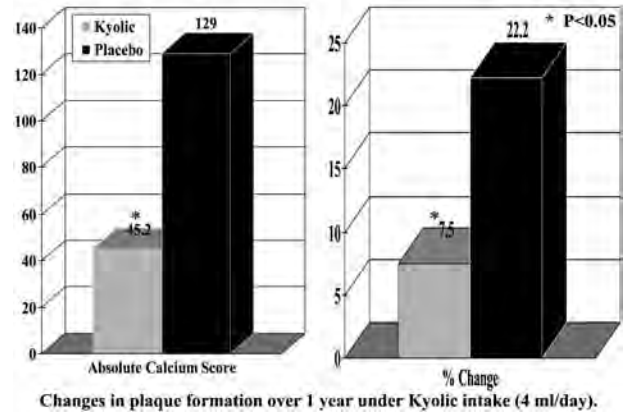
**Conclusion.** Electron beam tomography is a noninvasive procedure and a well-validated tool for examining cardiovascular diseases, to measure precise quantity of CC, which is

**TABLE 2**

*Possible mechanisms by which garlic may inhibit atherosclerosis*

Inhibition of stenosis caused by damage induced by balloon catheterization (in vivo)
Inhibition of cell transformation and cell growth in the smooth muscle cells (in vitro)
Inhibition of lipid accumulation into macrophage (foam cells) (in vitro)
Inhibition of LDL oxidation-caused endothelial cell damage in artery (in vitro)
Inhibition of LDL oxidation-induced free radical generation from damaged endothelial cells in artery (in vitro)
Inhibition of glutathione depletion from the endothelial cells (in vitro)
Activation of cNOS (in vitro)
Increase of Nitrous Oxide metabolites; cNOS activation (in vivo)
Lowering of cholesterol, raising of HDL cholesterol
Lowering blood pressure
Reduction of homocysteine
Improvement of endothelium function (in vivo)

**Changes in Plaque Burden over 1 year**



**FIGURE 1** Changes in plaque burden over 1 y.

linearly correlated with the amount of associated atherosclerotic plaque, and track atherosclerotic plaque over time. Because AGE has been shown to have several potential anti-atherosclerotic properties, it was chosen as the agent of study to evaluate its ability to inhibit progression of coronary atherosclerosis. The exact mechanism by which garlic and AGE may inhibit atherosclerosis is still unknown. Campbell et al. (40) found a direct effect of AGE on atherosclerosis using both molecular techniques in vitro and in vivo models. The possible mechanisms by which garlic can inhibit coronary plaque formation are listed in Table 2. In general, intimal-cell hyperplasia followed by fatty streaks develops before arterial calcification. AGE may exert anti-atherogenic effects through inhibition of both smooth-muscle phenotypic change and proliferation and on lipid accumulation in the artery wall and into the macrophage. In addition, inhibiting damage of the endothelial cells and transforming smooth muscle cells as shown in the several studies using AGE suggest that AGE may have an effect of controlling arterial function and improving endothelial function through inhibiting the damage of nitric oxide synthesis. Data suggests garlic may increase glutathione levels and protection of endothelial cells by reducing oxidant stress, especially LDL oxidation, a recognized risk factor in cardiovascular disease (49).

It is of special interest that garlic was not given as an alternative, but rather in addition to statin drugs. Despite the small study size, patients given AGE demonstrated a significant slowing of the accumulation of coronary artery calcification during this randomized, placebo-controlled trial. The difference in progression was significant, whether measured by absolute plaque volume or percent change (Fig. 1). This was found to be complementary to the effects of statin therapy. This effect of AGE may be related with the reduction of multiple risk factors in cardiovascular diseases, such as homocysteine, LDL, LDL oxidation, blood coagulations, and others. Larger studies will be needed to validate this finding and to derive the mechanism by which garlic may provide cardiovascular benefit.

**LITERATURE CITED**

- Libby P, Schoenbeck U, Mach F, Selwyn AP, Ganz P. Current concepts in cardiovascular pathology: the role of LDL cholesterol in plaque rupture and stabilization. *Am J Med.* 1998;104:14S-8S.
- Ross R. Atherosclerosis—an inflammatory disease. *N Engl J Med.* 1999;340:115-26.

3. Blankenhorn DH, Stern D. Calcification of the coronary arteries. *Am J Roentgenol Radiol Ther Nucl Med.* 1959;81:772-7.
4. Beadenkopf WG, Daoud AS, Love BM. Calcification in the coronary arteries and its relation of atherosclerosis and myocardial infarction. *Am J Roentgenol Radiol Ther Nucl Med.* 1964;92:985-71.
5. Eggen DA, Strong JP, McGill HC. Coronary calcification: relationship to clinically significant coronary lesions and retrace, sex and topographic distribution. *Circulation.* 1965;32:948-55.
6. McCarthy JH, Palmer FJ. Incidence and significance of coronary artery calcification. *Br Heart J.* 1974;36:499-506.
7. Sangiorgi G, Rumberger JA, Severson A, Edwards WD, Gregoire J, Fitzpatrick LA, Schwartz RS. Arterial calcification and not lumen stenosis is highly correlated with atherosclerotic plaque burden in humans: a histologic study of 723 coronary artery segments using noncalcifying methodology. *J Am Coll Cardiol.* 1998;31:126-33.
8. Rumberger JA, Simons DB, Fitzpatrick LA, Sheedy PF, Schwartz RS. Coronary artery calcium areas by electron beam computed tomography and coronary atherosclerotic plaque area: a histopathologic correlative study. *Circulation.* 1995;92:2157-62.
9. Mintz GS, Pichard AD, Popma JJ, Kent KM, Sattler LF, Bucher TA, Leon MB. [REMOVED ADVANCE FIELD]Determinants and Correlates of Target Lesion Calcium in Coronary Artery Disease: A Clinical, Angiographic and Intravascular Ultrasound Study. *J Am Coll Cardiol.* 1997;29:268-74.
10. Baumgart D, Schimmernd A, Goerge G, Haude M, Ge J, Adamzik M, Sehnt C, Altmairer K, Groenemeyer D, et al. Comparison of electron beam computed tomography with intracoronary ultrasound and coronary angiography for detection of coronary atherosclerosis. *J Am Coll Cardiol.* 1997;30:57-64.
11. Rumberger JA, Sheedy PF, Breen FJ, Schwartz RS. Electron beam CT coronary calcium score cutpoints and severity of associated angiography/luminal stenosis. *J Am Coll Cardiol.* 1997;29:1542-8.
12. Detrano R, Tang W, Kang X, Mahatsavanya P, McCrae M, Ganner D, Peng SK, Measham C, Molloi S, et al. Accurate coronary calcium phosphate mass measurements from electron beam computed tomograms. *Am J Card Imaging.* 1995;9:167-73.
13. Mautner GC, Mautner SL, Froslich J, Feuerstein JM, Proschan MA, Doppman JL. Coronary artery calcification: assessment with electron beam CT and histomorphometric correlation. *Radiology.* 1994;192:819-23.
14. Baumgart D, Schimmernd A, Goerge G, Haude M, Ge J, Adamzik M, Sehnt C, Altmairer K, Groenemeyer D, et al. Comparison of electron beam computed tomography with intracoronary ultrasound and coronary angiography for detection of coronary atherosclerosis. *J Am Coll Cardiol.* 1997;30:57-64.
15. Budoff MJ, Georgiou D, Brody A, Agatston AS, Kennedy J, Wolkoff C, Stanford W, Shields P, Lewis RJ, et al. Ultrasound computed tomography as a diagnostic modality in the detection of coronary artery disease—a multicenter study. *Circulation.* 1996;93:898-904.
16. Guerci AD, Spadero LA, Popma JJ, Goodman KJ, Brundage BH, Budoff MJ, Lerner G, Vizza RF. Relation of coronary calcium score by electron beam computed tomography to arteriographic findings in asymptomatic and symptomatic adults. *Am J Cardiol.* 1997;79:128-33.
17. Rumberger JA, Sheedy PF, Breen FJ, Schwartz RS. Electron beam CT coronary calcium score cutpoints and severity of associated angiography/luminal stenosis. *J Am Coll Cardiol.* 1997;29:1542-8.
18. Greenland P, LaBree LA, Azen SP, Doherty TM, Detrano RC. Coronary artery calcium combined with Framingham score for risk prediction in asymptomatic individuals. *JAMA.* 2004;291:210-5.
19. Shaw LJ, Raggi P, Schisterman E, Berman DS, Callister TQ. Prognostic value of cardiac risk factors and coronary artery calcium screening for all-cause mortality. *Radiology.* 2003;228:826-33.
20. Kondos GT, Hoff JA, Sevrukov A, Daviglus ML, GarSIDE DB, Devries SS, Chonka EV, Liu K. Electron-beam tomography coronary artery calcium and cardiac events: A 37-month follow-up of 5,635 initially asymptomatic low-to-intermediate-risk adults. *Circulation.* 2003;107:2571-6.
21. Arad Y, Goodman K, Roth M, Newman D, Guerci AD. Coronary calcification, coronary risk factors, and atherosclerotic cardiovascular disease events: The St. Francis Heart Study. *J Am Coll Cardiol.* 2005;46:158-65.
22. De Backer G, Ambrosioni E, Borch-Johnsen K, Brotons C, Cifkova R, Dallongeville J, Ebrahim S, Faergeman O, Graham I, et al. European guidelines on cardiovascular disease prevention in clinical practice. *Eur Heart J.* 2003;24:1601-10.
23. Greenland P, Abrams J, Aurigemma GP, Bond MG, Clark LT, Criqui MH, Crouse JR, Friedman L, Fuster V, et al. Prevention Conference V: Beyond secondary prevention: Identifying the high-risk patient for primary prevention: noninvasive tests of atherosclerotic burden: Writing Group III. *Circulation.* 2000;101:E16-22.
24. Hecht HS. Practice guidelines for electron beam tomography: A report of the Society of Atherosclerosis Imaging. *Am J Cardiol.* 2000;86:705-6.
25. Grundy SM, Cleeman JI, Merz CN, Brewer HB, Jr., Clark LT, Hunnigbake DB, Pasternak RC, Smith SC, Jr., Stone NJ. Implications of recent clinical trials for the National Cholesterol Education Program Adult Treatment Panel III guidelines. *Circulation.* 2004;110:227-39.
26. Taylor AJ, Merz CN, Udelsion JE. 34th Bethesda Conference: Executive summary—can atherosclerosis imaging techniques improve the detection of patients at risk for ischemic heart disease? *J Am Coll Cardiol.* 2003;41:1860-2.
27. Mieres JH, Shaw LJ, Arai A, Budoff MJ, Flamm SD, Hundley WG, Marwick TH, Mosca L, Patel AR, et al. Role of non-invasive testing in the clinical evaluation of women with suspected coronary artery disease: American Heart Association consensus statement from the Cardiac Imaging Committee, Council on Clinical Cardiology, and the Cardiovascular Imaging and Intervention Committee, Council on Cardiovascular Radiology and Intervention, American Heart Association. *Circulation.* 2005;111:682-96.
28. Wang S, Detrano RC, Secot A, Tang A, Doherty TM, Puentes G, Wong N, Brundage BH. Detection of coronary calcification with electron-beam computed tomography: evaluation of interexamination reproducibility and comparison of three image acquisition protocols. *Am Heart J.* 1996;132:550-8.
29. Kaufmann RB, Sheedy PF, Breen JF, Kelezberg JR, Kruger BL, Schwartz RS, Moll PP. Detection of heart calcification with electron beam CT: Interobserver and intraobserver reliability for scoring quantification. *Radiology.* 1994;190:347-52.
30. Agatston AS, Janowitz WR, Hildner FJ, Zusmer NR, Viamonte M, Detrano R. Quantification of coronary artery calcium using ultrastatic computed tomography. *J Am Coll Cardiol.* 1990;15:827-32.
31. Shields JP, Melke CH, Rockwood TH, Short RA, Viren FK. Reliability of electron beam CT to detect coronary artery calcification. *Am J Card Imaging.* 1995;9:62-6.
32. Mao S, Bakhteshi H, Lu B, Liu SC, Oudiz RJ, Budoff MJ. Effect of ECG triggering on reproducibility of coronary artery calcium scoring. *Radiology.* 2001;220:707-11.
33. Callister TQ, Raggi P, Cool B, Lippolis NJ, Russo DJ. Effect of HMG-CoA reductase inhibitors on coronary artery disease as assessed by electron-beam computed tomography. *N Engl J Med.* 1998;339:1972-8.
34. Budoff MJ, Grassman BO, Bakhteshi H, Friedman BC, Brundage BH. Rates of progression of coronary calcification by electron beam computed tomography. *Circulation.* 1998;98:1-656.
35. Raggi P, Cool B, Shaw LJ, Aboulhson J, Takasu J, Budoff M, Callister TQ. Progression of coronary calcium on serial electron beam tomographic scanning is greater in patients with future myocardial infarction. *Am J Cardiol.* 2003;92:827-9.
36. Raggi P, Callister TQ, Shaw LJ. Progression of coronary artery calcium and risk of first myocardial infarction in patients receiving cholesterol-lowering therapy. *Atheroscler Thromb Vasc Biol.* 2004;24:1272-7.
37. Neil HA, Sillig CA, Lancaster T, Hodgeman J, Vos K, Moore JW, Jones L, Cahill J, Fowler GH. Garlic powder in the treatment of moderate hyperlipidaemia: a controlled trial and meta-analysis. *J R Coll Physicians Lond.* 1996;30:329-34.
38. Warshafsky S, Kainer RS, Sivak SL. Effect of garlic on total cholesterol, a meta-analysis. *Ann Intern Med.* 1993;119:599-605.
39. Steiner M, Kham AH, Holbert D, Lin RIS. A double-blind crossover study in moderately hypercholesterolemic men that compared the effect of aged garlic extract and placebo administration on blood lipids. *Am J Clin Nutr.* 1996;64:868-70.
40. Campbell JH, Eftandy JL, Smith NU, Campbell GR. Molecular basis by which garlic suppresses atherosclerosis. *J Nutr.* 2001;131:1006S-9S.
41. Steiner M, Li W. Aged garlic extract, a modulator of cardiovascular risk factors: a dose-finding study on the effects of AGE on platelet functions. *J Nutr.* 2001;131(3s):980S-4S.
42. Rahnman K, Billington D. Dietary supplementation with aged garlic extract inhibits ADP-induced platelet aggregation in humans. *J Nutr.* 2000;130:2662-5.
43. Lau BH. Suppression of LDL oxidation by garlic. *J Nutr.* 2001;131:985S-8S.
44. Pittler MH, Ernst E. Complementary therapies for peripheral arterial disease: systematic review. *Atherosclerosis.* 2005;181:1-7.
45. Ho SE, Ide N, Lau BH. S-allyl cysteine reduces oxidant load in cells involved in the atherogenic process. *Phytotherapy.* 2001;8:39-46.
46. Morihara N, Sumitoka I, Moriyuchi T, Uda N, Kyo E. Aged garlic extract enhances production of nitric oxide. *Life Sci.* 2002;71:509-17.
47. Budoff MJ, Takasu J, Flores FR, Nihara Y, Lu B, Lau BH, Rosen RT, Artagase H. Inhibiting progression of coronary calcification using aged garlic extract in patients receiving statin therapy: a preliminary study. *Prev Med.* 2004;39:985-91.
48. Steiner M, Lin RI. Changes in platelet function and susceptibility of lipoproteins to oxidation associated with administration of Aged Garlic Extract. *J Cardiovasc Pharmacol.* 1998;31:904-8.
49. Libby P, Schoenbeck U, Mach F, Selwyn AP, Ganz P. Current concepts in cardiovascular pathology: the role of LDL cholesterol in plaque rupture and stabilization. *Am J Med.* 1998;104:14S-8S.

# Exhibit RX 1 Attachment D



Contents lists available at ScienceDirect

Maturitas

journal homepage: [www.elsevier.com/locate/maturitas](http://www.elsevier.com/locate/maturitas)



## Aged garlic extract lowers blood pressure in patients with treated but uncontrolled hypertension: A randomised controlled trial<sup>☆</sup>

Karin Ried<sup>\*</sup>, Oliver R. Frank, Nigel P. Stocks

Discipline of General Practice, School of Population Health and Clinical Practice, The University of Adelaide, Adelaide, South Australia 5005, Australia

### ARTICLE INFO

#### Article history:

Received 14 April 2010

Received in revised form 18 May 2010

Accepted 2 June 2010

#### Keywords:

Cardiovascular health  
Uncontrolled hypertension  
Aged garlic extract  
Complementary medicine

### ABSTRACT

**Objective:** To assess the effect, tolerability and acceptability of aged garlic extract as an adjunct treatment to existing antihypertensive medication in patients with treated, but uncontrolled, hypertension.

**Design:** A double-blind parallel randomised placebo-controlled trial involving 50 patients whose routine clinical records in general practice documented treated but uncontrolled hypertension. The active treatment group received four capsules of aged garlic extract (960 mg containing 2.4 mg S-allylcysteine) daily for 12 weeks, and the control group received matching placebos. The primary outcome measures were systolic and diastolic blood pressure at baseline, 4, 8 and 12 weeks, and change over time. We also assessed tolerability during the trial and acceptability at 12 weeks.

**Results:** In patients with uncontrolled hypertension (SBP  $\geq$  140 mm Hg at baseline), systolic blood pressure was on average  $10.2 \pm 4.3$  mm Hg ( $p = 0.03$ ) lower in the garlic group compared with controls over the 12-week treatment period. Changes in blood pressure between the groups were not significant in patients with SBP < 140 mm Hg at baseline. Aged garlic extract was generally well tolerated and acceptability of trial treatment was high (92%).

**Conclusion:** Our trial suggests that aged garlic extract is superior to placebo in lowering systolic blood pressure similarly to current first line medications in patients with treated but uncontrolled hypertension.

© 2010 Elsevier Ireland Ltd. All rights reserved.

### 1. Introduction

High blood pressure is an important risk factor for cardiovascular disease (CVD). In Australia, 30% or 3.7 million adults are hypertensive (systolic blood pressure (SBP)  $\geq$  140 mm Hg or diastolic blood pressure (DBP)  $\geq$  90 mm Hg) [1]. Only half of the people with hypertension receive antihypertensive medication, however, 60% of patients on treatment are inadequately controlled [2]. Primary prevention of CVD is important; adequate risk factor management is associated with a fourfold larger reduction in deaths than secondary prevention of CVD and with a higher life expectancy of 21 years on average [3].

As hypertension is the most frequently managed problem in Australian general practice, accounting for 9.6% of GP visits [4], and the use of complementary and alternative medicine (CAM) by

Australians is high [5], there is scope to explore the integration of CAM in the therapy of patients with treated, but uncontrolled, hypertension.

Garlic supplements have been associated with a blood pressure lowering effect of clinical significance in patients with untreated hypertension. Systolic blood pressure was on average  $8 \pm 3$  mm Hg lower in the garlic group compared to controls in two recent meta-analyses [6,7]. This reduction in blood pressure is of a similar magnitude as that achieved by current first line treatment with antihypertensive medication and is clinically highly relevant; it has been shown that a drop in systolic blood pressure by 5 mm Hg reduces the risk of cardiovascular disease by 8–20% [8,9].

While the majority of trials in these meta-analyses had used garlic in form of garlic powder supplements, current evidence suggests aged garlic extract (AGE) to be a more reliable treatment option. Aged garlic extract is regarded as safe and more tolerable than garlic powder [10,11], and superior to raw or cooked garlic in relation to its antihypertensive properties [10,12]. In addition, the active component S-allylcysteine (SAC) in AGE is less volatile than allicin in garlic powder, and therefore more easily standardised [13].

The antihypertensive properties of garlic have been linked to stimulation of intracellular nitric oxide (NO) and hydrogen sulphide (H<sub>2</sub>S) production, and blockage of angiotensin II production, which

<sup>☆</sup> Trial registration number: ACTRN12609000151235, Australian New Zealand Trial Registry, <http://www.anzctr.org.au>.

<sup>\*</sup> Corresponding author at: Discipline of General Practice, The University of Adelaide, Eleanor Herralld Bld, Level 3, Frome Rd, Adelaide, South Australia 5045, Australia. Tel.: +61 8 8303 6281; fax: +61 8 8303 3511.

E-mail addresses: [karin.ried@adelaide.edu.au](mailto:karin.ried@adelaide.edu.au) (K. Ried), [Oliver.frank@adelaide.edu.au](mailto:Oliver.frank@adelaide.edu.au) (O.R. Frank), [Nigel.stocks@adelaide.edu.au](mailto:Nigel.stocks@adelaide.edu.au) (N.P. Stocks).

in turn promote vasodilation and thus reduction in blood pressure [14,15].

Our trial is the first to assess the effect, tolerability and acceptability of aged garlic extract as an adjunct treatment to existing antihypertensive medication in patients with treated, but uncontrolled, hypertension.

## 2. Subjects and methods

### 2.1. Subjects

Adult patients with uncontrolled hypertension (SBP  $\geq$  140 or DBP  $\geq$  90 mmHg as recorded on their medical record in the last 12 months) from two general practices in metropolitan Adelaide, South Australia, were invited to participate in this double-blind placebo-controlled parallel RCT. We primarily sought patients already taking conventional antihypertensive medication, such as angiotensin converting enzyme inhibitors (ACEI), angiotensin II receptor antagonists (A2RA), beta-blockers (BB), calcium channel blockers (CBB) or diuretics (D), and whose general practitioners (GPs) were not planning to change prescribed medication during the trial. Patients were excluded if they had unstable other medical conditions or serious illness, e.g. dementia, terminal illness, recent bereavement, multiple chronic conditions, secondary hypertension, recent significant medical diagnosis, or pregnancy. Patients with poor comprehension of written or spoken English, or taking daily garlic supplements were also excluded. We identified patients by a search of electronic medical records using the practices' clinical software package and the PEN Computer Systems Audit Tool (CAT) [16], and further assessed eligibility in liaison with the four GPs whose patients were involved in the trial. Patients interested in the trial provided written consent by response to the invitation letter. The trial was approved by the Human Research Ethics Committee at The University of Adelaide.

### 2.2. Allocation and treatment

Consenting patients were randomly allocated to either the garlic or placebo group using a computer-generated random number table provided by an independent statistical consultant. Patients in the garlic group were assigned four capsules daily of Kyolic® (Garlic High Potency Everyday Formula 112, Wakunga/Wagner®) [17] containing 960 mg of aged garlic extract (AGE) and 2.4 mg S-allylcysteine (SAC) for 12 weeks. The daily dosage is equivalent to about 2.5 g of fresh garlic and comparable to the dosage used in the majority of previous trials on garlic supplements and blood pressure [6,7]. Placebo capsules for the control group were matched to the active capsules in number, size, colour, and odour. Active and placebo capsules were packaged in identical opaque containers. Sachets with a drop of liquid AGE were added to give a garlic odour to all containers. Patients, as well as investigators, research nurses and GPs were blinded to the group allocation. Success of the blinding of patients was evaluated at the end of the intervention by asking patients to which group they thought they had been assigned. Patients were instructed to take all four capsules at the same time of day or two in the morning and two in the evening, preferably with food. Patients' preferences regarding timing of doses were recorded during the trial and any changes in administration and reasons for changes were noted. Patients were reminded to keep taking their usual prescribed medication. Compliance was assessed by daily diary entries.

### 2.3. Blood pressure monitoring

Primary outcome measures were systolic and diastolic blood pressure at 4, 8 and 12 weeks compared with baseline. Blood pres-

sure (BP) was taken by a trained research nurse using a calibrated and validated digital sphygmomanometer with appropriate sized cuffs (Omron HEM-907, JA Davey Pty Ltd.; calibrated against a mercury sphygmomanometer). Blood pressure was measured with the participant in a seated position and the arm supported at heart level, after 5 min rest, and abstinence from food (including nutritional supplements) and caffeinated beverages for a minimum of 30 min prior to BP measurement [18]. At the participant's baseline assessment, BP was measured using both arms. Thereafter the arm with the higher reading was used. The Omron HEM-907 was set to record three BP readings automatically at intervals of 30 s. If the difference between the SBP readings was more than 8 mmHg, a further three measures was taken. The mean of whichever set of three BP measurements had the smaller variation was used in the analysis. Following baseline measurement, BP was measured at approximately the same time of day at 4-weekly intervals (baseline, 4, 8 and 12 weeks).

### 2.4. Tolerability and acceptability

Tolerability of trial medication was monitored throughout the trial by questionnaire at the 4-weekly appointments. An exit questionnaire administered at 12 weeks assessed patient's ease of use and acceptability of the trial medication for the duration of the study, and explored willingness to continue the trial treatment long term, using 5-point Likert-scales and open ended questions. The acceptability questionnaire had been tested in a previous trial [19]. Patients who dropped out from the trial were followed-up by phone to assess acceptability and reasons for withdrawal.

### 2.5. Audit of medication and cardiovascular risk factors

At enrolment, details of patients' current antihypertensive medication (class, dosage) and cardiovascular risk factors including age, gender, cholesterol levels (total/HDL-C ratio), smoking habits, and diabetic status were obtained from medical records by the research nurse, and by interview of patients to ascertain family history of premature cardiovascular disease (CVD) occurring in male first degree relatives <55 years, or female first degree relatives <65 years of age. Height and weight were measured to calculate Body Mass Index (BMI). Baseline blood pressure and other cardiovascular risk factors were used to calculate absolute cardiovascular risk using the NZ Cardiovascular Risk Calculator [20]. Patients' medical records were audited again at the end of the trial to ascertain any changes in medications during the trial.

### 2.6. Sample size

A sample size of 25 patients per group was estimated as being able to detect a difference of  $8 \pm 3$  mm in systolic blood pressure between active treatment and control group with a power of  $\geq 80\%$  and 95% confidence, allowing for a 10% drop-out or non-attendance at all appointments, and adjusting for clustering (design effect of 1.2). Assuming a response rate of 20–25%, we estimated that we needed to approach approximately 200–250 patients. Two general practices in metropolitan Adelaide each with access to about 160 adult patients with uncontrolled hypertension were involved.

### 2.7. Statistical analyses

Analyses were performed using SPSS version 15.0 and SAS version 9.1. Statistical significance was set at  $p < 0.05$ .

Differences between groups at baseline in continuous variables (age, BMI, cholesterol, BP) were assessed by Student's *t*-test and categorical variables (gender, smoking habits, diabetic status, family

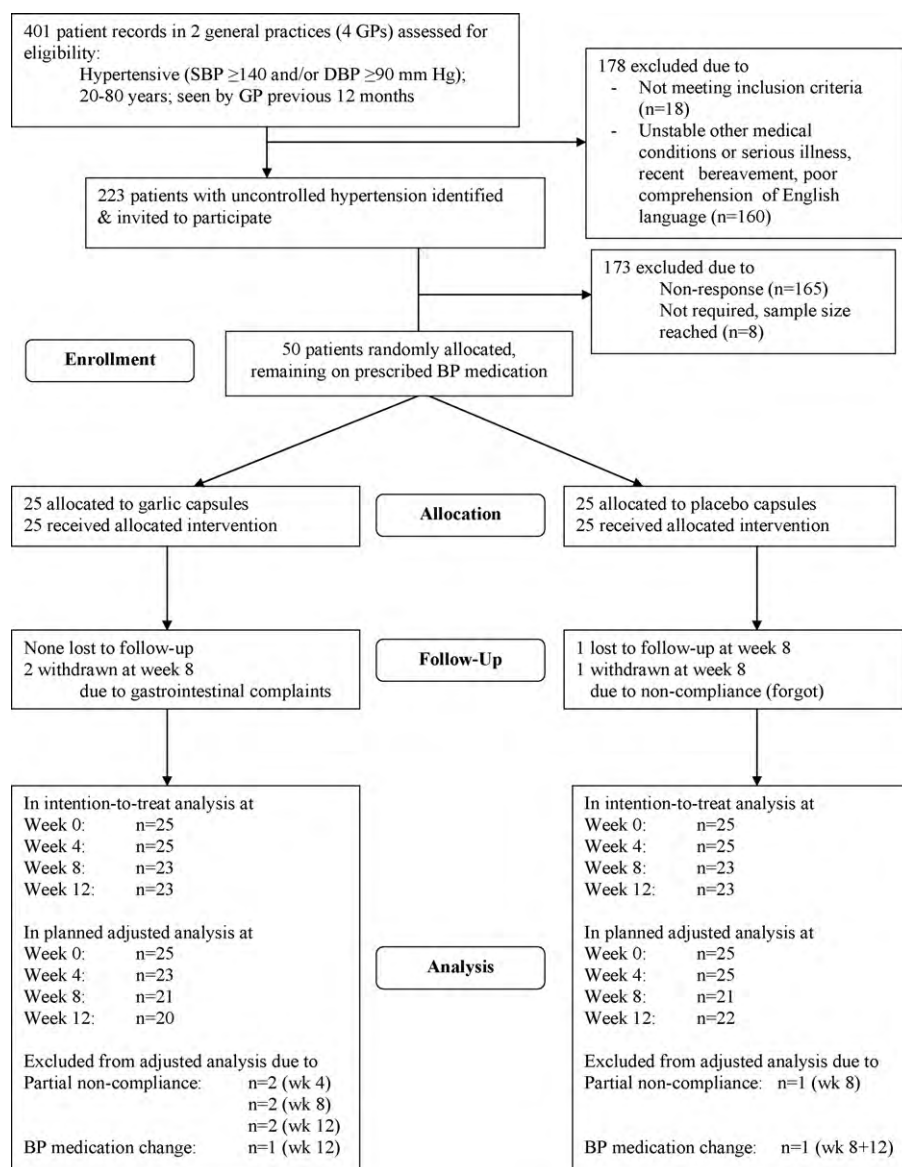


Fig. 1. Flow chart. Abbreviations: BP, blood pressure; DBP, diastolic blood pressure; GP, general practitioner; n, number; SBP, systolic blood pressure; wk, week.

history of premature CVD, and class of antihypertensive medication) by chi-square test, and absolute CVD risk by Fisher's Exact test.

A mixed model analysis was used to assess differences in mean SBP and DBP between groups over time using data at 4, 8 and 12 weeks compared with baseline while allowing for attrition and cluster effect and inclusion of confounding variables. Compound symmetry was assumed.

Primary analyses were conducted on intention-to-treat group comparisons followed by adjustment for poor compliance or BP medication change, as these factors were expected to influence the primary outcome measure.

Pre-planned subgroup analyses by baseline blood pressure using the mixed model were done, comparing treatment groups within subgroups of patients with (a) SBP ≥ 140 mm Hg at baseline or (b) with SBP < 140 mm Hg at baseline as measured under trial conditions.

Tolerability was analysed qualitatively and differences between the groups assessed by chi-square test. Differences in acceptability of the intervention and willingness for long-term treatment between groups at 12 weeks were assessed by Fisher's Exact test.

### 3. Results

#### 3.1. Study sample

The trial was conducted in Adelaide, South Australia, between March and September 2009. Fifty patients with uncontrolled hypertension on medical record were enrolled in the trial (response rate 26% of 223 invited), and 25 each randomised to the garlic and placebo groups, respectively (Fig. 1). Comparison of baseline characteristics revealed no significant difference between groups in most parameters, and borderline significance in the mean number of BP medication classes prescribed (Table 1). Forty percent of patients were taking one class of BP medication, 26% were taking two, while 30% were taking three or more BP medication classes. The most prescribed class of BP medication was diuretics (54%); almost half in the garlic group took A2RA alone or in combination with other medication (48%), while 44% of patients in the control group were on ACEI (Fig. 2). Meaningful subgroup analysis by medication class was not possible due to small numbers in each medication regimen.

**Table 1**  
 Baseline characteristics.

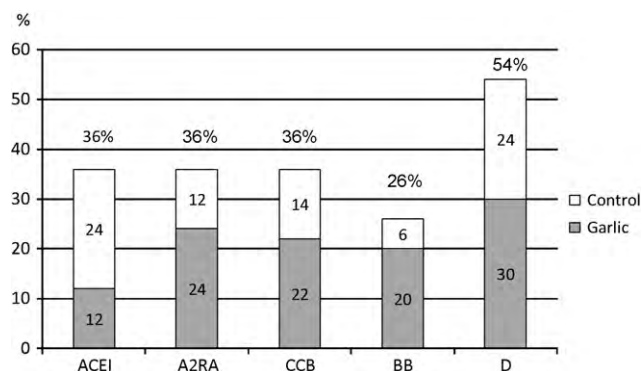
	Garlic group n = 25	Control group n = 25
Male [%]	68%	68%
Age [y] <sup>a</sup>	66 ± 9	66 ± 9
SBP on medical record [mm Hg] <sup>a</sup>	146.2 ± 10.5	151.1 ± 10.4
DBP on medical record [mm Hg] <sup>a</sup>	79.3 ± 11.8	80.4 ± 7.9
Number of BP medications <sup>a,b</sup>	2.2 ± 1.1	1.6 ± 0.9 <sup>c</sup>
Current smoker	4%	12%
BMI <sup>a</sup>	31 ± 5.8	29.1 ± 4.7
Total cholesterol [mmol/l] <sup>a</sup>	5.0 ± 1.1	5.3 ± 0.9
Diabetes	20%	32%
Family history premature CVD	8 (32%)	7 (28%)
Absolute CVD risk		
Mild (5–10%)	8 (32%)	6 (24%)
Moderate (1–15%)	2 (24%)	12 (48%)
High (5–20%)	7 (28%)	3 (12%)
Very high (>20%)	4 (16%)	4 (16%)

Y, years; BMI, Body Mass Index; mmol/l, millimole per litre; CVD, cardiovascular disease; SBP, systolic blood pressure; DBP, diastolic blood pressure.

<sup>a</sup> Mean ± SD.

<sup>b</sup> Mean number of prescribed blood pressure medication classes per person. Range 0–4, including ACEI, A2RA, BB, CCB, D.

<sup>c</sup> Significance of difference between the groups was assessed by *t*-test or chi-square test. Differences were insignificant for baseline characteristics, but number of BP medication per person (*p* = 0.049).



**Fig. 2.** Antihypertensive medication classes by treatment group at baseline. Some patients took multiple medication classes. See Table 1 for mean ± SD in each group. Abbreviations: ACEI, angiotensin converting enzyme inhibitors; A2RA, angiotensin II receptor antagonists; CCB, calcium channel blockers; BB, beta-blockers; D, diuretics.

### 3.2. Blood pressure

To be included in the trial, participants needed to have a diagnosis of uncontrolled hypertension on medical record: mean of at least two SBP readings of ≥ 140 (*n* = 45) or DBP ≥ 90 mm Hg (*n* = 5) in the last 12 months (Table 1). However, when measured under trial conditions, after 5 min rest, only 40% of participants displayed a mean SBP ≥ 140 mmHg at baseline, and 8% a mean of DBP ≥ 90 mm Hg. We subsequently stratified analyses by baseline blood pressure, for SBP: ‘uncontrolled hypertensive’ subgroup

**Table 2**  
 Systolic and diastolic blood pressure (SBP/DBP) outcomes.

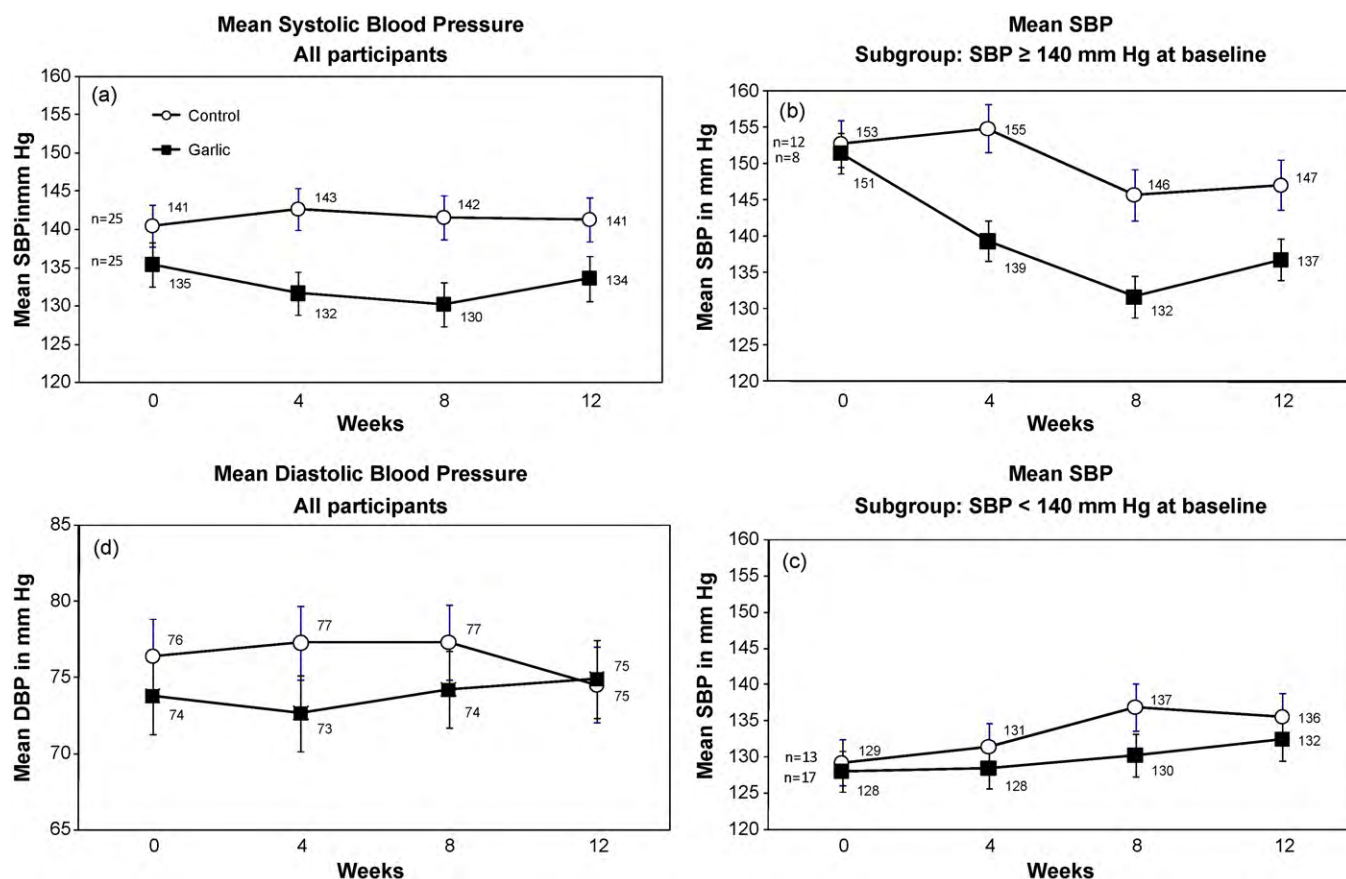
Analysis	Week	Garlic group			Control group			Mean difference (SE) between groups over time in mmHg; <i>p</i> -value <sup>a</sup>
		<i>n</i>	Mean (SD) in mmHg	Change to baseline within group in mmHg	<i>n</i>	Mean (SD) in mmHg	Change to baseline within group in mmHg	
<b>SBP</b>								
All participants (ITT)	0	25	135.4 (14.1)		25	140.5 (14.7)		
	4	25	133.2 (13.2)	−2.2	25	142.7 (17.0)	+2.2	
	8	23	131.8 (11.7)	−3.6	23	139.1 (12.4)	−1.4	
	12	23	136.2 (13.8)	+0.8	23	139.3 (12.6)	−1.2	
	0–12							−6.6 (3.3); <i>p</i> = 0.383
All participants <sup>b</sup>	0	25	135.4 (14.1)		25	140.5 (14.7)		
	4	23	132.2 (12.0)	−3.2	25	142.7 (17.0)	+2.2	
	8	21	130.6 (10.5)	−4.8	21	139.4 (12.2)	−1.1	
	12	20	133.5 (11.5)	−1.9	22	139.8 (12.7)	−1.2	
	0–12							−9.0 (3.3); <i>p</i> = 0.321
Subgroup <sup>b</sup> : BL ≥ 140 mmHg	0	8	151.2 (7.7)		12	152.8 (9.3)		
	4	7	139.4 (9.0)	−11.8	12	154.9 (11.8)	+2.1	
	8	7	131.7 (4.3)	−19.5	9	143.4 (5.2)	−9.4	
	12	6	136.0 (8.0)	−15.2	10	145.4 (3.5)	−7.4	
	0–12							−10.2 (4.3); <i>p</i> = 0.036 <sup>c</sup>
Subgroup <sup>b</sup> : BL < 140 mmHg	0	17	128.0 (9.4)		13	129.2 (8.0)		
	4	16	129.1 (12.0)	+1.1	13	131.4 (12.9)	+2.2	
	8	14	130.0 (12.6)	+2.0	12	136.4 (15.1)	+7.2	
	12	14	132.4 (12.4)	+4.4	12	135.1 (13.5)	+5.9	
	0–12							−3.6 (3.3); <i>p</i> = 0.634
<b>DBP</b>								
All participants <sup>b</sup>	0	25	74.0 (10.3)		25	76.4 (13.2)		
	4	23	72.5 (13.8)	−1.5	25	77.3 (12.6)	+0.9	
	8	22	74.7 (11.6)	+0.7	23	76.6 (10.6)	+0.2	
	12	20	75.5 (13.6)	+1.5	22	73.1 (10.8)	−3.3	
	0–12							+2.5 (3.3); <i>p</i> = 0.242

BL, baseline; ITT, intention-to-treat analysis; mmHg, millimetre mercury.

<sup>a</sup> Mean differences include data at 4, 8 and 12 weeks compared with baseline using mixed model analysis.

<sup>b</sup> Planned analyses adjusted for partial non-compliance and BP medication change.

<sup>c</sup> Significant difference between groups: *p* < 0.05.



**Fig. 3.** Mean systolic blood pressure (SBP) ± standard error (SE) over the 12-week intervention period of (a) all participants, (b) subgroup with uncontrolled hypertension (SBP ≥ 140 mm Hg at baseline), (c) subgroup with controlled hypertension (SBP < 140 mm Hg at baseline), and (d) mean diastolic blood pressure (DBP) ± standard error (SE) of all participants.

with mean SBP ≥ 140 mm Hg at baseline and ‘controlled hypertensive’ subgroup with mean SBP < 140 mm Hg at baseline. Due to the small number of patients with diastolic hypertension, a subgroup analysis of DBP by hypertension status was not meaningful.

Intention-to-treat analyses of SBP including all participants did not reveal a significant difference between the groups over time including data from baseline to 12 weeks (Table 2). Analyses adjusted for partial non-compliance and BP medication change including all participants was consistent with intention-to-treat analyses (Fig. 3a, Table 2).

However, a marked difference in treatment effect was revealed in pre-planned subgroup analyses stratified by baseline SBP. A significant treatment effect over 12 weeks was apparent between garlic and control groups in patients with uncontrolled hypertension at baseline (mean difference in SBP ± SE:  $-10.2 \pm 4.3$ ,  $p = 0.0361$ ), whereas no significant differences between the treatment arms were found in the subgroup of patients with controlled hypertension (Fig. 3b and c, Table 2).

Diastolic blood pressure including all participants was not significantly different between the garlic and control groups over time (Fig. 3d, Table 2).

### 3.3. Tolerability and acceptability

Attrition was low: one participant was lost-to-follow-up (control), and three participants withdrew during the trial, one due to non-compliance (“kept forgetting”; control group), and two due to experiencing gastrointestinal discomfort (garlic group). Compliance was high: five participants (four in

the garlic and one in the control group) were partially non-compliant due to other events such as hospital stays (Fig. 1).

Tolerability of trial capsules was generally high. A quarter (24%) of the participants taking the garlic capsules reported belching, reflux, and taste sensations, while 8% of those taking the placebo capsules reported similar adverse effects ( $p = 0.25$ ). However, these effects were regarded as minor and participants found ways to reduce them including sucking on mints, splitting the daily dosage, or taking the capsules with food. Only two participants (8%) in the garlic group stopped taking their capsules after 2 months because of gastrointestinal complaints (garlic versus control:  $p = 0.5$ ).

Most of the participants in our trial found that taking four trial capsules daily was easy (93%) and acceptable (92%). Two-thirds of participants (65%) preferred to take all four capsules at once, while some (35%) divided the dosage into 2 capsules twice daily. A few participants (14%) found the capsules a little large to take easily. All but two participants in the garlic group (92%) were willing to continue taking garlic supplements if it helped with their blood pressure, compared to two-thirds (66%) in the control group. For 14% of participants a limiting factor for continuation of treatment with garlic capsules were the estimated costs of \$1.20 (Australian) for four capsules per day (garlic versus control:  $p = 0.05$ ).

At the end of the intervention, almost 58% of participants in the garlic group guessed their allocated treatment group correctly (4% incorrect, 38% unsure), in comparison to 24% of participants in the control group (24% incorrect, 52% unsure) ( $p = 0.02$ ).



#### 4. Discussion

Our trial suggests that aged garlic extract is superior to placebo in lowering systolic blood pressure in patients with treated, but uncontrolled, hypertension. Aged garlic extract was generally well tolerated, and the level of blood pressure reduction achieved was comparable to that of common antihypertensive medication ( $-10.2 \pm 4.3$  mm Hg,  $p=0.03$ ) over 12 weeks in patients with SBP  $\geq 140$  mm Hg at baseline. In contrast, no significant difference between the treatment groups was found in the patient subgroup with SBP  $< 140$  mm Hg at baseline. This marked difference in treatment effect dependent on baseline blood pressure is consistent with meta-analyses of trials on garlic supplements in untreated patients [6,7], in which garlic supplements were found to be superior to placebo in lowering blood pressure in hypertensive patients (SBP  $\geq 140$  mm Hg at baseline) but not in patients with SBP  $< 140$  mm Hg.

Additionally, we found acceptability of trial capsules to be high (92%), and three-quarters (75%) of participants indicated that they would be willing to continue with the treatment in consultation with their physician, if it was available.

Our patient sample represented a general practice population in urban Australia (mean age (SD)  $66 \pm 9$  years, 68% males) with a mean blood pressure on medical record comparable to Australian population with treated hypertension [2]. A greater proportion of patients in our trial were prescribed diuretics compared to the hypertensive Australian population (54% versus 23%) [21], whereas ACEI were less prominent (36%) in our sample if compared nationally (47–56%) [22]. Medication regimen might reflect preferences of physicians involved in the trial.

Our study has a few limitations. First, in this trial we included patients diagnosed with treated, but uncontrolled hypertension according to their medical record. However, an unexpected high proportion (62%) of eligible patients was found to have controlled hypertension under trial conditions. As this study was to assess feasibility of recruitment, as well as tolerability and acceptability of the intervention in addition to efficacy, all patients remained in the study. In order to assess the effect of aged garlic extract on blood pressure in hypertensive patients, we stratified our analyses into subgroups of patients with uncontrolled and controlled systolic hypertension. Due to the small number of patients with diastolic hypertension, subgroup analyses of DBP were not meaningful.

Second, despite randomisation, mean baseline blood pressure differed by 5 mm Hg between treatment groups, albeit this difference was not statistically significant. In addition, mixed model analyses over time were adjusted for baseline blood pressure. In future trials, assessment of baseline blood pressure under trial conditions before enrolment and block randomisation by ranked mean baseline BP might balance BP values between the groups.

Third, blinding of patients might have been hampered to some extent due to some patients in the garlic group experiencing distinctive taste sensations after ingestion of the trial capsules, and/or patients noticing lower than usual blood pressure readings during the intervention period. Blinding of patients may be improved in future trials by instructing patients to take trial capsules with or immediately after a main meal to reduce chances of belching, reflux and taste sensations; and by better blinding of patients to BP readings until the end of the trial.

In our trial, two patients in the garlic group withdrew after 2 months due to gastrointestinal discomfort. While rare, gastrointestinal disturbances have been reported previously when garlic supplements were taken in therapeutic dosages by similar proportions of patients [23,24]. Individual detoxification capacity of sulphur-compounds in garlic is influenced by genetic variation of sulphur-transferase enzymes, in particular sulphite oxidase, as well as inflammatory status [25]. Enzyme capacity is further dependent

on molybdenum and vitamin B12 levels [26]. Lower tolerance of sulphur-containing foods such as garlic, onion, and leek, can be reversed by supplementation with molybdenum and/or vitamin B12 [26]. It may be speculated that the two patients in our trial had reduced detoxification capacity; it would be interesting to investigate whether tolerance levels of garlic supplementation can be improved by supplementation with molybdenum and vitamin B12.

Furthermore, it remains to be investigated whether lower dosages of aged garlic extract than those used in this trial may also be effective in reducing blood pressure in treated but uncontrolled hypertensive patients, while at the same time tolerability and blinding might be improved and costs of treatment reduced. Additionally, it would also be of interest to explore whether patients taking ACE inhibitors or A2RA respond differently to aged garlic extract compared with patients taking other antihypertensive medication classes, due to similar blood pressure lowering mechanisms.

Given that popularity of complementary therapies is high [5], and patients' motivation and satisfaction influence persistence to treatment plans [27,28], further research on aged garlic extract for hypertension is warranted.

#### 5. Conclusions

Our trial suggests that aged garlic extract may be a useful adjunct therapy to conventional medications in uncontrolled hypertension. Future larger trials are needed to confirm our findings of effectiveness on systolic hypertension, ascertain the effect on diastolic hypertension, investigate dose-response relationships, examine effect in association to conventional blood pressure medication classes, and explore whether supplementation with molybdenum and vitamin B12 improves some patients' tolerance of garlic.

#### Contributors

All authors conceptualised the study, obtained funding and oversaw data collection. KR undertook data analysis and interpretation in discussion with co-authors. KR prepared the manuscript with contributions from co-authors. All authors approved the final version. None of the authors had a personal or financial conflict of interest.

Trial material was provided by Vitaco Health (NZ) Ltd., Auckland, New Zealand, who were not involved in study design, data collection, analysis and preparation of manuscript.

#### Conflict of interest

None.

#### Funding

This study was supported by a Project Seeding Grant from the Australian Government Primary Health Care Research Evaluation Development (PHCRED) Program.

#### Acknowledgments

We thank all patients, general practices, doctors and staff for their participation in the trial. We are grateful to the two research nurses, Lisa Clements and Andrea Nangle, who were instrumental in liaising with practices and patients and collecting data. We acknowledge Dr Nancy Briggs and Michelle Lorimer who provided statistical advice.

## References

- [1] Heart Foundation. The shifting burden of cardiovascular disease in Australia. Access Economics Pty Ltd.; 2005.
- [2] Briganti EM, Shaw JE, Chadban SJ, et al. Untreated hypertension among Australian adults: the 1999–2000 Australian Diabetes, Obesity and Lifestyle Study. *Med J Aust* 2003;179(3):135–9.
- [3] Unal B, Critchley JA, Capewell S. Modelling the decline in coronary heart disease deaths in England and Wales, 1981–2000: comparing contributions from primary prevention and secondary prevention. *BMJ* 2005;331(7517):614.
- [4] Britt H, Miller G, Charles J, et al. General practice activity in Australia 2006–07. General practice series no. 21. Cat. no. GEP 21. Canberra: Australian Institute of Health and Welfare; 2008.
- [5] MacLennan AH, Myers SP, Taylor AW. The continuing use of complementary and alternative medicine in South Australia: costs and beliefs in 2004. *Med J Aust* 2006;184(1):27–31.
- [6] Reinhart KM, Coleman CI, Teevan C, Vachhani P, White CM. Effects of garlic on blood pressure in patients with and without systolic hypertension: a meta-analysis. *Ann Pharmacother* 2008;42(12):1766–71.
- [7] Ried K, Frank OR, Stocks NP, Fakler P, Sullivan T. Effect of garlic on blood pressure: a systematic review and meta-analysis. *BMC Cardiovasc Disord* 2008;8:13.
- [8] Chobanian AV, Bakris GL, Black HR, et al. The seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC 7 report. *JAMA* 2003;289(19):2560–72.
- [9] McInnes GT. Lowering blood pressure for cardiovascular risk reduction. *J Hypertens Suppl* 2005;23(1):S3–8.
- [10] Harauma A, Moriguchi T. Aged garlic extract improves blood pressure in spontaneously hypertensive rats more safely than raw garlic. *J Nutr* 2006;136(3 Suppl.):769S–73S.
- [11] Hoshino T, Kashimoto N, Kasuga S. Effects of garlic preparations on the gastrointestinal mucosa. *J Nutr* 2001;131(3s):1109S–13S.
- [12] Braun L, Cohen M. Herbs & natural supplements: an evidence-based guide. Elsevier; 2007.
- [13] Lawson LD, Gardner CD. Composition, stability, and bioavailability of garlic products used in a clinical trial. *J Agric Food Chem* 2005;53(16):6254–61.
- [14] Al-Qattan KK, Thomson M, Al-Mutawa'a S, Al-Hajeri D, Drobiova H, Ali M. Nitric oxide mediates the blood-pressure lowering effect of garlic in the rat two-kidney, one-clip model of hypertension. *J Nutr* 2006;136(3 Suppl.):774S–6S.
- [15] Benavides GA, Squadrito GL, Mills RW, et al. Hydrogen sulfide mediates the vasoactivity of garlic. *Proc Natl Acad Sci USA* 2007;104(46):17977–82.
- [16] PEN Computer Systems Pty Ltd., Parramatta, NSW, Australia. [www.pencs.com.au](http://www.pencs.com.au).
- [17] Kyolic® garlic high potency everyday formula 112. Nutra-Life Health & Fitness Australia Pty Ltd.; Vitaco Health (NZ) Ltd. [<http://health.nutralife.co.nz/Product.aspx?id=122>].
- [18] Gentilcore D, Jones KL, O'Donovan DG, Horowitz M. Postprandial hypotension—novel insights into pathophysiology and therapeutic implications. *Curr Vasc Pharmacol* 2006;4(2):161–71.
- [19] Ried K, Frank O, Stocks N. Dark chocolate or tomato extract for prehypertension: a randomised controlled trial. *BMC Complement Altern Med* 2009;9:22.
- [20] New Zealand Cardiovascular Risk Calculator. [www.nzgg.org.nz](http://www.nzgg.org.nz).
- [21] AIHW Australian GP Statistics and Classification Centre. SAND abstract no. 113 from the BEACH program: management of hypertension and hypercholesterolaemia among general practice patients. Sydney: AGPSCC University of Sydney; 2008. ISSN 1444-9072.
- [22] Simons LA, Ortiz M, Calcino G. Persistence with antihypertensive medication: Australia-wide experience, 2004–2006. *Med J Aust* 2008;188(4):224–7.
- [23] Beck E, Gruenwald J. Allium sativum in der Stufentherapie der Hyperlipidaemie. *Med Welt* 1993;44:516–20.
- [24] Borrelli F, Capasso R, Izzo AA. Garlic (*Allium sativum* L.): adverse effects and drug interactions in humans. *Mol Nutr Food Res* 2007;51(11):1386–97.
- [25] Waring RH, Klovra LZ, Harris RM. Diet and individuality in detoxification. *J Nutr Environment Med* 2007;16(2):95–105.
- [26] Meletis CD. Cleansing of the human body. A daily essential process. *Altern Complement Ther* 2001;7(4):196–202.
- [27] Gohar F, Greenfield SM, Beevers DG, Lip GY, Jolly K. Self-care and adherence to medication: a survey in the hypertension outpatient clinic. *BMC Complement Altern Med* 2008;8:4.
- [28] Lachaine J, Petrella RJ, Merikle E, Ali F. Choices, persistence and adherence to antihypertensive agents: evidence from RAMQ data. *Can J Cardiol* 2008;24(4):269–73.

ORIGINAL ARTICLE

# Aged garlic extract reduces blood pressure in hypertensives: a dose–response trial

K Ried<sup>1,2</sup>, OR Frank<sup>1</sup> and NP Stocks<sup>1</sup>

**BACKGROUND/OBJECTIVES:** Hypertension affects about 30% of adults worldwide. Garlic has blood pressure-lowering properties and the mechanism of action is biologically plausible. Our trial assessed the effect, dose–response, tolerability and acceptability of different doses of aged garlic extract as an adjunct treatment to existing antihypertensive medication in patients with uncontrolled hypertension.

**SUBJECTS/METHODS:** A total of 79 general practice patients with uncontrolled systolic hypertension participated in a double-blind randomised placebo-controlled dose–response trial of 12 weeks. Participants were allocated to one of three garlic groups with either of one, two or four capsules daily of aged garlic extract (240/480/960 mg containing 0.6/1.2/2.4 mg of S-allylcysteine) or placebo. Blood pressure was assessed at 4, 8 and 12 weeks and compared with baseline using a mixed-model approach. Tolerability was monitored throughout the trial and acceptability was assessed at 12 weeks by questionnaire.

**RESULTS:** Mean systolic blood pressure was significantly reduced by  $11.8 \pm 5.4$  mm Hg in the garlic-2-capsule group over 12 weeks compared with placebo ( $P = 0.006$ ), and reached borderline significant reduction in the garlic-4-capsule group at 8 weeks ( $-7.4 \pm 4.1$  mm Hg,  $P = 0.07$ ). Changes in systolic blood pressure in the garlic-1-capsule group and diastolic blood pressure were not significantly different to placebo. Tolerability, compliance and acceptability were high in all garlic groups (93%) and highest in the groups taking one or two capsules daily.

**CONCLUSIONS:** Our trial suggests aged garlic extract to be an effective and tolerable treatment in uncontrolled hypertension, and may be considered as a safe adjunct treatment to conventional antihypertensive therapy.

*European Journal of Clinical Nutrition* (2013) **67**, 64–70; doi:10.1038/ejcn.2012.178; published online 21 November 2012

**Keywords:** hypertension; garlic; nutritional medicine

## INTRODUCTION

Hypertension affects one billion or one in four adults worldwide, and attributes to about 40% of cardiovascular-related deaths.<sup>1,2</sup> Current medical treatment with standard antihypertensive medication is not always effective, leading to a large proportion of uncontrolled hypertension. In Australia, 24% or 3 million of the adult population remained uncontrolled hypertensive in 2003.<sup>3</sup> In addition, side effects and complexity of treatment influence treatment adherence.<sup>4,5</sup> As interest in and use of complementary and alternative medicines is high in patients with cardiovascular disease,<sup>6,7</sup> there is a need to explore the integration of complementary and alternative medicine into the treatment of hypertension.

Garlic supplements have been associated with a blood pressure (BP)-lowering effect of clinical significance in hypertensive patients.<sup>8–10</sup> Although there are several garlic preparations on the market, including garlic powder, garlic oil and raw or cooked garlic, aged garlic extract is the preparation of choice for BP treatment. Aged garlic extract contains the active and stable component S-allylcysteine, which allows standardisation of dosage.<sup>11</sup> In addition, aged garlic extract has a higher safety profile than other garlic preparations, and does not cause bleeding problems if taken with other blood-thinning medicines such as warfarin.<sup>12–14</sup>

The antihypertensive properties of garlic have been linked to stimulation of intracellular nitric oxide and hydrogen sulphide production, and blockage of angiotensin II production, which in turn promote vasodilation and thus reduction in BP.<sup>15–18</sup>

Here we assess the effect, dose–response, tolerability and acceptability of different doses of aged garlic extract as an adjunct treatment to existing antihypertensive medication in patients with uncontrolled hypertension.

## SUBJECTS AND METHODS

### Subjects and study design

Adult patients with uncontrolled hypertension (systolic BP (SBP)  $\geq 140$  mm Hg as recorded on their medical records in the past 6 months) from two general practices in metropolitan Adelaide, South Australia, were invited to participate in this double-blind randomised placebo-controlled parallel 12-week trial. We included primarily patients who were on an established plan of prescription antihypertensive medication for at least 2 months, including angiotensin-converting enzyme inhibitors, angiotensin II receptor blockers, calcium channel blockers, diuretics or  $\beta$ -blockers, and whose general practitioner was not planning to change the medication plan during the trial. We excluded patients with unstable or serious illness, for example, dementia, terminal illness, recent bereavement, secondary hypertension, recent significant medical diagnosis or pregnancy. Patients who were not able to provide informed consent, or were taking daily garlic

<sup>1</sup>Discipline of General Practice, The University of Adelaide, Adelaide, South Australia, Australia and <sup>2</sup>National Institute of Integrative Medicine, Melbourne, Victoria, Australia. Correspondence: Dr K Ried, National Institute of Integrative Medicine, 759 Burwood Road, Hawthorn East, Victoria 3123, Australia.

E-mail: karinried@niim.com.au or karin.ried@adelaide.edu.au

Received 7 August 2012; revised 5 October 2012; accepted 12 October 2012; published online 21 November 2012

supplements, were also excluded. We identified patients by search of electronic medical records using the practice clinical software package and the PEN Computer Systems Clinical Audit Tool,<sup>19</sup> and assessed eligibility in liaison with the patients' treating general practitioners. Patients who were interested in participating in the trial provided written consent by response to the invitation letter. Patients' eligibility was assessed at their first visit with the research nurse at their usual practice. Only patients whose SBP was  $\geq 135$  mmHg under trial conditions were enrolled in the trial. The study was approved by the Human Research Ethics Committees at the Royal Adelaide Hospital and The University of Adelaide. The trial was registered with the Australian New Zealand Clinical Trials Registry, number ACTRN12611000581965.

### Allocation and treatment

Consenting eligible patients were randomly allocated to one of three garlic groups (g1, g2 and g4) or placebo using a computer-generated random number table provided by an independent consulting statistician. Patients were assigned either one, two or four capsules daily of Kyolic aged garlic extract (High Potency Everyday Formula 112; Wakunaga/Wagner, Sydney, Australia)<sup>20</sup> containing either 240/480/960 mg of aged garlic extract and 0.6/1.2/2.4 mg S-allylcysteine or placebo capsules for 12 weeks. Placebo capsules were matched in number, shape, size, colour and odour to the active capsules and were packaged in identical opaque containers by independent staff not involved in the trial. Sachets with a drop of liquid Kyolic were added to the containers for garlic odour. Patients, investigators and the research nurse were blinded to treatment allocation. Blinding success of patients was assessed at the end of the trial by questionnaire. Patients were instructed to take all trial capsules with the evening meal. Patients were reminded to take their usual prescription medication as instructed by their doctor. Compliance was assessed by daily entries in provided calendars.

### BP monitoring

Primary outcome measures were SBP and diastolic BP (DBP) at 4, 8 and 12 weeks compared with baseline. BP was taken by a trained research nurse using a single calibrated and validated digital sphygmomanometer with appropriate sized cuffs (Omron HEM-907; JA Davey Pty Ltd, Melbourne, VIC, Australia). The display of the sphygmomanometer was positioned away from the patient to assure blinding to the BP readings. BP measurements were taken with the patient in a seated position with their arm supported at heart level, after 5 min rest, after abstinence from food, nutritional supplements, caffeinated beverages and smoking for a minimum of 2 h before the appointment at approximately the same time/day of the week. BP was recorded as three serial measurements at intervals of 30 s. The mean of the three BP measurements was used in the analysis. At the patients' baseline assessment, BP was measured on both arms, and the arm with the higher mean reading was used in subsequent visits. If the three SBP readings had more than 8 mmHg difference, a second BP series was recorded.

### Tolerability and acceptability

Tolerability of trial medication was monitored throughout the trial by questionnaire at the 4-weekly appointments. Acceptability and willingness to continue the trial treatment was assessed at 12 weeks using a questionnaire tested in previous trials.<sup>10,21</sup> Patients who dropped out from the trial were followed up by phone to assess acceptability and their reasons for withdrawal.

### Sample size

A sample size of 84 patients, 21 in each of the four groups, was calculated based on the following assumptions: (a) to detect a difference of 10 mmHg SBP (s.d. = 10) in BP change between each of the active treatment (g1, g2 and g4:  $n = 21, 21$  and  $21$ ) and placebo groups ( $p_{\text{total}} = p1 + p2 + p4$  capsules:  $n = 7 + 7 + 7 = 21$ ), with 80% power and 95% confidence;<sup>10</sup> (b) to account for 10% drop-out or non-attendance at one or more appointments; (c) to adjust for clustering using a design effect of 1.2 based on the formula: Design effect =  $(1 + (\text{size of cluster} - 1) \text{ intracluster correlation coefficient of } 0.02)$ . Assuming a response rate of 15%, we estimated that we would need to invite about 840 hypertensive patients from the two large general practices.

### Statistical analysis

Analyses were performed using PASW version 18 and SAS version 9.3. Statistical significance was set at  $P < 0.05$ . Differences between the groups in baseline characteristics were assessed by  $\chi^2$  and Fisher's exact test of binominal variables (gender, smoking, family history of premature cardiovascular disease, type of BP medication), by Kruskal–Wallis test for ordinal variables (number of BP medication) or one-way analysis of variance with Bonferroni adjustment and *post hoc* Dunnett's test for continuous variables (age, body mass index (BMI), blood lipids) after testing for their normal distribution by Kolmogorov–Smirnov test.

A linear mixed-effects model analysis was used to assess the mean differences of SBP and DBP between the groups at 4, 8 and 12 weeks and over time compared with baseline. Compound symmetry was assumed. For covariate analysis, we incorporated the following variables into the model to test for potential confounding: age, BMI, gender, smoking status and number of BP medicines. Analysis by type of BP medication was not meaningful because of small patient numbers in the subgroups.

Primary analyses were by intention to treat, including all available data regardless of protocol deviations, and planned adjusted analysis, excluding data points owing to BP medication change or participant's non-compliance.

Tolerability was analysed descriptively and differences between the groups assessed by  $\chi^2$  test. Differences in acceptability of the treatment between the groups were assessed by Kruskal–Wallis test. Blinding success was assessed by Fisher's exact test for garlic versus placebo, and Kruskal–Wallis test to ascertain differences between the garlic groups.

## RESULTS

### Participants

The trial was conducted in Adelaide, South Australia, between August 2011 and March 2012. Patients with uncontrolled hypertension on medical record were recruited from two metropolitan general practices. Of the 840 patients invited, 14% responded and were screened for eligibility, and 84 patients were enrolled randomly allocated to one of four treatment groups. Five patients withdrew before further assessment because of personal reasons unrelated to the trial (Figure 1). Baseline characteristics of the 79 patients participating in the trial were not significantly different between the garlic and placebo groups (Table 1). A total of 42 men and 37 women with a mean age of  $70 \pm 12$  years participated in the trial. Participants took on average  $2 \pm 1$  different types of antihypertensive medication (range 0–4), with angiotensin II receptor blockers the most often prescribed (46%). Family history of cardiovascular disease was reported by almost half of the participants, including premature cardiovascular events by 15% (Table 1).

### Compliance and withdrawals

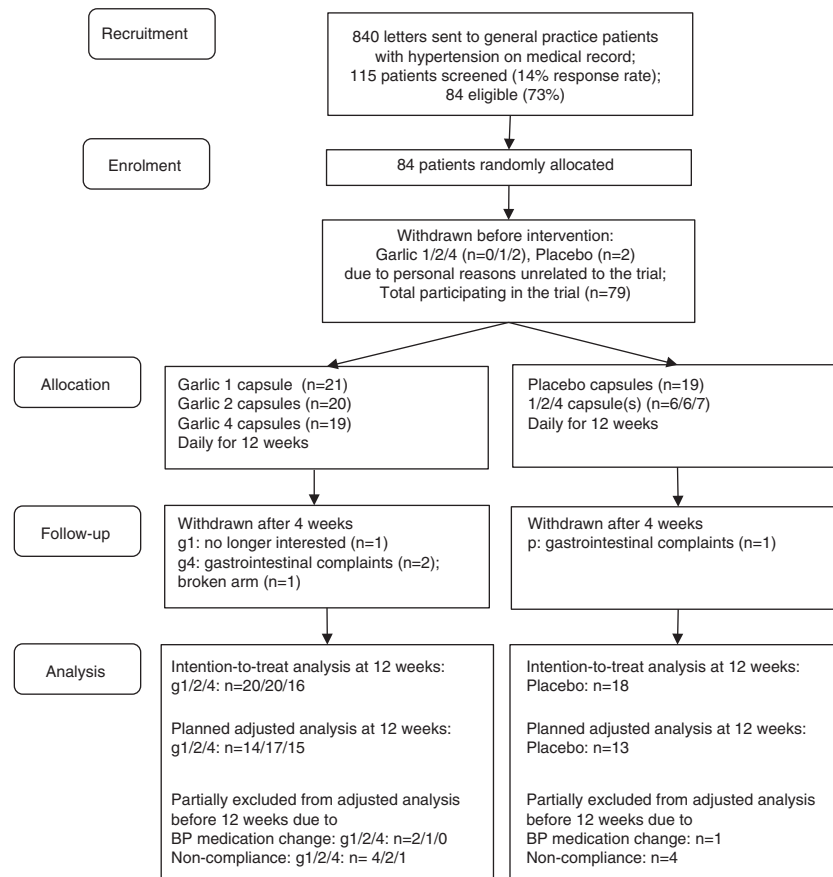
Despite doctors being aware of a patient's participation in this trial, BP medication regimen was changed for four participants during the trial (g1:  $n = 2$  and g2:  $n = 1$  before 4 weeks;  $P = 1$  before 12 weeks). As change in BP medication was expected to have influenced patient's BP and biased the effect of the trial supplement, the correlating data points were excluded from planned adjusted analysis.

Patient's compliance was assessed by calendar entries. We excluded data points from planned adjusted analysis if compliance was  $< 80\%$ , which was more pronounced around the Christmas/New Year's holiday period.

Five patients withdrew after 4 weeks, three due to gastrointestinal complaints (g4:  $n = 2$ ;  $P = 1$ ), one due to a broken arm (g4:  $n = 1$ ) and one was no longer interested in participating (g1:  $n = 1$ ).

### Blood pressure

Intention-to-treat analysis of 79 patients revealed a significant reduction in SBP from baseline in the garlic-2 group compared with placebo over 12 weeks (mean diff. SBP  $\pm$  s.e. (95% confidence



**Figure 1.** Trial flow chart. g1, garlic-1-capsule group; g2, garlic-2-capsule group; g4, garlic-4-capsule group; p, placebo group.

interval) =  $-9.7 \pm 4.8$  ( $-19.3; -0.1$ ) mm Hg;  $P=0.03$ ; Table 2). Intention-to-treat analysis of DBP did not reveal a significant effect of treatment between the groups.

In the planned adjusted analysis, we excluded patients whose prescription BP medication was changed by their doctor between baseline and visit 1 at 4 weeks measurements ( $n=4$ ) and those with poor compliance ( $n=2$ ), as these deviations from protocol would have influenced BP readings. Figure 2 illustrates the results of planned adjusted analysis of 74 patients, which revealed a significant difference in reduction of SBP between the garlic-2 group and placebo at 8 and 12 weeks, and over time compared with baseline (g2; 0–12 weeks: mean diff. SBP  $\pm$  s.e. (95% confidence interval) =  $-11.8 \pm 5.4$  ( $-22.6; -1.0$ ) mm Hg;  $P=0.006$ ; Table 2). SBP reduction in the garlic-4 group reached borderline significance at 8 weeks compared with placebo. Although SBP dropped significantly within the garlic-1 group at 12 weeks, the change did not reach statistical significance when compared with placebo.

Treatment did not have a noticeable effect in all patients. Change of SBP ranged from  $-40$  to  $+5$  mm Hg across all groups. SBP did not change by more than 5 mm Hg in a third of the participants (33.8%) over the course of the trial independent of group allocation (SBP change  $<5$  mm Hg: g1 = 43%; g2 = 25%; g4 = 26%, p = 32%). Covariate analysis by gender, age, BMI, smoking status and number of BP medication did not explain differences in patients' response to treatment. Analysis by type of BP medication was limited by the small sample sizes in subgroups and complicated by the number of drug combinations, and did not reveal any influence of BP medication type on the treatment effect.

Planned adjusted analysis of DBP revealed the largest reduction in DBP in the garlic-2 group (mean diff. DBP  $\pm$  s.e. (95% confidence

interval):  $-5.3 \pm 4.2$  ( $-13.7; 3.1$ ) mm Hg), albeit insignificantly different to placebo (Table 2 and Figure 2).

#### Tolerability, acceptability and blinding

Three participants (4%) withdrew because of gastrointestinal side effects after 4 weeks, two in the garlic-4 group and one in the placebo group ( $P>0.05$ ). Participants in the garlic groups reported minor complaints in the first week of the trial, including constipation, bloating, flatulence, reflux, garlic taste and difficulty swallowing the capsules (23%), and dry mouth and cough in the garlic-1 ( $n=2$ ) and placebo group ( $n=1$ ) (Table 3). A larger number of participants reported side effects in the garlic-4 group compared with the garlic-2 and garlic-1 groups, albeit not statistically significant. Participants found ways to overcome the reported minor complaints, for example, by taking the capsules in the morning rather than in the evening.

Most of the participants found taking the trial capsules easy (g<sub>all</sub>: 83%; p: 84%) and acceptable (g<sub>all</sub>: 93%; p: 90%; Table 3). There was a trend towards greater ease and acceptability with the allocation of fewer capsules daily (garlic-1 and -2 versus garlic-4), albeit this difference was not statistically significant. Most of the participants (g<sub>all</sub>: 80%; p: 74%) reported that they would be willing to continue taking the capsules after the trial was finished, if the treatment was effective in reducing their BP. About two-thirds of participants (g<sub>all</sub>: 65%; p: 58%) were willing to pay the estimated out-of-pocket costs of A\$0.3 per capsule. Participants were more willing to continue and carry the costs if fewer capsules would have to be taken daily (garlic-1 and -2 versus garlic-4,  $P<0.05$ ).

Blinding success was measured at the end of the trial by questionnaire. A third of the participants correctly guessed their allocation to either a garlic (33%) or placebo group (37%), whereas

**Table 1.** Baseline characteristics of participants

Characteristics	All participants <sup>a</sup> (n = 79)	Garlic 1 (n = 21)	Garlic 2 (n = 20)	Garlic 4 (n = 19)	Placebo (n = 19)
Gender (m/f)	42/37	12/9	12/8	9/10	9/10
	<i>Mean ± s.d. (range)</i>	<i>Mean ± s.d.</i>			
Age (years)	69.8 ± 11.9 (42–101)	70.1 ± 12.4	67.5 ± 11.8	70.4 ± 13.1	71.5 ± 10.9
BMI (kg/m <sup>2</sup> )	29.3 ± 4.9 (16.5–40.2)	29.7 ± 5.8	28.8 ± 5.3	28.8 ± 4.0	29.9 ± 4.5
Total cholesterol (mmol/l)	5.1 ± 1.2 (3.0–8.5)	5.0 ± 1.0	4.6 ± 0.9	5.4 ± 1.2	5.5 ± 1.3
LDL cholesterol (mmol/l)	2.9 ± 1.0 (0.9–6.0)	2.6 ± 0.7	2.6 ± 0.8	3.2 ± 1.3	3.3 ± 1.2
HDL cholesterol (mmol/l)	1.4 ± 0.3 (0.9–2.3)	1.4 ± 0.3	1.4 ± 0.3	1.4 ± 0.4	1.4 ± 0.4
Triglycerides (mmol/l)	1.7 ± 1.0 (0.5–6.1)	1.9 ± 1.1	1.7 ± 1.4	1.7 ± 0.7	1.6 ± 0.8
Mean number of BP drugs	1.7 ± 0.9 (0–4)	1.9 ± 1.1	1.6 ± 0.7	1.5 ± 0.9	1.8 ± 0.9
			N (%)		
Current smoker	9 (9)	1 (5)	5 (33)	1 (5)	1 (5)
Family history of CVD	38 (48)	14 (67)	13 (65)	11 (58)	10 (53)
Myocardial infarction	18 (23)	5 (24)	4 (20)	4 (21)	5 (26)
Stroke	13 (17)	5 (24)	3 (15)	3 (16)	2 (11)
Hypertension	10 (13)	4 (19)	2 (10)	1 (5)	3 (16)
CAD, pacemaker, bypass	7 (9)		4 (20)	3 (16)	
Premature CVD <sup>b</sup> (m < 55 years, f < 65 years)	12 (15); 25% of all CVD	4 (19)	4 (20)		4 (21)
Type of BP drug					
A2RB	36 (46)	8 (38)	9 (45)	8 (42)	11 (58)
D	31 (39)	10 (48)	6 (30)	4 (21)	11 (58)
CCB	30 (38)	8 (38)	9 (45)	9 (47)	4 (21)
ACEI	27 (34)	10 (48)	6 (30)	6 (32)	5 (26)
BB	12 (15)	4 (19)	1 (5)	3 (16)	4 (21)
Number of BP drug types					
0	3 (4)	1 (5)		2 (11)	8 (42)
1	32 (41)	7 (33)	11 (55)	7 (37)	8 (42)
2	31 (39)	8 (38)	7 (35)	7 (37)	2 (11)
3	10 (13)	3 (14)	2 (10)	3 (16)	1 (5)
4	3 (4)	2 (10)			

Abbreviations: A2RB, angiotensin II receptor blocker; ACEI, angiotensin converting enzyme inhibitor; BB, β-blockers; BMI, body mass index; CAD, coronary artery disease; BP, blood pressure; CCB, calcium channel blockers; CVD, cardiovascular disease; D, diuretics; f, female; HDL, high-density lipoprotein; LDL, low-density lipoprotein; m, male; s.d., standard deviation. <sup>a</sup>No significant differences in baseline values between garlic and placebo groups. <sup>b</sup>Includes myocardial infarction, stroke, coronary artery disease, but does not include hypertension only.

more than half of the participants were unsure of their allocation (58% garlic groups, 63% placebo), and 8% of participants in a garlic group incorrectly thought they had taken placebo capsules. A slightly greater proportion of participants in the garlic-4 group had guessed correctly, albeit differences between the groups were not statistically significant.

**DISCUSSION**

Our trial suggests aged garlic extract to be superior to placebo in lowering SBP in patients with uncontrolled hypertension. A dosage of two capsules daily containing 480 mg of aged garlic extract and 1.2 mg of S-allylcysteine significantly lowered SBP by mean SBP ± s.e. = - 11.8 ± 5.4 mm Hg (P = 0.006) compared with placebo over 12 weeks, was well tolerated and highly acceptable. The observed reduction in SBP is comparable to that achieved with commonly prescribed antihypertensive medicines, and is of clinical significance, whereby a reduction of about 10 mm Hg in SBP is associated with a risk reduction in cardiovascular disease by 16–40%.<sup>22,23</sup>

The larger daily dosage of four capsules of aged garlic extract also lowered SBP, albeit the mean difference of SBP ± s.e. = - 7.4 ± 4.1 mm Hg at 8 weeks compared with placebo was of borderline significance (P = 0.07). The smaller reduction in SBP in

the garlic-4 group compared with the garlic-2 group may have been linked to the poorer compliance and lesser tolerability seen in the garlic-4 group. A dosage of one capsule of aged garlic extract daily did not lower SBP significantly different to placebo.

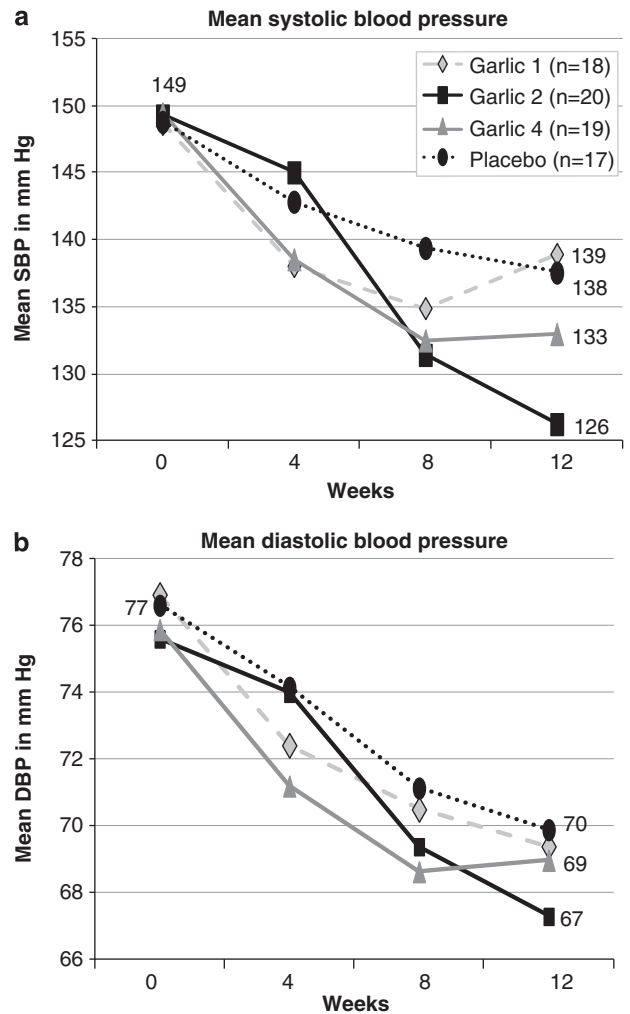
In all, 4% of participants (3 out of 79) withdrew from the trial after 4 weeks because of gastrointestinal complaints, two in the garlic-4 group and one in the placebo-4 group. Although rare, gastrointestinal disturbances have been reported in other trials using therapeutic dosages of garlic by similar proportions of participants.<sup>10,24,25</sup> Lower tolerance of sulphur-containing foods such as garlic and onion has been linked to genetic variation in detoxification pathways of sulphur-transferase enzymes, as well as inflammatory status, and levels of molybdenum and vitamin B12.<sup>26,27</sup>

Other minor side effects were reported by a third (32%) of the participants in the garlic-4 group, and 15% in the garlic-2 and garlic-1 groups compared with 5% in the placebo group. Minor side effects included bloating, flatulence and reflux. However, most side effects were reported in the first week of the trial, and participants found ways to overcome these, for example, by taking the trial capsules in the morning rather than in the evening. Greater tolerability, compliance, acceptance and willingness to continue and pay for capsules were associated with a lower dosage and fewer capsules daily.

**Table 2.** Dose-response effect of garlic on blood pressure

Analysis	Weeks		Garlic 1		Garlic 2		Garlic 4		Placebo		Mean difference (95%CI) between groups		
	n	Mean (s.e.)	n	Mean (s.e.)	n	Mean (s.e.)	n	Mean (s.e.)	n	Mean (s.e.)	Garlic 1 vs placebo	Garlic 2 vs placebo	Garlic 4 vs placebo
SBP ITT <sup>a</sup> (n = 79)	0	150.8 (2.8)	20	149.3 (2.9)	19	149.4 (3.0)	19	148.6 (3.0)	19	148.6 (3.0)	2.2 (-6.1;0.4)	0.7 (-7.7; 9.1)	0.8 (-7.6;9.2)
	4	137.8 (2.9)	20	145.8 (2.9)	18	138.3 (3.0)	19	141.0 (3.0)	19	141.0 (3.0)	-3.2 (-11.4;5)	4.8 (-3.6;13.2)	-2.7 (-11.1;5.7)
	8	137.3 (2.9)	20	131.4 (2.9)	16	133.8 (3.2)	18	139.1 (3.0)	18	139.1 (3.0)	-1.8 (-10.2;6.6)	-7.7 (-16.1;0.7)	-5.3 (-14.1;3.5)
	12	142.8 (3.0)	18	126.9 (3.0)	16	134.1 (3.2)	17	135.9 (3.1)	17	135.9 (3.1)	6.8 (-1.8;15.4)	-9.1 (-17.7; -0.5)*	-1.9 (-10.9;7.1)
	Change <sup>c</sup> 0-12	-8.1 (4.0)		-22.4 (4.0)		-15.4 (4.2)		-12.7 (4.2)		-12.7 (4.2)	4.6 (-7.1;6.2)	-9.7 (-19.3; -0.1)*	-2.7 (-14.7;9.3)
Planned adjusted <sup>b</sup> ITT <sup>a</sup> (n = 74)	0	148.7 (2.8)	20	149.3 (2.6)	19	149.4 (2.7)	17	148.8 (2.8)	17	148.8 (2.8)	-0.2 (-8.2;7.8)	0.5 (-7.3;8.3)	0.6 (-7.2;8.4)
	4	137.7 (2.8)	19	144.5 (2.7)	18	138.3 (2.7)	16	142.8 (2.9)	16	142.8 (2.9)	-5.1 (-13.1;2.9)	1.7 (-6.1;9.5)	-4.5 (-12.5;3.5)
	8	135.2 (2.8)	20	131.4 (2.6)	15	132.6 (2.9)	16	140.0 (2.9)	16	140.0 (2.9)	-4.8 (-16.4; -0.8)	-8.6 (-16.4; -0.8)*	-7.4 (-15.6;0.8)*
	12	138.8 (3.1)	17	126.8 (2.8)	15	132.4 (3.0)	14	138.1 (3.1)	14	138.1 (3.1)	0.7 (-19.8; -3)	-11.4 (-19.8; -3)**	-5.7 (-14.3;2.9)
	Change <sup>c</sup> 0-12	-9.8 (4.0)		-22.5 (3.7)		-17.1 (3.9)		-10.7 (4.0)		-10.7 (4.0)	0.9 (-22.6; -1)	-11.8 (-22.6; -1)**	-6.4 (-17.4;4.6)
DBP ITT <sup>a</sup> (n = 79)	0	77.1 (2.7)	20	75.6 (2.8)	19	75.9 (2.8)	19	76.0 (2.8)	19	76.0 (2.8)	1.1 (-6.7;8.9)	-0.4 (-8.7;2)	-0.1 (-7.7;7.5)
	4	72.1 (2.8)	16	67.1 (2.8)	16	70.1 (3.0)	17	70.2 (2.9)	17	70.2 (2.9)	2.0 (-6.1;0)	-3.0 (-11.5)	-0.1 (-8.3;8.1)
	8	72.1 (2.8)	16	67.1 (2.8)	16	70.1 (3.0)	17	70.2 (2.9)	17	70.2 (2.9)	2.0 (-6.1;0)	-3.0 (-11.5)	-0.1 (-8.3;8.1)
	12	72.1 (2.8)	16	67.1 (2.8)	16	70.1 (3.0)	17	70.2 (2.9)	17	70.2 (2.9)	2.0 (-6.1;0)	-3.0 (-11.5)	-0.1 (-8.3;8.1)
	Change <sup>c</sup> 0-12	-5.0 (4.0)		-8.5 (4.0)		-5.9 (4.0)		-5.8 (4.0)		-5.8 (4.0)	1.1 (-6.7;8.9)	-0.4 (-8.7;2)	-0.1 (-7.7;7.5)
Planned adjusted <sup>b</sup> ITT <sup>a</sup> (n = 74)	0	76.9 (2.9)	20	75.6 (2.8)	19	75.9 (2.8)	17	76.6 (3.0)	17	76.6 (3.0)	-1.9 (-10.5;6.7)	-5.3 (-13.7;3.1)	-2.4 (-10.8;6)
	4	70.0 (3.1)	17	66.6 (2.8)	15	69.5 (3.0)	14	71.9 (3.1)	14	71.9 (3.1)	1.1 (-6.7;8.9)	-0.4 (-8.7;2)	-0.1 (-7.7;7.5)
	8	70.0 (3.1)	17	66.6 (2.8)	15	69.5 (3.0)	14	71.9 (3.1)	14	71.9 (3.1)	1.1 (-6.7;8.9)	-0.4 (-8.7;2)	-0.1 (-7.7;7.5)
	12	70.0 (3.1)	17	66.6 (2.8)	15	69.5 (3.0)	14	71.9 (3.1)	14	71.9 (3.1)	1.1 (-6.7;8.9)	-0.4 (-8.7;2)	-0.1 (-7.7;7.5)
	Change <sup>c</sup> 0-12	-6.9 (1.9)		-9.0 (1.8)		-6.4 (1.9)		-4.7 (1.9)		-4.7 (1.9)	1.1 (-6.7;8.9)	-0.4 (-8.7;2)	-0.1 (-7.7;7.5)

Abbreviations: CI, confidence interval; NE, not estimated; s.e., standard error; all values in mmHg. \*P<0.05; \*\*P<0.01; <sup>a</sup>ITT, intention-to-treat analysis includes all data points available regardless of protocol deviations, including change of prescription blood pressure medication, or non-compliance. <sup>b</sup>Planned adjusted analysis excluded data points after prescription blood pressure medication was changed during the trial, or because of participant's non-compliance. <sup>c</sup>Mean difference (s.e.) in blood pressure within group over time (0-12 weeks); 95% CI = mean ± 2 s.e.



**Figure 2.** Effect of aged garlic extract on blood pressure. Mean SBP (a) and DBP (b) over 12 weeks of all participants in the planned adjusted analysis.

Our trial had limited power to detect any significant changes in DBP between the garlic groups and placebo, as participants were selected on the basis of systolic hypertension, subsequently including <13% of participants with essential hypertension (DBP >90 mmHg; 5-20% in each group). A trend towards greater reduction in DBP was observed in the garlic-2 groups compared with placebo (mean diff. DBP ± s.e.: -5.3 ± 4.2 mmHg), albeit not statistically significant. Our trial was also underpowered to undertake meaningful analysis by type of BP medication, complicated by the number and combination of antihypertensives possible.

The results of this trial are in line with our previous findings of aged garlic extract being effective in reducing SBP in hypertensives.<sup>10</sup> Here we demonstrate that a daily dosage of two capsules of the high potency formula of aged garlic extract is effective and more practical than a daily dosage of four capsules. Furthermore, our findings indicate that a dosage of one capsule of high potency formula was not sufficient to reduce effectively SBP, highlighting the importance of correct dosing and choice of product formulation.

Dosage of the active ingredient S-allylcysteine in aged garlic extract is crucial to effectiveness in reducing BP, and needs to be

**Table 3.** Tolerability and acceptability

	Total number	Group <sup>c</sup>			
		Garlic 1 n = 21	Garlic 2 n = 20	Garlic 4 n = 19	Placebo n = 19
<b>(A) Tolerability</b>					
Side effects		N (%)			
Gastrointestinal discomfort				2 (11)	1 (5)
Constipation <sup>a</sup>				1 (5)	
Bloating, flatulence <sup>a</sup>			1 (5)	1 (5)	
Reflux <sup>a</sup>		1 (5)		4 (21)	
Garlic taste <sup>a</sup>			2 (10)		
Dry mouth, cough <sup>a</sup>		2 (10)			1 (5)
Difficulty swallowing because of number and size of capsules				2 (11)	
Total side effects		3 (14)	3 (15)	8 (42)	2 (11)
<b>(B) Acceptability<sup>b</sup></b>					
Ease of taking capsules	+ +/+ - - / - ←	13/6 (91) 0 (0)	12/6 (90) 0 (0)	8/5 (68) 1/0 (5)	9/7 (84) 0/1 (5)
Acceptability	+ +/+ - - / - ←	12/8 (95) 0 (0)	11/9 (100) 0 (0)	6/1 (84) 1/0 (5)	6/11 (90) 0/1 (5)
Willingness to continue after trial	+ +/+ - - / - ←	11/8 (91) 0 (0)	5/11 (80) 1/0 (5)	5/8 (68) 2/0 (11)	7/7 (74) 0/1 (5)
Willingness to pay for supplement <sup>d</sup>	+ +/+ - - / - ←	9/4 (62) 0 (0)	1/13 (70) 1/1 (10)	3/9 (63) 3/0 (16)	6/5 (58) 1/1 (11)

<sup>a</sup>Participants reported minimal side effects in the first week of the trial, but did not find these side effects bothersome and found ways to overcome these.  
<sup>b</sup>Responses to questions of acceptability were assessed on a five-point Likert scales ranging from 1 = very easy/very acceptable/strongly agree (+ +) to 5 = very hard/very unacceptable/strongly disagree (- -). <sup>c</sup>Reported side effects and acceptability of treatment were not statistically significant between the garlic and placebo groups. <sup>d</sup>The willingness to pay for supplements was stronger in the garlic-1-capsule group compared with garlic-2 and -4 capsule groups ( $P < 0.05$ ).

reviewed when comparing results to other trials testing garlic products.<sup>8,9</sup>

Our trial tested the effect of aged garlic extract as an adjunctive antihypertensive treatment in a mainly older population (mean age 70 ± 12 years). It would be interesting to explore the effectiveness in other age groups with uncontrolled, treated or untreated hypertension.

In about 30% of participants, SBP did not waver for more than 5 mm Hg during the course of the trial, suggesting an underlying unresponsiveness to antihypertensive treatment. Future trials could explore potential underlying factors, such as genetic variations in the aldosterone synthase gene/enzyme pathway, which has been suggested to influence the response to antihypertensive treatment.<sup>28,29</sup>

Larger trials are required to explore any effect of other antihypertensive medicines that patients are already taking on the effectiveness of adjunct therapy with aged garlic extract. It would also be interesting to explore the effect of aged garlic extract on other cardiovascular risk factors and the influence of standard drug therapy on its effectiveness. Moreover, long-term trials would provide insights into the effect of aged garlic extract on cardiovascular morbidity and mortality.

In summary, our trial suggests aged garlic extract to be an effective and tolerable treatment in uncontrolled hypertension, and may be considered as a safe adjunct treatment to conventional antihypertensive therapy.

**CONFLICT OF INTEREST**

The authors declare no conflict of interest.

**ACKNOWLEDGEMENTS**

We thank all patients, general practices, doctors and staff for their participation in the trial. We are grateful to our research nurse, Karen Bellchambers, who was instrumental in liaising with practices and patients and collecting data. We thankfully acknowledge statistical advice by Dr Nancy Briggs and Thomas Sullivan. This trial was supported by a Royal Adelaide Hospital New Investigator Clinical Project Grant (11RAHRC-7360). KR was supported by the Australian Government-funded Primary Health Care Research Evaluation and Development (PHCRED) Programme. Trial capsules were provided by Vitaco Health Ltd, Sydney, Australia, which was not involved in study design, data collection, analysis or preparation of the manuscript.

**AUTHOR CONTRIBUTIONS**

All authors conceptualised the study and oversaw data collection. KR undertook data analysis and interpretation in discussion with biostatisticians. KR prepared the manuscript with contributions from co-authors. All authors approved the final version.

**REFERENCES**

- 1 Kearney PM, Whelton M, Reynolds K, Muntner P, Whelton PK, He J. Global burden of hypertension: analysis of worldwide data. *Lancet* 2005; **365**: 217–223.
- 2 Martiniuk AL, Lee CM, Lawes CM, Ueshima H, Suh I, Lam TH *et al*. Hypertension: its prevalence and population-attributable fraction for mortality from cardiovascular disease in the Asia-Pacific region. *J Hypertens* 2007; **25**: 73–79.
- 3 Briganti EM, Shaw JE, Chadban SJ, Zimmet PZ, Welborn TA, McNeil JJ *et al*. Untreated hypertension among Australian adults: the 1999–2000 Australian Diabetes, Obesity and Lifestyle Study. *Med J Aust* 2003; **179**: 135–139.
- 4 Olsen H, Klemetsrud T, Stokke HP, Tretli S, Westheim A. Adverse drug reactions in current antihypertensive therapy: a general practice survey of 2586 patients in Norway. *Blood Press* 1999; **8**: 94–101.



- 5 Vermeire E, Hearnshaw H, Van Royen P, Denekens J. Patient adherence to treatment: three decades of research. A comprehensive review. *J Clin Pharm Ther* 2001; **26**: 331–342.
- 6 Wood MJ, Stewart RL, Merry H, Johnstone DE, Cox JL. Use of complementary and alternative medical therapies in patients with cardiovascular disease. *Ann Heart J* 2003; **145**: 806–812.
- 7 Yeh GY, Davis RB, Phillips RS. Use of complementary therapies in patients with cardiovascular disease. *Am J Cardiol* 2006; **98**: 673–680.
- 8 Ried K, Frank OR, Stocks NP, Fakler P, Sullivan T. Effect of garlic on blood pressure: a systematic review and meta-analysis. *BMC Cardiovasc Disord* 2008; **8**: 13.
- 9 Reinhart KM, Coleman CJ, Teevan C, Vachhani P, White GM. Effects of garlic on blood pressure in patients with and without systolic hypertension: a meta-analysis. *Ann Pharmacother* 2008; **42**: 1766–1771.
- 10 Ried K, Frank OR, Stocks NP. Aged garlic extract lowers blood pressure in patients with treated but uncontrolled hypertension: a randomised controlled trial. *Maturitas* 2010; **67**: 144–150.
- 11 Lawson LD, Gardner CD. Composition, stability, and bioavailability of garlic products used in a clinical trial. *J Agric Food Chem* 2005; **53**: 6254–6261.
- 12 Hoshino T, Kashimoto N, Kasuga S. Effects of garlic preparations on the gastrointestinal mucosa. *J Nutr* 2001; **131**: 1109S–11135S.
- 13 Haranuma A, Moriguchi T. Aged garlic extract improves blood pressure in spontaneously hypertensive rats more safely than raw garlic. *J Nutr* 2006; **136**: 769S–7735S.
- 14 Macan H, Uyikimpang R, Alconcel M, Takasu J, Razon R, Amagase H et al. Aged garlic extract may be safe for patients on warfarin therapy. *J Nutr* 2006; **136**: 793S–7955S.
- 15 Al-Gattan KK, Thomson M, Al-Mutawa S, Al-Hajeri D, Droblova H, Ali M. Nitric oxide mediates the blood-pressure lowering effect of garlic in the rat two-kidney, one-clip model of hypertension. *J Nutr* 2006; **136**: 774S–7765S.
- 16 Benavides GA, Squadrito GL, Mills RW, Patel HD, Isbell TS, Patel RP et al. Hydrogen sulfide mediates the vasoactivity of garlic. *Proc Natl Acad Sci USA* 2007; **104**: 17977–17982.
- 17 Castro C, Lorenzo AG, Gonzalez A, Cruzado M. Garlic components inhibit angiotensin II-induced cell-cycle progression and migration: involvement of cell-cycle inhibitor p27(Kip1) and mitogen-activated protein kinase. *Mol Nutr Food Res* 2010; **54**: 781–787.
- 18 Suetsuna K. Isolation and characterization of angiotensin I-converting enzyme inhibitor dipeptidases derived from *Allium sativum* L. (garlic). *J Nutr Biochem* 1998; **9**: 415–419.
- 19 PEN Computer Systems Pty Ltd, Paramatta, NSW, Australia. Available at <http://www.clinicalaudit.com.au/>.
- 20 Kyolic Garlic High Potency Everyday Formula 112. Wagner, Vitaco Health (NZ) Ltd, Sydney, Australia. Available at [http://www.wagnereproducts.com.au/products-and-supplements/product-list/product-details/\\_prod\\_/kyolic-high-potency-everyday-formula](http://www.wagnereproducts.com.au/products-and-supplements/product-list/product-details/_prod_/kyolic-high-potency-everyday-formula).
- 21 Ried K, Frank OR, Stocks NP. Dark chocolate or tomato extract for prehypertension: a randomised controlled trial. *BMC Complement Altern Med* 2009; **9**: 22.
- 22 Lewington S, Clarke R, Qizilbash N, Peto R, Collins R. Age-specific relevance of usual blood pressure to vascular mortality: a meta-analysis of individual data for one million adults in 61 prospective studies. *Lancet* 2002; **360**: 1903–1913.
- 23 McInnes GT. Lowering blood pressure for cardiovascular risk reduction. *J Hypertens Suppl* 2005; **23**: S3–S8.
- 24 Beck E, Gruenewald J. *Allium sativum* in der Stufentherapie der Hypertlipidaemie. *Med Welt* 1993; **44**: 516–520.
- 25 Borrelli F, Capasso R, Izzo AA. Garlic (*Allium sativum* L.): adverse effects and drug interactions in humans. *Mol Nutr Food Res* 2007; **51**: 1386–1397.
- 26 Warning RH, Klovra LZ, Harris RM. Diet and individuality in detoxification. *J Nutr Environ Med* 2007; **16**: 95–105.
- 27 Meletis CD. Cleansing of the human body. A daily essential process. *Altern Complement Therap* 2001; **7**: 196–202.
- 28 Tavenne K, de Groot M, de Boer A, Klungel O. Genetic polymorphisms related to the renin-angiotensin-aldosterone system and response to antihypertensive drugs. *Expert Opin Drug Metab Toxicol* 2010; **6**: 439–460.
- 29 Casiglia E, Tikhonoff V, Mazza A, Rynkiewicz A, Limon J, Caffi S et al. C-344T polymorphism of the aldosterone synthase gene and blood pressure in the elderly: a population-based study. *J Hypertens* 2005; **23**: 1991–1996.



This work is licensed under the Creative Commons Attribution-NonCommercial-No Derivative Works 3.0 Unported License. To view a copy of this license, visit <http://creativecommons.org/licenses/by-nc-nd/3.0/>

## Exhibit RX 2

**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.<sup>1</sup> 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.

---

<sup>1</sup> 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.<sup>2</sup> This process causes

---

<sup>2</sup> 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,<sup>3</sup> or other garlic preparations. PX 3, Sacks Report, p. 6-8.<sup>4</sup>

Contempt defendants advertised their BG18 and Black Garlic Botanical products using multi-page mailers sent to consumers<sup>5</sup> throughout the United States. The mailers contained a variety of claims about the dangers of cardiovascular disease<sup>6</sup> 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 Mailer<sup>7</sup>

---

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

<sup>3</sup> 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.

<sup>4</sup> 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).

<sup>5</sup> *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.

<sup>6</sup> For example, the Black Garlic Botanicals mailer’s front page features a large photograph of a distressed, older man clasp 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).

<sup>7</sup> 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).<sup>8</sup>
- “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 Mailer<sup>9</sup>

- 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).

---

<sup>8</sup> 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.

<sup>9</sup> 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.<sup>10</sup>

#### **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

---

<sup>10</sup> 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”<sup>11</sup> 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”)

---

<sup>11</sup> PX 2, Lewis Decl., Att. I (HRL005069).

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

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).

---

<sup>12</sup> 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.

<sup>13</sup> *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.<sup>14</sup> 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

---

<sup>14</sup> 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.<sup>15</sup> 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

---

<sup>15</sup> 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.<sup>16</sup> 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.

---

<sup>16</sup> 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,<sup>17</sup> 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.

---

<sup>17</sup> *See* PX 2, Lewis Decl., Att. L, M.

Respectfully submitted,

Dated: Dec. 17, 2019

/s/ Elizabeth J. Averill  
ELIZABETH J. AVERILL  
KRISTY M. TILLMAN  
Federal Trade Commission  
Division of Enforcement  
600 Pennsylvania Ave., NW, Mailstop CC-9528  
Washington, DC 20580  
(202) 326-2993, eaverill@ftc.gov  
(202) 326-3025, ktillman@ftc.gov  
(202) 326-3197 (Fax)

Attorneys for Plaintiff  
Federal Trade Commission

AARON M. FREY  
Attorney General, State of Maine

/s/ Brendan F.X. O'Neil  
BRENDAN F.X. O'NEIL  
LINDA CONTI  
Assistant Attorneys General  
6 State House Station  
Augusta, ME 04333  
(207) 626-8842, Brendan.oneil@maine.gov  
(207) 626-8591, Linda.conti@maine.gov  
(207) 624-7730 (Fax)

Attorneys for Plaintiff  
State of Maine



**CERTIFICATE OF SERVICE**

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

Joshua M. Russ, Esq.  
Joel Reese, Esq.  
Reese Marketos LLP  
750 N. Saint Paul St., Suite 600  
Dallas, Texas 75201

*Attorneys for Health Research Laboratories, LLC, Whole Body Supplements, LLC, and Kramer Duhon*

Dated: Dec. 17, 2019

/s/ Elizabeth J. Averill  
ELIZABETH J. AVERILL  
Federal Trade Commission  
Division of Enforcement  
600 Pennsylvania Ave., NW, Mailstop CC-9528  
Washington, DC 20580  
(202) 326-2993, [eaverill@ftc.gov](mailto:eaverill@ftc.gov)  
(202) 326-3197 (Fax)

Attorney for Federal Trade Commission

**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' CONSOLIDATED EXHIBITS IN SUPPORT OF MOTION FOR  
ORDER TO SHOW CAUSE AND MOTION TO MODIFY**

**Plaintiffs’ Consolidated Exhibits in Support of Motion for Order to Show Cause  
 and Motion to Modify**

<b>Exhibit No.</b>	<b>Description</b>
<b>PX 1</b>	Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief entered in <i>FTC and Maine v. Health Research Laboratories, LLC, et al.</i> , No. 2:17-cv-00467-JDL (Jan. 16, 2018) (Dkt. 15)
<b>PX 2</b>	<p><b>Lewis Declaration</b></p> <p><b>Att. A</b> - Acknowledgments of Receipt of Order for Kramer Duhon and Health Research Laboratories</p> <p><b>Att. B</b> - Submission from Health Research Laboratories and Kramer Duhon to FTC dated 3/29/2018</p> <p><b>Att. C</b> - Submission from Health Research Laboratories and Kramer Duhon to FTC dated 5/4/2018</p> <p><b>Att. D</b> - Letter from M. Lederer to A. Lustigman dated 5/21/2018</p> <p><b>Att. E</b> - Email exchange between M. Lederer and A. Lustigman</p> <p><b>Att. F</b> - Supplemental Statement of Compliance from Health Research Laboratories and Kramer Duhon dated 6/6/2018</p> <p><b>Att. G</b> - Product labels marked HRL004909-4919 submitted to FTC on 6/6/2018</p> <p><b>Att. H</b> - Black Garlic Botanicals Mailer submitted to FTC on 6/6/2018, HRL004984-4999</p> <p><b>Att. I</b> - The Ultimate Heart Formula Mailer submitted to FTC on 6/6/2018, HRL005068-5083</p> <p><b>Att. J</b> - Neupathic Mailer submitted to FTC on 6/6/2018, HRL005036-5051</p> <p><b>Att. K</b> - Letter from A. Lustigman to R. Frisby dated 4/10/2019</p> <p><b>Att. L</b> - Submission from Health Research Laboratories and Kramer Duhon to FTC on 8/8/2019, HRL008148</p> <p><b>Att. M</b> - Submission from Health Research Laboratories and Kramer Duhon to FTC on 9/27/2019, HRL008163</p> <p><b>Att. N</b> - Certified copies of filings for Whole Body Supplements, LLC with the State of Nevada, Office of the Secretary of State</p>

<b>Exhibit No.</b>	<b>Description</b>
<b>PX 3</b>	<b>Expert Report of Frank Sacks, M.D.</b>
<b>PX 4</b>	<b>Expert Report of Charles Burant, M.D., Ph.D.</b>
<b>PX 5</b>	<b>Declaration of Adam Rottner</b> Att. A – Neupathic website capture Att. B – Black Garlic Botanicals website capture Att. C – Ultimate Heart Formula website capture Att. D – BG18 website capture
<b>PX 6</b>	<b>Declaration of James Prunty</b> Att. 1 – BG18 Mailer
<b>PX 7</b>	Unpublished orders cited in Plaintiffs’ Motion to Modify
<b>PX 8</b>	<b>Averill Declaration</b> Att. A – July 3, 2019 Email from Andrew Lustigman, Esq. Att. B – Attachment to July 3, 2019 Email from Andrew Lustigman, Esq.

**PX 1**

IN THE UNITED STATES DISTRICT COURT  
 FOR THE DISTRICT OF MAINE

FEDERAL TRADE COMMISSION and STATE OF MAINE,	)	
	)	
Plaintiffs,	)	Case No. 2:17-cv-00467-JDL
	)	
v.	)	<b>STIPULATED FINAL JUDGMENT</b>
	)	<b>AND ORDER FOR PERMANENT</b>
HEALTH RESEARCH LABORATORIES, LLC, a limited liability company, and	)	<b>INJUNCTION AND OTHER</b>
	)	<b>EQUITABLE RELIEF</b>
	)	
KRAMER DUHON, individually and as an owner and officer of HEALTH RESEARCH LABORATORIES, LLC,	)	
	)	
Defendants.	)	
	)	

Plaintiffs, the Federal Trade Commission (“FTC” or “Commission”) and the State of Maine, as represented in this matter by the Office of the Attorney General of Maine (“Maine AG”) (collectively, “Plaintiffs”), filed a Complaint for Permanent Injunction and Other Equitable Relief against Defendants pursuant to Section 13(b) of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. § 53(b), pursuant to Section 4(a) of the Telemarketing and Consumer Fraud and Abuse Prevention Act (“Telemarketing Act”), 15 U.S.C. § 6103(a), and pursuant to Section 209 of the Maine Unfair Trade Practices Act (“Maine UTPA”), 5 M.R.S.A. § 209, to obtain permanent injunctive relief, rescission or reformation of contracts, restitution, the refund of monies paid, disgorgement of ill-gotten monies, and other equitable relief for Defendants’ acts or practices in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, the Telemarketing Act, 15 U.S.C. §§ 6101-6108, the FTC’s Trade Regulation Rule entitled “Telemarketing Sales Rule” (“TSR”), 16 C.F.R. Part 310, the Electronic Fund Transfer Act

(“EFTA”), 15 U.S.C. §§ 1693-1693r, and its implementing Regulation E, 12 C.F.R. § 1005.10, and Section 207 of the Maine UTPA, 5 M.R.S.A. § 207, in connection with the labeling, advertising, marketing, distribution, and sale of products purported to cause weight loss, treat arthritis and relieve joint and back pain, and prevent or mitigate cognitive decline.

The Commission, the State of Maine, and Defendants Health Research Laboratories, LLC and Kramer Duhon (hereafter collectively, “Defendants”), stipulate to the entry of this Final Judgment and Order for Permanent Injunction and Other Equitable Relief to resolve all matters in dispute in this action between them, including the allegations in the Complaint.

### **FINDINGS**

1. This Court has jurisdiction over this matter.
2. The Complaint charges that Defendants participated in deceptive acts or practices in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, the Telemarketing Act, 15 U.S.C. §§ 6101-6108, the TSR, 16 C.F.R. Part 310, the EFTA, 15 U.S.C. §§ 1693-1693r, and its implementing Regulation E, 12 C.F.R. § 1005.10, and Section 207 of the Maine UTPA, 5 M.R.S.A. § 207, in connection with the labeling, advertising, marketing, distribution, and sale of products purported to cause weight loss, treat arthritis and relieve joint and back pain, and prevent or mitigate cognitive decline.
3. Defendants neither admit nor deny any of the allegations in the Complaint, except as specifically stated in this Order. Defendants admit the facts necessary to establish jurisdiction only for purposes of this action.
4. Defendants waive any claim that they may have under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action through the date of this Order. The parties agree to bear their own costs and attorney fees.

5. Defendants and Plaintiffs waive all rights to appeal or otherwise challenge or contest the validity of this Order.

## DEFINITIONS

For the purpose of this Order, the following definitions apply:

1. **“Charge” or “Charged”** means any attempt to collect money or other consideration from a consumer, including but not limited to causing billing information to be submitted for payment, including against the consumer’s credit card, debit card, bank account, telephone bill, or other account.

2. **“Clear(ly) and Conspicuous(ly)”** means that a required disclosure is difficult to miss (*i.e.*, easily noticeable) and easily understandable by ordinary consumers, including in all of the following ways:

A. In any communication that is solely visual or solely audible, the disclosure must be made through the same means through which the communication is presented. In any communication made through both visual and audible means, such as a television advertisement, the disclosure must be presented simultaneously in both the visual and audible portions of the communication even if the representation requiring the disclosure is made in only one means;

B. A visual disclosure, by its size, contrast, location, the length of time it appears, and other characteristics, must stand out from any accompanying text or other visual elements so that it is easily noticed, read, and understood;

C. An audible disclosure, including by telephone or streaming video, must be delivered in a volume, speed, and cadence sufficient for ordinary consumers to easily hear and understand it;



D. In any communication using an interactive electronic medium, such as the Internet or software, the disclosure must be unavoidable;

E. The disclosure must use diction and syntax understandable to ordinary consumers and must appear in each language in which the representation that requires the disclosure appears;

F. The disclosure must comply with these requirements in each medium through which it is received, including all electronic devices and face-to-face communications;

G. The disclosure must not be contradicted or mitigated by, or inconsistent with, anything else in the communication; and

H. When the representation or sales practice targets a specific audience, such as children, the elderly, or the terminally ill, “ordinary consumers” includes reasonable members of that group.

3. “**Close Proximity**” means that the disclosure is very near the triggering representation. For example, a disclosure made through a hyperlink, pop-up, interstitial, or other similar technique is not in close proximity to the triggering representation.

4. “**Corporate Defendant**” means Health Research Laboratories, LLC, and its successors and assigns.

5. “**Covered Product**” means any Dietary Supplement, Food, or Drug, including BioTherapex and NeuroPlus.

6. “**Defendants**” means the Individual Defendant and the Corporate Defendant, individually, collectively, or in any combination.

7. “**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 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.

8. **“Drug”** means: (1) 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; (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (3) articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and (4) articles intended for use as a component of any article specified in (1), (2), or (3); but does not include devices or their components, parts, or accessories.

9. **“Essentially Equivalent Product”** means a product that contains the identical ingredients, except for inactive ingredients (*e.g.*, 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 is unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product.

10. **“Food”** means: (1) any article used for food or drink for humans or other animals; (2) chewing gum; and (3) any article used for components of any such article.

11. **“Including”** means including but not limited to.

12. “**Individual Defendant**” means Kramer Duhon.

13. “**Negative Option Feature**” means, in an offer or agreement to sell or provide any good, program, or service, a provision under which the consumer’s silence or failure to take an affirmative action to reject a good, program, or service, or to cancel the agreement, is interpreted by the seller or provider as acceptance or continuing acceptance of the offer.

14. “**Person**” means a natural person, an organization, or other legal entity, including a corporation, partnership, sole proprietorship, limited liability company, association, cooperative, or any other group or combination acting as an entity.

15. “**Preauthorized Electronic Fund Transfer**” as defined by the Electronic Fund Transfer Act, 15 U.S.C. § 1693a(10), means an electronic fund transfer authorized in advance to recur at substantially regular intervals.

## I.

### BANNED WEIGHT-LOSS CLAIMS

**IT IS HEREBY ORDERED** that Defendants, Defendants’ 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 the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Dietary Supplement, over-the-counter Drug, patch, cream, wrap, or other product worn on the body or rubbed into the skin, are permanently restrained and enjoined from representing, or assisting others in representing, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, illustration, trademark, or trade name, that such product:

- A. Causes weight loss of two pounds or more a week for a month or more without dieting or exercise;

- B. Causes substantial weight loss no matter what or how much the consumer eats;
- C. Causes permanent weight loss;
- D. Blocks the absorption of fat or calories to enable consumers to lose substantial weight;
- E. Safely enables consumers to lose more than three pounds per week for more than four weeks;
- F. Causes substantial weight loss for all users; or
- G. Causes substantial weight loss by wearing a product on the body or rubbing it into the skin.

## II.

### **PROHIBITED REPRESENTATIONS: OTHER WEIGHT-LOSS CLAIMS, JOINT-RELATED DISEASE CLAIMS, AND ALZHEIMER'S DISEASE, MEMORY, AND COGNITIVE PERFORMANCE CLAIMS**

**IT IS FURTHER ORDERED** that Defendants, Defendants' 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 the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, are permanently restrained and enjoined from making, or assisting others in making, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, any representation, other than representations covered under the Section of this Order entitled Banned Weight-Loss Claims, that, in humans, such product:

- A. Causes or assists in causing weight loss, including any specific amount of weight loss;
- B. Causes or assists in causing fat loss, including any specific amount of fat loss;

- C. Treats or cures rheumatism, arthritis, or osteoarthritis;
- D. Relieves joint pain, back pain, or muscle pain;
- E. Protects the brain against Alzheimer's disease or dementia;
- F. Reverses memory loss;
- G. Improves memory, concentration, or cognitive performance; or
- H. 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. For purposes of this Section, competent and reliable scientific evidence shall consist of human clinical testing of the Covered Product, or of an Essentially Equivalent Product, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, 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. Such testing must be: (1) randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing. In addition, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as described in the Section entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to Plaintiffs. Persons covered by this Section have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

### III.

#### **PROHIBITED REPRESENTATIONS: OTHER HEALTH-RELATED CLAIMS**

**IT IS FURTHER ORDERED** that Defendants, Defendants' 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, are permanently restrained and enjoined from making, or assisting others in making, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, any representation about the health benefits, safety, performance, or efficacy of any Covered Product, other than representations covered under the Sections of this Order entitled Banned Weight-Loss Claims and Prohibited Representations: Other Weight-Loss Claims, Joint-Related Disease Claims, and Alzheimer's Disease, Memory, and Cognitive Performance Claims, 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 disease, 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 Section, competent and reliable scientific evidence means tests, analyses, research, or studies (1) that have been conducted and evaluated in an objective manner by experts in the relevant disease, 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 the Section entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to Plaintiffs. Persons covered by this Section have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

#### **IV.**

#### **PROHIBITED REPRESENTATIONS REGARDING TESTS, STUDIES, OR OTHER RESEARCH**

**IT IS FURTHER ORDERED** that Defendants, Defendants' 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 the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product are permanently restrained and enjoined from misrepresenting, in any manner, expressly or by implication, including through the use of any product name, endorsement, depiction, or illustration:

- A. That any Covered Product is scientifically proven to protect the brain against Alzheimer's disease or dementia, reverse memory loss, or improve memory, concentration, or cognitive performance;
- B. That the performance or benefits of any Covered Product are scientifically or clinically proven or otherwise established; or

- C. The existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research.

V.

**FDA-APPROVED CLAIMS**

**IT IS FURTHER ORDERED** that nothing in this Order prohibits Defendants, Defendants' officers, agents, employees, or all other persons in active concert or participation with any of them from:

A. For any drug, making a representation that is approved in labeling for such drug under any tentative final or final monograph promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and

B. For any product, making a representation that is specifically authorized for use in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990 or permitted under Sections 303-304 of the Food and Drug Administration Modernization Act of 1997.

VI.

**PRESERVATION OF RECORDS RELATING TO COMPETENT AND RELIABLE HUMAN CLINICAL TESTS OR STUDIES**

**IT IS FURTHER ORDERED** that, with regard to any human clinical test or study ("test") upon which Defendants rely to substantiate any claim covered by this Order, Defendants shall 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 Defendant; (2) any Defendant's officers, agents, representatives, or employees; (3) any other person or entity in active concert or participation with any Defendant; (4) any person or entity affiliated with or acting on behalf of any Defendant; (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 Section, "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 Defendants, Defendants 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 Defendant's size and complexity, the nature and scope of Defendants' activities, and the sensitivity of the personal information collected from or about the participants.

## VII.

### **PROHIBITED REPRESENTATIONS RELATED TO ENDORSEMENTS**

**IT IS FURTHER ORDERED** that Defendants, Defendants' 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 the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, are permanently restrained and enjoined from misrepresenting, in any manner, expressly or by implication, including through the use of any good or service name, endorsement, depiction, or illustration, that:

- A. Any person is an expert with respect to the endorsement message provided by that person;
- B. Purported consumers who appear in advertising obtained a reported result through use of those goods or services; and
- C. Experts are providing their objective, independent opinions regarding the efficacy of any good or service.

## VIII.

### OTHER PROHIBITED MISREPRESENTATIONS

**IT IS FURTHER ORDERED** that Defendants, Defendants' 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 the advertising, marketing, promotion, offering for sale, sale, or distribution of any good or service, are permanently restrained and enjoined from misrepresenting, or assisting others in misrepresenting, expressly or by implication:

- A. That consumers are receiving a money-back guarantee, a free trial offer, a risk-free trial offer, a free gift, or a bonus;
- B. The total cost to purchase, receive, or use the good or service, including shipping, handling, processing, and any additional financial obligations that may be incurred as a result of accepting the free product, service, or offer;
- C. The timing or manner of any Charge or bill;
- D. Any material restrictions, limitations, or conditions to purchase, receive, or use the good or service;
- E. Any material aspect of the performance, efficacy, nature, or central characteristics of the good or service;
- F. To the extent applicable, that customs duties or taxes may be assessed by the relevant taxing authority; and
- G. Any material aspect of the nature or terms of a refund, return, cancellation, exchange, or repurchase policy for the good or service, including the deadline (by date or frequency) by which the consumer must act.

## IX.

### REQUIRED DISCLOSURES

**IT IS FURTHER ORDERED** that, in connection with the advertising, marketing, promotion, offering for sale, sale, or distribution of any good or service, Defendants and their 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, are permanently restrained and enjoined from:

A. Failing to Clearly and Conspicuously disclose, or assisting others in failing to Clearly and Conspicuously disclose, before consumers are asked to reveal billing information such as account number or to consent to any purchase in connection with any claim that a good or service is offered on a “free,” “risk-free,” “trial,” “no obligation,” “reduced,” discounted basis, or words of similar import, the following material terms and conditions of any offer:

1. In Close Proximity to such claim, the total cost to purchase, or receive, or use any good or service that is the subject of the sales offer, including shipping, handling, and processing;
2. The amount, timing, and manner of payment of all fees, Charges, or other amounts that a consumer will be Charged or billed, and any additional financial obligations that may be incurred as a result of accepting the free product, service, or offer; and
3. The terms and conditions of any refund, cancellation, exchange, or purchase policy or policies, including the specific steps and means by which such requests must be submitted, and the telephone number, email address, web address, or street address to which such requests must be

directed, including the deadline (by date or frequency) by which the consumer must act, and, if there is a policy of not making refunds, cancellations, exchanges, or repurchases, a statement regarding this policy; and

B. Obtaining, or assisting others in obtaining, billing information such as account number from a consumer for any transaction involving a good or service that includes a Negative Option Feature, without first disclosing Clearly and Conspicuously, and in Close Proximity to where a consumer provides billing information:

1. The extent to which the consumer must take affirmative action(s) to avoid any Charges: a) for the offered good or service, b) of an increased amount after any trial or promotional period ends, and c) on a recurring basis;
2. The total cost (or range of costs) the consumer will be Charged (including shipping, handling, and processing), the date the initial Charge will be submitted for payment, and, if applicable, the frequency of such Charges unless the consumer timely takes affirmative steps to prevent or stop such Charges;
3. The deadline(s) (by date or frequency) by which the consumer must affirmatively act in order to stop all recurring Charges, whether such recurring charges are refundable and, if so, the terms and conditions of any refund policy;
4. The name of the seller or provider of the good or service and, if the name of the seller or provider will not appear on billing statements, the billing descriptor that will appear on such statements;

5. A description of the good or service;
6. Any Charge or cost for which the consumer is responsible in connection with the cancellation of an order or the return of a good; and
7. The mechanism to stop any recurring Charges.

In addition, for any transaction involving a sale of a good or service to a consumer through a Negative Option Feature, within 10 days after the date of the sale, Defendants must send the consumer written confirmation of the transaction, either by email or first class mail, according to the consumer's preference, which is identified as a written confirmation in the email subject line or on the outside of the envelope. Such written confirmation must include Clear and Conspicuous disclosure of all the information required by this Subsection IX.B(1)-(7) above, and must specify the procedures by which consumers can cancel or obtain a refund if a refund is offered.

## X.

### EXPRESS INFORMED CONSENT

**IT IS FURTHER ORDERED** that Defendants, Defendants' 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 the advertising, marketing, promotion, offering for sale, sale, or distribution of any good or service, are permanently restrained and enjoined from using billing information to obtain payment from a consumer, unless, prior to using such billing information to obtain payment, they obtain the express informed consent of the consumer.

A. For all written offers with a Negative Option Feature (including over the Internet or other web-based applications or services), a consumer's express informed consent must be

obtained, prior to Defendants' obtaining any billing information from consumers, through a check box, signature, or other substantially similar method, that consumers must affirmatively select or sign to accept the Negative Option Feature. Immediately adjacent to such check box, signature, or substantially similar method, Defendants must disclose all costs associated with the Negative Option Feature, including shipping, handling, and processing, that the consumer is agreeing to pay such costs, the length of any trial period, and the date by which consumers must cancel to avoid being Charged. This disclosure must contain no additional information and must be Clear and Conspicuous in relation to any other information provided on the page relating to costs, risks, or obligations associated with any Negative Option Feature, including any terms referring to "free," "trial," and "processing fee."

B. For all oral offers including a Negative Option Feature, Defendants must, in addition to disclosing the information identified in the Section entitled Required Disclosures, and prior to obtaining any billing information such as account number from a consumer, obtain affirmative and unambiguous oral confirmation that the consumer:

1. Consents to authorizing payment for any goods or services, including shipping, handling, and processing;
2. Understands that the transaction includes a Negative Option Feature; and
3. Understands the specific affirmative steps the consumer must take to prevent further Charges.

Defendants must maintain for 3 years from the date of each transaction an unedited voice recording of the entire transaction, including the prescribed statements set out in the Section entitled Required Disclosures. Each recording must be retrievable by date and by the

consumer's name, telephone number, or billing information and must be provided upon request and without Charge to the consumer, the consumer's bank, or any law enforcement entity.

## **XI.**

### **PROHIBITIONS CONCERNING REFUNDS AND CANCELLATIONS**

**IT IS FURTHER ORDERED** that Defendants, Defendants' 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 the advertising, marketing, promotion, offering for sale, sale, or distribution of any good or service, are permanently restrained and enjoined from:

A. Failing to honor a refund, return, or cancellation request that complies with any policy to make refunds or allow returns or cancellations; and

B. Failing to provide a simple mechanism for a consumer to immediately stop any recurring Charge for such good or service, at least one of which is as simple and easy to use as the mechanism the consumer used to initiate the Charges.

1. For consumers who entered into the agreement to purchase a good or service including a Negative Option Feature over the Internet or through other web-based applications or services, Defendants must provide a mechanism for consumers to stop the recurring Charge over the Internet or through such other web-based application or service.
2. For consumers who entered into the agreement to purchase a good or service including a Negative Option Feature through an oral offer and acceptance, Defendants must maintain a telephone number through which the consumer can easily cancel the good or service, seek a refund for past



Charges where such refund is offered, and immediately stop all further Charges. Defendants must answer all calls to this telephone number during normal business hours.

## **XII.**

### **COMPLIANCE WITH THE ELECTRONIC FUND TRANSFER ACT**

**IT IS FURTHER ORDERED** that Defendants, Defendants' 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 the advertising, marketing, promotion, offering for sale, sale, or distribution of any good or service, are permanently restrained and enjoined, in connection with any person who purchases any good or service subsequent to the date of this Order, and who uses a debit card or other means of electronic fund transfer, from:

A. Failing to obtain written authorization for Preauthorized Electronic Fund Transfers from a consumer's account before initiating any Preauthorized Electronic Fund Transfer, as required by Section 907(a) of the Electronic Fund Transfer Act, 15 U.S.C. § 1693e(a), and Section 1005.10(b) of Regulation E, 12 C.F.R. § 1005.10(b), as more fully set out in Section 1005.10 of the Consumer Financial Protection Bureau's Official Staff Commentary to Regulation E, 12 C.F.R. § 1005, Supp. I; and

B. Failing to maintain procedures reasonably adapted to avoid an unintentional failure to obtain written authorization for a Preauthorized Electronic Fund Transfer, as required in Section 1005.10 of the Consumer Financial Protection Bureau's Official Staff Commentary to Regulation E, 12 C.F.R. § 1005, Supp. I.

### **XIII.**

#### **MONETARY JUDGMENT AND CONSUMER REDRESS**

**IT IS FURTHER ORDERED** that:

- A. Judgment in the amount of \$3,700,514 is hereby entered in favor of the Commission against Defendants, jointly and severally, as equitable monetary relief.
- B. Defendants are ordered to pay to the Commission \$800,000. Defendants stipulate that they have posted \$450,000 into the escrow account of their undersigned counsel for no purpose other than payment to the Commission. Defendants will remit the balance of \$350,000 to the escrow account of their undersigned counsel prior to submission of this Order to the Court for approval. The escrowed funds shall be paid to the Commission within 7 days of the Court's entry of this Order and shall be transferred in accordance with the wire transfer instructions previously provided to counsel by a representative of the Commission.
- C. Upon satisfaction of the obligations described in Subsection B above, the remainder of the judgment as to the Defendants shall be suspended subject to Subsections E and F below.
- D. In the event of default of any obligation to make payments under this Order, including, but not limited to, failure to pay \$800,000 to the Commission pursuant to Section B, above, interest shall accrue as computed pursuant to 28 U.S.C. § 1961(a) from the date of default to the date of payment. In the event such default continues for 10 calendar days beyond the date any payments are due, the entire judgment amount of \$3,700,514 shall immediately become due and payable.
- E. Plaintiffs' agreement to the suspension of part of the judgment is expressly premised upon the truthfulness, accuracy, and completeness of Defendants' sworn financial

statements and related documents (collectively, “financial representations”) submitted to Plaintiffs, namely the following:

1. the Financial Statement of Individual Defendant Kramer Duhon signed on December 19, 2016, including the attachments (HRL003490-3504; HRL004034);
2. the Financial Statement of Corporate Defendant Health Research Laboratories, LLC, signed by Kramer Duhon, President, on December 18, 2016, including the attachments (HRL003474-3489); and
3. the additional documentation and information submitted by letter from Defendants’ counsel Andrew Lustigman to Commission counsel Elizabeth Nach, dated December 22, 2016; January 13, 2017; February 8, 2017; February 17, 2017; February 28, 2017; March 31, 2017; and April 20, 2017; including all attachments thereto (bates-stamped HRL003227-4894 and 117 un-stamped JP Morgan investment account statements).

F. The suspension of the judgment will be lifted as to any Defendant if, upon motion by either of Plaintiffs, the Court finds that such Defendant failed to disclose any material asset, materially misstated the value of any asset, or made any other material misstatement or omission in the financial representations identified in Subsection E above.

G. If the suspension of the judgment is lifted, the judgment becomes immediately due as to the Defendant or Defendants causing the suspension to be lifted in the amount specified in Subsection A above (which the parties stipulate only for purposes of this Section represents the consumer injury alleged in the Complaint), less any payment previously made pursuant to this Section, plus interest computed from the date of entry of this Order.

H. All money paid to the Commission pursuant to this Order may be deposited into a fund administered by the Commission or its designee to be used for equitable relief, including

consumer redress and any attendant expenses for the administration of any redress fund. If a representative of the Commission decides that direct redress to consumers is wholly or partially impracticable or money remains after redress is completed, the money shall be divided with the State of Maine. Any money not transferred to the State of Maine or not used by the Commission for equitable relief, including consumer information remedies, is to be deposited to the U.S. Treasury as disgorgement. Defendants have no right to challenge any actions the Commission or its representatives may take pursuant to this Subsection.

I. All money paid to the State of Maine pursuant to this Order must be deposited into the Attorney General's other special revenue account and used for consumer education, consumer protection, antitrust enforcement, or for any lawful purpose at the sole discretion of the Attorney General.

J. Defendants relinquish dominion and all legal and equitable right, title, and interest in all assets transferred pursuant to this Order and may not seek the return of any assets.

K. The facts alleged in the Complaint will be taken as true, without further proof, in any subsequent civil litigation by or on behalf of either of Plaintiffs, in a proceeding to enforce their rights to any payment or monetary judgment pursuant to this Order, such as a nondischargeability complaint in any bankruptcy case.

L. The facts alleged in the Complaint establish all elements necessary to sustain an action by either of Plaintiffs pursuant to Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S.C. § 523(a)(2)(A), and this Order will have collateral estoppel effect for such purposes.

M. Defendants acknowledge that their Taxpayer Identification Numbers (Social Security Numbers or Employer Identification Numbers), which Defendants previously submitted

to Plaintiffs, may be used for collecting and reporting on any delinquent amount arising out of this Order, in accordance with 31 U.S.C. § 7701.

#### XIV.

#### COOPERATION WITH FTC AND MAINE

**IT IS FURTHER ORDERED** that Defendants must fully cooperate with representatives of the Commission, the Maine AG, and any of their representatives in this case and in any investigation related to or associated with the transactions or the occurrences that are the subject of the Complaint. Defendants must provide truthful and complete information, evidence, and testimony. Individual Defendant must appear and Corporate Defendant must cause its officers, employees, representatives, or agents to appear for interviews, discovery, hearings, trials, and any other proceedings that a representative of the Commission or the Maine AG may reasonably request upon 5 days' written notice, or other reasonable notice, at such places and times as a Commission or Maine AG representative may designate, without the service of a subpoena. Defendants may have counsel present.

#### XV.

#### CUSTOMER INFORMATION

**IT IS FURTHER ORDERED** that Defendants' officers, agents, and employees, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, are permanently restrained and enjoined from directly or indirectly:

A. Failing to provide sufficient customer information to enable the Commission to efficiently administer consumer redress. If a representative of the Commission requests in writing any information related to redress, Defendants must provide it, in the form prescribed by the Commission, within 14 days.

B. Disclosing, using, or benefitting from customer information, including the name, address, telephone number, email address, Social Security number, 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 Defendant obtained prior to entry of this Order in connection with the labeling, advertising, marketing, distribution, or sale of any formulation of BioTherapex or NeuroPlus; and

C. Failing to destroy such customer information in all forms in their possession, custody, or control within 30 days after receipt of written direction to do so from representatives of both the Commission and the Maine AG.

*Provided, however,* that customer information need not be destroyed, and may be disclosed, to the extent requested by a government agency or required by law, regulation, or court order.

## XVI.

### ORDER ACKNOWLEDGMENTS

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

A. Each Defendant, within 7 days of entry of this Order, must submit to the Commission and the Maine AG an acknowledgment of receipt of this Order sworn under penalty of perjury.

B. For 10 years after entry of this Order, the Individual Defendant for any business involved in the sale or marketing of any Covered Product that such Defendant, individually or collectively with the Corporate Defendant, is the majority owner or controls directly or indirectly, and the Corporate Defendant, must deliver a copy of this Order to:

1. All principals, officers, directors, and LLC managers and members;
2. All employees, agents, and representatives with managerial responsibility who participate in the manufacturing, labeling, advertising, marketing, distribution, or sale of any Covered Product or service; and
3. Any business entity resulting from any change in structure as set forth in the Section titled Compliance Reporting.

Delivery must occur within 7 days of entry 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 Defendant delivered a copy of this Order, that Defendant must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

## **XVII.**

### **COMPLIANCE REPORTING**

**IT IS FURTHER ORDERED** that Defendants make timely submissions to the Commission and to the Maine AG:

A. Sixty days after entry of this Order, each Defendant must submit a compliance report, sworn under penalty of perjury:

1. Each Defendant must: (a) identify the primary physical, postal, and email address and telephone number as designated points of contact, which Plaintiffs' representatives may use to communicate with Defendant; (b) identify all of that Defendant'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 the other Defendant (which Individual Defendant must describe if he knows or should know due to his own involvement);

(d) describe in detail whether and how that Defendant is in compliance with each Section of this Order; and (e) provide a copy of each Order Acknowledgment obtained pursuant to this Order, unless previously submitted to Plaintiffs.

2. Additionally, the Individual Defendant must: (a) identify all telephone numbers and all physical, postal, email, and Internet addresses, including all residences; (b) identify all business activities, including any business for which such Defendant performs services whether as an employee or otherwise and any entity in which such Defendant has any ownership interest; and (c) describe in detail such Defendant's involvement in each such business, including title, role, responsibilities, participation, authority, control, and any ownership.

B. For 10 years after entry of this Order, each Defendant must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:

1. Each Defendant must report any change in: (a) any designated point of contact; (b) the structure of the Corporate Defendant or any entity that Defendants have any ownership interest in or control 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 Defendant must report any change in:
  - (a) names, including aliases or fictitious names, or residence addresses; or
  - (b) titles or roles in any business activity, including any business for which such Defendant performs services whether as an employee or otherwise and any entity in which such Defendant has any ownership interest, and identify the name, physical address, and any Internet address of the business or entity.

C. For a period of 20 years, each Defendant must submit to the Commission and the Maine AG notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Defendant within 14 days of its filing.

D. Any submission to the Commission or the Maine AG 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, N.W., Washington, D.C. 20580. The subject line must begin: *FTC v. Health Research Laboratories, LLC, et al.*, and the number X180007.

F. Unless otherwise directed by a Maine AG representative in writing, all submissions to the Maine AG pursuant to this Order must be sent by overnight courier (not the U.S. Postal Service) to: Office of the Attorney General of Maine, Consumer Protection Division, 111 Sewall Street, 6<sup>th</sup> Floor, Augusta, ME 04330. The subject line must begin: *Order in re State of Maine v. Health Research Laboratories, LLC, et al.*, and must identify the Court and docket number of this Order as ordered by the Court.

### **XVIII.**

#### **RECORDKEEPING**

**IT IS FURTHER ORDERED** that in connection with the sale of any Covered Product, Defendants must create certain records for 10 years after entry of the Order, and retain each such record for 8 years. Specifically, the Corporate Defendant and the Individual Defendant for any business that such Defendants, individually or collectively, is a majority owner or controls directly or indirectly, must create and retain the following records:

- A. Accounting records showing the revenues from all goods or services sold, all costs incurred in generating those revenues, and the resulting net profit or loss;
- B. Personnel records showing, for each person providing services, whether as an employee or otherwise, that person's: name; address; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;
- C. Complaints and full or partial 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 the Maine AG; and
- E. A copy of each unique advertisement or other marketing material.

## XIX.

### COMPLIANCE MONITORING

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

A. Within 14 days of receipt of a written request from a representative of the Commission or the Maine AG, each Defendant must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury; appear for depositions; and produce documents for inspection and copying. Plaintiffs are also authorized to obtain discovery, without further leave of court, using any of the procedures prescribed by Federal Rules of Civil Procedure 29, 30 (including telephonic depositions), 31, 33, 34, 36, 45, and 69.

B. For matters concerning this Order, Plaintiffs are authorized to communicate directly with each Defendant. Defendants must permit Plaintiffs' representatives to interview any employee or other person affiliated with any Defendant who has agreed to such an interview. The person interviewed may have counsel present.

C. Plaintiffs may use all other lawful means, including posing, through their representatives, as consumers, suppliers, or other individuals or entities, to Defendants or any individual or entity affiliated with Defendants, 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. Nothing in this Order limits the Maine AG's lawful use of compulsory process, pursuant to section 211 of the Maine UTPA, 5 M.R.S.A. § 211. Defendants hereby consent to the disclosure by the Maine AG to any law enforcement agency and any representative of the State of Maine of any material or

information produced by Defendants pursuant to section 211 of the Maine UTPA, whether produced before or after the date of this Order.

D. Upon written request from a representative of the Commission or the Maine AG, any consumer reporting agency must furnish consumer reports concerning Individual Defendant, pursuant to Section 604(1) of the Fair Credit Reporting Act, 15 U.S.C. § 1681b(a)(1).

**XX.**

**RETENTION OF JURISDICTION**

**IT IS FURTHER ORDERED** that this Court shall retain jurisdiction of this matter for purposes of construction, modification, and enforcement of this Order.

**IT IS SO ORDERED** this 16<sup>th</sup> day of January, 2018.

/s/ Jon D. Levy  
**U.S. DISTRICT JUDGE**

**IT IS SO STIPULATED** this 30<sup>th</sup> day of November, 2017.

DAVID C. SHONKA  
Acting General Counsel

/s/ Elizabeth K. Nach  
Elizabeth K. Nach  
James A. Prunty  
Federal Trade Commission  
600 Pennsylvania Avenue, NW  
Washington, D.C. 20580  
Telephone: 202-326-2611, -2438  
Facsimile: 202-326-3259  
Email: enach@ftc.gov, jprunty@ftc.gov  
Attorneys for Plaintiff  
FEDERAL TRADE COMMISSION

**IT IS SO STIPULATED** this 30<sup>th</sup> day of November, 2017.

JANET T. MILLS  
Attorney General, State of Maine

/s/ Brendan F.X. O'Neil  
Brendan F.X. O'Neil  
Linda J. Conti  
Assistant Attorney General  
Office of the Attorney General of Maine  
6 State House Station  
Augusta, Maine 04333-0006  
Telephone: 207-626-8842, -8591  
Facsimile: 207-624-7730  
Email: brendan.oneil@maine.gov  
linda.conti@maine.gov

**IT IS SO STIPULATED** this 30<sup>th</sup> day of November, 2017.

HEALTH RESEARCH LABORATORIES, LLC  
By:

/s/ Kramer Duhon  
KRAMER DUHON, individually, and as an owner  
and officer of HEALTH RESEARCH  
LABORATORIES, LLC

**IT IS SO STIPULATED** this 30<sup>th</sup> day of November, 2017.

ATTORNEYS FOR DEFENDANTS HEALTH  
RESEARCH LABORATORIES, LLC AND  
KRAMER DUHON

/s/ Andrew B. Lustigman  
Andrew B. Lustigman, Esq.  
Olshan Frome Wolosky LLP  
1325 Avenue of the Americas  
New York, NY 10019  
Telephone: (212) 451-2258  
Facsimile: (212) 451-2222  
Email: alustigman@olshanlaw.com  
*Pro hac vice forthcoming*

/s/ David J. Marchese  
Appearing on behalf of Defendants  
Health Research Laboratories, LLC and  
Kramer Duhon

David J. Marchese, Esq.  
Drummond & Drummond, LLP  
1 Monument Way  
Portland, ME 04101  
Telephone: 207-774-0317  
Email: dmarchese@ddlaw.com

**PX 2**

DECLARATION OF LESLIE LEWIS

My name is Leslie Lewis. I declare under penalty of perjury under the laws of the United States that the following is true. If called as a witness, I could and would competently testify as follows.

1. I am a U.S. citizen over the age of 18 and am employed as a Litigation Support Specialist in the Federal Trade Commission’s Bureau of Consumer Protection, Division of Enforcement (“Division of Enforcement”). My business address is 600 Pennsylvania Avenue, N.W., CC-9528, Washington, D.C. 20580. I performed all activities described herein as part of my job responsibilities.

2. My duties as a Litigation Support Specialist include receiving documents and correspondence, including U.S. mail, courier deliveries, and electronic submissions. I also organize and maintain many of the paper and electronic records for the Division of Enforcement including on the Division of Enforcement’s network computer drive. I also act as an official custodian of records and provide assistance to case teams as requested.

3. In the regular course of my work, I also monitor the email account Debrief@ftc.gov and process the intake of correspondence and materials emailed to that address. My regular practice is to save email communications and materials that are sent to Debrief@ftc.gov in the Enforcement Database described below.

4. In addition, I serve as Administrator of the Enforcement Database. The Enforcement Database is an Oracle 11g database application that is used to store copies of final injunctive orders obtained in consumer protection cases brought by the Federal Trade Commission (“FTC”) as well as submissions made by parties to the FTC following the entry of orders such as compliance reports, acknowledgment forms, and correspondence. The Enforcement Database is



also frequently used to preserve correspondence between FTC attorneys and parties that are subject to orders.

5. I have performed these functions both before and since the Court entered a Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief on January 16, 2018 in *FTC and Maine v. Health Research Laboratories, LLC et al.*, 2:17-cv-00467-JDL (“Order”).

6. The Order requires defendants to submit an acknowledgment of receipt of the Order to the Division of Enforcement. I searched the Enforcement Database and found an acknowledgment of receipt submitted by Kramer Duhon and Health Research Laboratories, LLC (collectively, “Defendants”) dated January 23, 2018. A true and correct copy of this acknowledgment form is attached hereto as Attachment A.

7. I have also searched the Division of Enforcement’s records for compliance reports and responses to requests for information submitted by Kramer Duhon and Health Research Laboratories, LLC to the Division of Enforcement. A subset of the documents I found as a result of my search are attached to this Declaration and described below.

8. A true and correct copy of a compliance report dated March 29, 2018 submitted by Defendants to the Division of Enforcement, and stored in the Enforcement Database, is included as Attachment B.

9. A true and correct copy of a supplemental compliance report dated May 4, 2018 and associated exhibits submitted by Defendants to the Division of Enforcement, and stored in the Enforcement Database, is included as Attachment C.

10. A true and correct copy of a May 21, 2018 letter from a staff attorney in the Division of Enforcement, Miriam Lederer, to counsel for Defendants, Andrew Lustigman, is included as Attachment D. This document is stored in the Enforcement Database.

11. A true and correct copy of an email exchange between Ms. Lederer, and Defendants' counsel, Andrew Lustigman, is included as Attachment E. This email correspondence copied Debrief@ftc.gov and was therefore stored in the Enforcement Database.

12. A true and correct copy of a Supplemental Statement of Compliance that Defendants submitted to the Division of Enforcement on June 6, 2018 and stored on the Division of Enforcement's network drive is included as Attachment F.

13. A true and correct copy of a pdf file with pages bates stamped HRL04909-4919 that Defendants submitted on June 6, 2018 to the Division of Enforcement is included as Attachment G. This file is stored on the Division of Enforcement's network drive.

14. A true and correct copy of a document bates stamped HRL004984-4999 that was submitted by Defendants to the Division of Enforcement on June 6, 2018 is included as Attachment H. This document is stored on the Division of Enforcement's network drive.

15. A true and correct copy of a document bates stamped HRL005068-5083 that was submitted by Defendants to the Division of Enforcement on June 6, 2018 is included as Attachment I. This document is stored on the Division of Enforcement's network drive.

16. A true and correct copy of a document bates stamped HRL005036-5051 that was submitted by Defendants to the Division of Enforcement on June 6, 2018 is included as Attachment J. This document is stored on the Division of Enforcement's network drive.

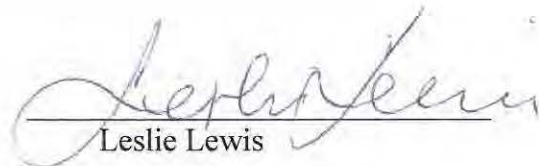
17. A true and correct copy of a letter dated April 10, 2019 from Defendants' counsel, Andrew Lustigman, to Division of Enforcement staff attorney, Robert Frisby, is included as Attachment K. This document is stored on the Division of Enforcement's network drive.

18. A true and correct copy of a document bates stamped HRL008148 that was submitted by Defendants to the Division of Enforcement on August 8, 2019 is included as Attachment L. This document is stored on the Division of Enforcement's network drive.

19. A true and correct copy of a document bates stamped HRL008163 that was submitted by Defendants to the Division of Enforcement on September 27, 2019 is included as Attachment M. This document is stored on the Division of Enforcement's network drive.

20. In addition, I requested certified copies of certain corporate filings for Whole Body Supplements, LLC from the State of Nevada, Office of the Secretary of State. True and correct copies of the certified documents that I received in response to this request are included as Attachment N.

Executed on: December 10, 2019  
Washington, D.C.

  
Leslie Lewis

**Lewis Declaration**

**ATTACHMENT A**

**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

**STATEMENT OF COMPLIANCE**

I, Kramer Duhon, on behalf of myself and Health Research Laboratories, LLC (hereinafter, "LLC"), do hereby state as follows:

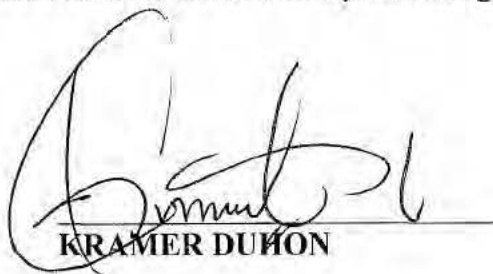
1. I have received a copy of the Stipulated Final Judgment And Order For Permanent Injunction And Other Equitable Relief that was filed and entered by the Court on or about January 16, 2018 (hereinafter, "the Order").

2. I further acknowledge that I have delivered or caused to be delivered a copy of the Order to all principals, officers, directors, and LLC managers and members and to all employees, agents and representatives with managerial responsibility who participate in the manufacturing, labeling, advertising, marketing, distribution, or sale of BioTherapex and NeuroPlus.

3. It is my understanding that complete full payment of \$800,000.00 has now been made to the Federal Trade Commission pursuant to Section XIII.B of the Order.

4. Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge and information.

Executed on January 23, 2018



KRAMER DUHON

**Lewis Declaration**

**ATTACHMENT B**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MAINE

FEDERAL TRADE COMMISSION and  
STATE of MAINE,

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

Plaintiffs,

-v.-

**CONFIDENTIAL SUBMISSION**

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

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

Defendants.

**DEFENDANTS' COMPLIANCE REPORT PURSUANT TO  
THE STIPULATED FINAL JUDGMENT AND ORDER FOR  
PERMANENT INJUNCTION AND OTHER EQUITABLE RELIEF**

I, Kramer Duhon, hereby submit this Compliance Report under the penalty of perjury in the above-captioned action, on behalf of myself and Health Research Laboratories, LLC, to the Federal Trade Commission and the State of Maine, pursuant to the Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief (hereinafter, the Order”).

The information in this Report is hereby deemed Confidential and should be given the level of confidential treatment accorded by provisions 15 U.S.C. §§46(f) and 57b-2 and the Federal Trade Commission Rules of Practice 16 C.F.R. §§4.10-4.11.

1. Pursuant to Section XVII.A.1. of Order, Health Research Laboratories, LLC and Kramer Duhon hereby identify:

(a) the following primary physical, postal, and e-mail addresses and telephone numbers as designated points of contact for which the Federal Trade Commission and the State of Maine may use to communicate with them:

Andrew B. Lustigman, Esq.  
Olshan Frome Wolosky, LLP  
1325 Avenue of the Americas  
New York, NY 10019  
Tel: 212.451.2300  
Fax: 212.451.2222



E-mail: [alustigman@olshanlaw.com](mailto:alustigman@olshanlaw.com)

(b) all businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses:

Health Research Laboratories, LLC  
Legal Address/Physical Address  
3064 Silver Sage Drive Suite 150/16250 Knoll Trail Drive Suite 150  
Carson City Nevada 89701/Dallas Texas 75248  
Office – 972-354-7330  
Email – [kramer@kramerduhon.com](mailto:kramer@kramerduhon.com)  
[www.hrlsupplements.com](http://www.hrlsupplements.com)

Whole Body Supplements, LLC  
Legal Address/Physical Address  
3064 Silver Sage Drive Suite 150/16250 Knoll Trail Drive Suite 150  
Carson City Nevada 89701/Dallas Texas 75248  
Office – 972-354-7330  
Email – [kramer@kramerduhon.com](mailto:kramer@kramerduhon.com)  
[www.wholebodysupplement.com](http://www.wholebodysupplement.com)

KMCL, LLC  
16250 Knoll Trail Drive Suite 150  
Dallas Texas 75248  
Office – 972-354-7330  
Email – [kramer@kramerduhon.com](mailto:kramer@kramerduhon.com)  
URL – N/A

(c) describe the activities of each business, including the goods and services offered, the means of advertising, marketing, and sales, and the involvement of the other Defendant:

Health Research Laboratories, LLC advertises and sells health and nutritional products to consumers on its website, [www.hrlsupplements.com](http://www.hrlsupplements.com), and via direct mail. A current list of the products being sold appears at [www.hrlsupplements.com](http://www.hrlsupplements.com). This entity is owned 100% by Kramer Duhon whose title is Chief Operating Officer.

Whole Body Supplements, LLC advertises and sells health and nutritional products to consumers on its website, [www.wholebodysupplement.com](http://www.wholebodysupplement.com) and via direct mail. A current list of the products being sold appears at [www.wholebodysupplement.com](http://www.wholebodysupplement.com). This entity is owned 100% by Kramer Duhon whose title is Chief Operating Officer.

KMCL, LLC is an inactive company that has no revenue since 2015. Final Return is being filed for the 2017 tax year.

(d) To the best of my information and belief, both myself, and Health Research Laboratories, LLC are in full compliance with the Order in that we have:

not made any banned weight-loss claims as defined in Section I of the Order;

not made any prohibited representations as defined in Sections II, III, IV, VII and VIII of the Order;

made the disclosures required by Section IX of the Order;

not violated the Express Informed Consent provisions contained in Section X of the Order;

not engaged in the prohibitions concerning refunds and cancellation contained in Section XI of the Order;

complied with Section XII of the Order concerning the Electronic Fund Transfer Act;

complied with the payment provisions of Section XIII.B of the Order; and

not refused any cooperation or destroyed any records with the Federal Trade Commission or the State of Maine as required by Sections XIV, XV, XVIII and XIX of the Order.

(e) provide a copy of each Order Acknowledgment obtained pursuant to this Order

See Exhibit A, attached.

2. Pursuant to Section XVII.A.2. of the Order, Kramer Duhon hereby:

(a) identifies all telephone numbers and all physical, postal, e-mail, and Internet addresses, including all residences:

Kramer R. Duhon  
REDACTED PII  
Dallas, Texas REDACTED  
Mobile – REDACTED PII  
Email – kramer@kramerduhon.com

(b) identifies the following businesses and/or business activities other than for Health Research Laboratories, LLC, for which such he performs services or has any ownership interest:

See Whole Body Supplement, LLC info in section 1.(b) above.

See KMCL, LLC info in section 1.(b) above.

(c) describes in detail his involvement in each such business, including title, role, responsibilities, participation, authority, control, and any ownership.

See info above in section 1.(c) above. Kramer Duhon is responsible for the operation of those businesses.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge and information.

Dated: 3/29/19

By:   
KRAMER DUHON

On behalf of himself and Health  
Research Laboratories, LLC

**Lewis Declaration**

**ATTACHMENT C**

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

**CONFIDENTIAL SUBMISSION**

**DEFENDANTS' SUPPLEMENTAL COMPLIANCE REPORT  
PURSUANT TO THE STIPULATED FINAL JUDGMENT AND ORDER  
FOR PERMANENT INJUNCTION AND OTHER EQUITABLE RELIEF**

I, Kramer Duhon, hereby submit this Supplemental Compliance Report under the penalty of perjury in the above-captioned action, on behalf of myself and Health Research Laboratories, LLC, to the Federal Trade Commission and the State of Maine, pursuant to correspondence from the Federal Trade Commission dated April 19, 2018 (hereinafter, "the Commission Request"):

1. The information in this Supplemental Report and all attachments hereto is hereby deemed Confidential and should be given the level of confidential treatment accorded by provisions 15 U.S.C. §§46(f) and 57b-2 and the Federal Trade Commission Rules of Practice 16 C.F.R. §§4.10-4.11.

2. Pursuant to paragraph 1 of the Commission Request, I attach hereto as Exhibit A a list of each recipient to whom I, on behalf of myself and Health Research Laboratories, LLC provided a copy of the Order (as that term is defined in the Commission Request) was delivered.

3. With respect to paragraph 2 of the Commission Request, the initial report provided the actual signed acknowledgments that were received and Exhibit A identifies each person's position and entity affiliation.

4. With respect to paragraph 3 of the Commission Request, the entity that provides post-sale customer support is Ship-Right Solutions, LLC, located at 165 Pleasant Avenue, South Portland, Maine 04106, telephone number 207-321-3500.

5. With respect to paragraph 3 of the Commission Request, I attach hereto as Exhibit B a list of the goods and services that have been sold since the date of the Order by Health Research Laboratories, LLC and Whole Body Supplements, LLC.

6. Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge, information and belief.

Dated: 5/4/18

By:   
KRAMER DUHON

On behalf of himself and Health Research Laboratories, LLC

**EXHIBIT A**

**Order Delivery and Acknowledgement List**

<u>Vendor Name</u>	<u>Name</u>	<u>Position/Title</u>	<u>Service Provided</u>
Ship-Right Solutions, LLC	Andrew Graham	Principle	Fulfillment
NexRep, LLC	Teddy Laiw	Principle	Inbound Telemarketing
Pure Source, Inc.	Joel Meyerson	Principle	Product Manufacturer
Dr. Richard Cohen	Self	Spokesperson	Expert Spokesperson
Impulse Media, Inc.	Joseph Russo	Principle	List Broker
Evolution Marketing Concepts	Scott Scordas	Principle	Print Broker
TLC Global Impression	Phil Teraca	Principle	Printer
PageOne Web Solutions	Patrick Sullivan	Principle	Web Host
Direct Access Marketing Services	Tom Saraco	Principle	Data House
Andy Lustigman	Self	Attorney	Legal
Sheldon Lustigman	Self	Attorney	Legal
Stephen Kimball	Self	Principle	Writer
Jennifer Osterhouse	Self	Principle	Artist



## **EXHIBIT B**

## Health Research Laboratories

### Product Offering List as of 4/1/18

ASCB 2.0  
AtheChel Advanced  
Betarol  
Biohepatocyte  
Biostem  
Black Garlic Botanicals  
BladderEze  
Clear Colon Defense  
Corexion  
CTG  
Glucophene Topical Gel  
GHGW50  
Hydroxin  
Joint Source Supplement  
Liver Renu  
Maximum T  
NaturClenz Health Supplement  
Neupathic with GLA  
NuroHealth  
Regimen Cell Rejuvenation  
RejuvaLifeRX Health Supplement  
Restorex Dietary Supplement  
T-Plus Rejuvenation  
The Ultimate Cardio Clense  
The Ultimate Formula  
Thyroid Essentilals  
Vialis

## Whole Body Supplements

### Product Offering List as of 4/1/18

Black Garlic BG18  
Genevin Dietary Supplement  
LiverVitals  
StimActiv Blue Green Algae Supplement  
Hydrafuel  
Neurocare

**Lewis Declaration**

**ATTACHMENT D**



UNITED STATES OF AMERICA  
FEDERAL TRADE COMMISSION  
WASHINGTON, D.C. 20580

Bureau of Consumer Protection  
Division of Enforcement

Minam R. Lederer  
Attorney

Email: mlederer@ftc.gov  
Direct Dial: 202-326-2975

May 21, 2018

**VIA ELECTRONIC MAIL**

Andrew B. Lustigman, Esq.  
Olshan Frome Wolosky LLP  
1325 Avenue of the Americas  
New York, NY 10019  
ALustigman@olshanlaw.com

Re: *FTC and State of Maine v. Health Research Laboratories, LLC, et al.*,  
Matter No. X180007

Dear Mr. Lustigman:

As my colleague, Christopher Erickson, indicated, I am now your point of contact on the above referenced matter ("Health Research Laboratories" or "HRL"). I am in receipt of Defendants' compliance report, submitted on March 29, 2018 ("Compliance Report"), as well as the supplemental response to the FTC's April 19, 2018 letter, submitted on May 11, 2018 (Supplemental Report). Based on these submissions, we note two deficiencies at this time.

First, Defendants have not provided a copy of each Order Acknowledgement. Pursuant to Section XVII of the Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief ("Order"), each Defendant needed to submit a compliance report that, among other things, "(e) provides a copy of each Order Acknowledgment obtained pursuant to this Order." The Supplemental Report Exhibit A listed thirteen entities or individuals who signed Acknowledgement Forms attesting to receiving copies of the Order on behalf of the entities and/or themselves.<sup>1</sup> Defendants' initial March 29, 2018 Compliance Report, however, only

<sup>1</sup> The following individuals are listed in Supplemental Report Ex. A as signing Acknowledgement Forms attesting to receipt of the Order: (1) Andrew Graham on behalf of Ship-Right Solutions, LLC; (2) Teddy Laiw on behalf of NextRep, LLC; (3) Joel Meyerson on behalf of Pure Source, Inc.; (4) Dr. Richard Cohen on behalf of himself as an "Expert Spokesperson"; (5) Joseph Russo on behalf of Impulse Media, Inc.; (6) Scott Scordas on behalf of Evolution Marketing Concepts; (7) Phil Terriaca on behalf of TLC Global Impression; (8) Patrick Sullivan on behalf of PageOne Web Solutions; (9) Tom Saraco on behalf of Direct Access Marketing Services; (10) Andy Lustigman on behalf of himself; (11) Sheldon Lustigman on behalf of himself; (12) Stephen Kimball on behalf of himself; and (13) Jennifer Osterhouse on behalf of herself.

produced seven signed Acknowledgement Forms. Pursuant to Section XVII(A)(1)(e), please produce the following forms: (1) Teddy Laiw on behalf of NextRep, LLC; (2) Scott Scordas on behalf of Evolution Marketing Concepts; (3) Tom Saraco on behalf of Direct Access Marketing Services; (4) Andy Lustigman on behalf of himself; (5) Stephen Kimball on behalf of himself; and (6) Jennifer Osterhouse on behalf of herself. The forms signed on behalf of entities should indicate that fact and include the entity name.

Relatedly, Specification 2 of the FTC's April 19, 2018 letter, asked Defendants to indicate whether the Individuals who did sign and submit Acknowledgement Forms, did so on behalf of an entity. Defendants' response only identified the signatory's entity affiliation. Please supplement your response to Specification 2 and indicate whether those individuals did, in fact, sign on behalf of their affiliated entities.

Second, Defendants have not provided sufficient detail as to how they are in compliance with each section of the Order. See Section XVII(A)(1)(d). The compliance report simply states that Defendants have "not made any banned weight-loss claims as defined in Section I of the Order; not made any prohibited representations as defined in Sections II, III, IV, VII and VIII of the Order; made the disclosures required by Section IX of the Order; not violated the Express Informed Consent provisions contained in Section X of the Order; not engaged in the prohibitions concerning refunds and cancellation contained in Section XI of the Order; complied with Section XII of the Order concerning the Electronic Fund Transfer Act . . . ." Compliance Report at 1(d), p. 3.

Therefore, pursuant to Section XIX of the Order, we have prepared some additional requests for information and documents. Please note that Section XIX requires responsive information – signed under penalty of perjury – to be submitted within 14 days after receipt of this request (June 4, 2018).

I am happy to look at any additional information or documents whose production you believe may help. If you have additional questions, you are welcome to contact me at (202) 326-2975 or at [mlederer@ftc.gov](mailto:mlederer@ftc.gov).

Sincerely,



Miriam R. Lederer

CC: [DEbrief@ftc.gov](mailto:DEbrief@ftc.gov)

## REQUEST FOR COMPLIANCE INFORMATION AND PRODUCTION OF DOCUMENTS

Please review carefully the Definitions and Instructions that appear after the Specifications and provide important information regarding compliance with this Request.

### I. SPECIFICATIONS

We continue the numbering of Specifications from where we left off in our April 19, 2018 Request.

5. For each product listed in Exhibit B of Your May 11, 2018 Supplemental Response (“Identified Products”), please list:
  - a. The date that You first started selling the product;
  - b. The date that You stopped selling the product, or, if You are still selling the product at present, simple state “present”; and
  - c. Whether the product listed, or an Essentially Equivalent Product (as defined in the Order), was ever sold by You under a different brand name, and if so, the name of that product and the date range that You sold such product.
  
6. Provide a copy of each unique version of Advertisements disseminated since April 19, 2017, for each of the Identified Products and each Essentially Equivalent Product of any of the Identified Products, in any medium, including, but not limited to, direct mail, product packaging (including labels), telemarketing scripts, on-hold scripts, upsell scripts, post-sale consumer support scripts, training materials provided to telemarketing firms or post-sale consumer support entities, the Internet, electronic mail, newspapers, magazines, television, radio, telephone, and audio programs transmitted over a telephone system. For websites, including social media websites, submit copies of each webpage, screen, banner advertisement, and the pages each clicks through to or displays. If the Advertisement cannot be printed, provide a copy of the electronic file.
  
7. For each Advertisement (provided in response to Specification 6), provide a dissemination schedule. “Dissemination Schedule” includes, but is not limited to, the following: (a) for promotional materials that were mailed or emailed, the dates when they were sent out; (b) for product packaging, the date upon which the packaging was first used; (c) for any scripts or training materials, the entities to whom such scripts or materials were distributed and the dates during which such scripts and materials were used; (d) for printed promotional materials that were not mailed, the name and date of the publication or place in which the promotional material appeared; (e) for Internet materials, the date that the promotional material was first placed on the Internet, the date (if any) that it was removed from the Internet, and the number of “hits” that the advertisement registered; and (f) for radio, audio, television, and video promotional materials, the date, time of day, location, and station name on which the material appeared.
  
8. Produce a copy of all Advertisements disseminated since April 19, 2017, for each of the Identified Products and each Essentially Equivalent Product of any of the Identified Products that You distributed to third-party retailers. To the extent those advertisements or materials were already submitted in response to Specification 6, you need not resubmit them and may instead simply identify the documents.

## II. DEFINITIONS

As used in this Request, the following definitions shall apply:

D-1. **“Advertisement”** or **“advertising”** or **“ad”** shall mean any written or verbal statement, illustration, or depiction, whether in English or any other language, that promotes the sale of a good or service or is designed to increase consumer interest in a brand, good, or service. Advertising media includes, but is not limited to: labeling, packaging, package inserts, radio, television, promotional materials, print (including but not limited to brochures, newspapers, magazines, pamphlets, leaflets, circulars, mailers, book inserts, free standing inserts, letters, catalogues, posters, charts, billboards, public transit cards, point of purchase displays), audio programs transmitted over a telephone system, telemarketing scripts, on-hold scripts, upsell scripts, training materials provided to telemarketing firms, program-length commercials (“infomercials”), the Internet, social media, and other digital content, including electronic newsletters. **“Marketing Materials”** are included in the terms **“advertisement,”** **“advertising,”** and **“ad.”**

D-2. **“And,”** as well as **“or,”** shall be construed both conjunctively and disjunctively, as necessary, in order to bring within the scope of any specification in this Schedule all information that otherwise might be construed to be outside the scope of the specification.

D-3. **“Any”** shall be construed to include **“all,”** and **“all”** shall be construed to include **“any.”**

D-4. **“Corporate Defendant”** or **“HRL”** shall mean **Health Research Laboratories, LLC**, its wholly or partially owned subsidiaries, unincorporated divisions, joint ventures, operations under assumed names, and affiliates, and all directors, officers, members, employees, agents, consultants, and other persons working for or on behalf of the foregoing.

D-5. **“Defendants”** or **“You”** or **“Your”** shall mean the Individual Defendant and the Corporate Defendant, individual, collectively, or in any combination.

D-6. **“Document”** shall mean the complete original and any non-identical copy, whether different from the original because of notations on the copy, different metadata, or otherwise, of any item covered by 15 U.S.C. § 57b-1(a)(5), 16 C.F.R. § 2.7(a)(2), or Federal Rule of Civil Procedure 34(a)(1)(A).

D-7. **“Each”** shall be construed to include **“every,”** and **“every”** shall be construed to include **“each.”**

D-8. **“Electronically Stored Information”** or **“ESI”** shall mean the complete original and any non-identical copy (whether different from the original because of notations, different metadata, or otherwise), regardless of origin or location, of any writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations stored in any electronic medium from which information can be obtained either directly or, if necessary, after translation by you into a reasonably usable form. This includes, but is not limited to, electronic mail, instant messaging, videoconferencing, and other electronic correspondence (whether active, archived, or in a deleted items folder), word processing files, spreadsheets, databases, and video and sound recordings, whether stored on: cards; magnetic or electronic tapes; disks; computer hard drives, network shares or servers, or

other drives; cloud-based platforms; cell phones, PDAs, computer tablets, or other mobile devices; or other storage media.

D-9. “**FTC**” or “**Commission**” shall mean the Federal Trade Commission.

D-10. “**Identify**” or “**the identity of**” requires identification of (a) natural persons by name, title, present business affiliation, present business address, telephone number, and email address or if a present business affiliation or present business address is not known, the last known business and home addresses; and (b) businesses or other organizations by name, address, and the identities of your contact persons at the business or organization.

D-11. “**Individual Defendant**” shall mean **Kramer Duhon**, and any of his wholly or partially owned companies, subsidiaries, unincorporated divisions, joint ventures, operations under assumed names, and affiliates, and all directors, officers, members, employees, agents, consultants, and other persons working for or on behalf of the foregoing.

D-12. “**Order**” shall mean the Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief entered on January 16, 2018, in *FTC v. Health Research Laboratories, LLC*, No. 2:17-cv-00467-JDL (D. Me.).

D-13. “**Referring to**” or “**relating to**” shall mean discussing, describing, reflecting, containing, analyzing, studying, reporting, commenting on, evidencing, constituting, setting forth, considering, recommending, concerning, or pertaining to, in whole or in part.

D-14. “**Request**” shall mean the Request for Compliance Information, including the Definitions, Instructions, and Specifications.

### III. INSTRUCTIONS

I-1. **Sharing of Information:** The FTC will use information you provide in response to this Request for the purpose of investigating violations of the Order and the laws the FTC enforces. We will not disclose such information under the Freedom of Information Act, 5 U.S.C. § 552. We also will not disclose such information, except as allowed under the FTC Act (15 U.S.C. § 57b-2), the Commission’s Rules of Practice (16 C.F.R. §§ 4.10 & 4.11), or if required by a legal obligation. Under the FTC Act, we may provide your information in response to a request from Congress or a proper request from another law enforcement agency. However, we will not publicly disclose such information without giving you prior notice.

I-2. **Withholding Requested Material/Privilege Claims:** If any material called for by this Request is withheld based on a claim of privilege, work product protection, or statutory exemption, or any similar claim, the claim must be asserted no later than the return date of this Request, and must include a submission, together with the claim, of a detailed log of the items withheld. The log must be in a searchable electronic format that identifies the basis for withholding the material and meets all the requirements set forth in 16 C.F.R. § 2.11(a)-(c). The information in the log shall be of sufficient detail to enable the Commission staff to assess the validity of the claim for each document, including attachments, without disclosing the protected information. If only some portion of any responsive material is privileged, all non-privileged portions of the material must be submitted. Otherwise,



produce all responsive information and material without redaction. 16 C.F.R. § 2.11(c). The failure to provide information sufficient to support a claim of protected status may result in denial of the claim. 16 C.F.R. § 2.11(a)(1).

I-3. **Document Retention:** You must retain all documentary materials used in preparing responses to the specifications of this Request. The FTC may require the submission of additional documents at a later time during this investigation. **Accordingly, you must suspend any routine procedures for document destruction and take other measures to prevent the destruction of documents that are in any way relevant to this investigation during its pendency, irrespective of whether you believe such documents are protected from discovery by privilege or otherwise.** See 15 U.S.C. § 50; *see also* 18 U.S.C. §§ 1505, 1519.

I-4. **Certification:** You must certify that the responses to this Request are complete and accurate. This certification shall be made by a declaration under penalty of perjury as provided by 28 U.S.C. § 1746.

I-5. **Scope of Search:** This Request covers documents and information in your possession or under your actual or constructive custody or control including, but not limited to, documents and information in the possession, custody, or control of your attorneys, accountants, directors, officers, employees, service providers, and other agents and consultants, whether or not such documents and information were received from or disseminated to any person or entity.

I-6. **Document Production:** Please send all responsive documents to Miriam Lederer, Federal Trade Commission, 600 Pennsylvania Ave., N.W., M.S. CC-9528, Washington, DC 20580. Please use a courier service such as Federal Express or UPS because heightened security precautions delay postal delivery to the FTC. You must inform FTC counsel by email or telephone how you intend to produce material responsive to this Request at least five days before the return date.

I-7. **Identification of Responsive Documents:** For specifications requesting production of documents, you must identify in writing the documents that are responsive to the specification. Documents that may be responsive to more than one specification of this Request need not be produced more than once. If any documents responsive to this Request have been previously supplied to the FTC, you may identify the document(s) previously provided and the date of submission.

I-8. **Maintain Document Order:** Documents should be produced in the order in which they appear in your files or as electronically stored and without being manipulated or otherwise rearranged; if documents are removed from their original folders, binders, covers, containers, or electronic source in order to be produced, then the documents shall be identified in a manner so as to clearly specify the folder, binder, cover, container, or electronic media or file paths from which such documents came.

I-9. **Numbering of Documents:** Submitted documents must be numbered by page (or file, for those documents produced in native electronic format) with a unique identifier such as a Bates identifier or document ID. Please indicate the total number of documents in your submission.

I-10. **Production of Copies:** Unless otherwise stated, you may submit copies in lieu of original documents if they are true, correct, and complete copies of the originals and you preserve and retain the originals in their same state as of the time you received this Request. Submission of copies

constitutes a waiver of any claim as to the authenticity of the copies should the FTC introduce such copies as evidence in any legal proceeding.

I-11. **Production in Color:** You must produce copies of advertisements in color, and you must produce copies of other materials in color if necessary to interpret them or render them intelligible.

I-12. **Electronic Stored Information:** See the attached FTC Bureau of Consumer Protection Production Requirements (“Production Requirements”), which detail all requirements for the production of electronically stored information to the FTC. You must discuss issues relating to the production of electronically stored information with the FTC staff **prior to production.**

I-13. **Sensitive Personally Identifiable Information (“Sensitive PII”) or Sensitive Health Information (“SHI”):** If any materials response to this Request contain Sensitive PII or SHI, please contact FTC counsel before producing those materials to discuss whether there are steps you can take to minimize the amount of Sensitive PII or SHI you produce, and how to securely transmit such information to the FTC.

Sensitive PII includes an individual’s Social Security number; an individual’s biometric data (such as fingerprints or retina scans, but not photographs); and an individual’s name, address, or phone number in combination with one or more of the following: date of birth, Social Security number, driver’s license number or state identification number (or foreign equivalent), passport number, financial account number, credit card number, or debit card number. SHI includes medical records and other individually identifiable health information relating to the past, present, or future physical or mental health or conditions of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.

I-14. **Interrogatory Responses:** For specification requesting answers to written interrogatories, answer each interrogatory and each interrogatory subpart separately and fully, in writing, and under oath.

**Federal Trade Commission Bureau of Consumer Protection**  
**Production Requirements**  
Revised February 2018

In producing information in to the FTC, you must comply with the following production requirements, unless the FTC agrees otherwise. If you have any questions about these requirements, please contact FTC Counsel before production.

**Production Format**

1. **General Format:** Provide load-ready electronic productions with: (a) an Opticon image load file (.OPT) containing a line for every image file; and (b) a delimited data load file (.DAT) containing a line for every document, with bates references, metadata fields, and native file links, where applicable.
2. **Electronically Stored Information (“ESI”):** Documents stored in electronic format in the ordinary course of business must be produced in the following format:
  - a. For ESI other than the categories described below, submit in native electronic format with extracted text or Optical Character Recognition (OCR), all metadata, and corresponding image renderings converted to Group IV, 300 DPI, single-page Tagged Image File Format (TIFF) or color JPEG images (if color is necessary to interpret the contents or render them intelligible).
  - b. For Microsoft Excel, Access, or PowerPoint files, submit in native format with extracted text and metadata. Data compilations in Excel spreadsheets or in delimited text formats must contain all underlying data, formulas, and algorithms without redaction.
  - c. For other spreadsheet, database, presentation, or multimedia formats; instant messages; or proprietary applications, discuss production format during the meet and confer.
3. **Hard Copy Documents:** Documents stored in hard copy in the ordinary course of business must be scanned and submitted as 300 DPI individual single page TIFFs (or color JPGs when necessary to interpret documents or render them intelligible), with corresponding document-level OCR text and logical document determination in an accompanying load file.
4. **Extracted Text/OCR:** Submit text as document-level text files, named for the beginning bates number, and organized into a folder separate from images. We cannot accept Unicode text files.
5. **Document Identification:** Provide a unique DocId or bates number for each hard copy or electronic document, consisting of a prefix and a consistent number of numerals using leading zeros. Do not use a space to separate the prefix from numbers.
6. **Attachments:** Preserve the parent/child relationship by producing attachments as separate documents, numbering them consecutively to the parent email, and including a reference to all attachments.
7. **Metadata Production:** For each document submitted electronically, include standard metadata fields in a standard ASCII delimited data load file. The first line of the data load file shall include the field names. Submit date and time data in separate fields. Use these delimiters in delimited data load files:

Description	Symbol	ASCII Character
Field Separator	<	20
Quote Character	”	254

Multi Entry delimiter	@	174
<Return> Value in data	~	126

8. **De-duplication:** Do not use de-duplication or email threading software without FTC counsel approval.
9. **Password-Protected Files:** Remove passwords prior to production. If password removal is not possible, provide the original and production filenames and the password under separate cover.
10. **Sensitive PII or SHI:** Use data encryption to protect any Sensitive PII or SHI (as defined in the CID Schedule). Provide encryption passwords in advance of delivery, under separate cover.

**Producing and Submitting Media to the FTC**

1. Prior to production, scan all media and data for viruses and confirm the media and data are virus-free.
2. For productions smaller than 50 GB, the FTC can accept electronic file transfer via FTC-hosted secure file transfer protocol (Accellion or SecureZip). Contact FTC counsel to request this option. The FTC cannot accept files via Dropbox, Google Drive, OneDrive, or other third-party file transfer sites.
3. Use the least amount of media necessary for productions. Acceptable media formats are CDs, DVDs, flash drives, and hard drives. Format all media for use with Windows 7.
4. Use a courier service (e.g., Federal Express, UPS) because heightened security measures delay postal delivery. Mark the exterior of all packages containing electronic media with the following:

**MAGNETIC MEDIA – DO NOT X-RAY  
MAY BE OPENED FOR INSPECTION**

5. Provide a production transmittal letter with each production that includes:
  - a. Production volume name (e.g., Volume 1), date of production, and numeric DocID number range of all documents included in the production;
  - b. List of custodians and the DocID number range for each custodian;
  - c. Total number of records and all underlying images, emails, and associated attachments, native files, and databases in the production
  - d. List of load file fields in the order in which they are organized in the data file.

**Lewis Declaration**

**ATTACHMENT E**

**DEbrief**

---

**From:** Lederer, Miriam  
**Sent:** Friday, June 01, 2018 8:34 AM  
**To:** Lustigman, Andrew B.  
**Cc:** DEbrief  
**Subject:** RE: FTC v. Health Research Laboratories, Case No. 2:12-cv-00467-JDL

Andy,

Thanks for the response – I understand your email to be confirmation that your client agrees to the below rolling production.

I will arrange for someone to send the SFTP link next week – please let me know the name and email address of whoever will be uploading the data. The link is active for 72 hours from the time it is sent.

Have a good weekend.

Miriam

---

**From:** Lustigman, Andrew B. [mailto:ALustigman@olshanlaw.com]  
**Sent:** Friday, June 01, 2018 8:31 AM  
**To:** Lederer, Miriam  
**Cc:** DEbrief  
**Subject:** Re: FTC v. Health Research Laboratories, Case No. 2:12-cv-00467-JDL

Thank you. We will likely produce electronically.

Sent from my iPhone

On Jun 1, 2018, at 6:17 AM, Lederer, Miriam <[mlederer@ftc.gov](mailto:mlederer@ftc.gov)> wrote:

Andy,

Despite the last minute nature of this request, I am still willing to recommend that we not move forward with a contempt action on the basis of your clients' failure to produce all compliance materials by June 4, 2018, i.e., the time set forth in the Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief ("Order"), provided that your clients can agree to the following rolling production of information and documents:

By June 6, 2018:

1. A full response to Specification 5
2. A partial response to Specification 6 as set forth in your email, specifically:
  - a. Producing the mailers, telemarketing scripts, and labels for the 10 products marketed by mail since January 2018;
  - b. For the Internet-only products, having your client certify that the Internet copy has not changed since January 2018, and that no other marketing materials exist

- (i.e. telemarketing scripts, labels, etc.). To the extent they do exist, those should be produced;
- c. Having your client certify that, since January 2018, no other marketing materials exist for the Identified Products (as defined by Specification 5).
  3. A partial response to Specification 8, limited to the period starting at January 2018 to the date of production.
  4. An updated certification of the distribution of the order, including any additional order acknowledgements that your client has received, as well as a supplemental response to Specification 2 as requested in my May 21, 2018 letter.

I will review the materials immediately and let you know, no later than June 12, 2018, whether we need any of the additional requested materials. If so, those remaining materials will still be due by June 25, 2018.

Please confirm that your client will agree to the above rolling production.

If you plan to produce materials electronically, please let me know in advance so that I can arrange for someone to send an SFTP link to whoever will be uploading the data.

Have a good weekend.

Miriam R. Lederer  
Attorney, Division of Enforcement  
Bureau of Consumer Protection  
Federal Trade Commission  
600 Pennsylvania Ave., N.W., CC-9528  
Washington, D.C. 20580  
Phone: 202.326.2975  
Fax: 202.326.3197

---

**From:** Lustigman, Andrew B. [<mailto:ALustigman@olshanlaw.com>]  
**Sent:** Thursday, May 31, 2018 4:49 PM  
**To:** Lederer, Miriam  
**Cc:** DEbrief  
**Subject:** RE: FTC v. Health Research Laboratories, Case No. 2:12-cv-00467-JDL

Thank you for your response. My client is out today, and I'm out tomorrow. Can you please agree to accept the materials below by Wednesday, June 6?

Andrew B. Lustigman

**OLSHAN**

OLSHAN FROME WOLOSKY LLP

1325 Avenue of the Americas  
(Entrance is on 53<sup>rd</sup> Street between Sixth and Seventh Avenues)  
New York, NY 10019  
Direct: 212.451.2258  
Facsimile: 212.451.2222  
Email: [ALustigman@olshanlaw.com](mailto:ALustigman@olshanlaw.com)  
Web: [www.olshanlaw.com](http://www.olshanlaw.com)

---

**From:** Lederer, Miriam [<mailto:mlederer@ftc.gov>]  
**Sent:** Wednesday, May 30, 2018 5:00 PM  
**To:** Lustigman, Andrew B. <[ALustigman@olshanlaw.com](mailto:ALustigman@olshanlaw.com)>  
**Cc:** DEbrief <[DEbrief@ftc.gov](mailto:DEbrief@ftc.gov)>  
**Subject:** RE: FTC v. Health Research Laboratories, Case No. 2:12-cv-00467-JDL

Andy –

Thanks for your email. As I indicated in our recent phone call, at this time, we are not willing to withdraw any of the Specifications set forth in our compliance Requests. We are, however, willing to work with you and your clients so that we get the information we need to monitor their compliance in a way that your clients believe will be less burdensome.

To that end, I am willing to recommend that we not move forward with a contempt action on the basis of your clients' failure to produce all compliance materials by June 4, 2018, i.e., the time set forth in the Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief ("Order"), if your clients can agree to the following rolling production of information and documents:

By June 4, 2018:

1. A full response to Specification 5
2. A partial response to Specification 6 as set forth in your email, specifically:
  - a. Producing the mailers, telemarketing scripts, and labels for the 10 products marketed by mail since January 2018;
  - b. For the Internet-only products, having your client certify that the Internet copy has not changed since January 2018, and that no other marketing materials exist (i.e. telemarketing scripts, labels, etc.). To the extent they do exist, those should be produced;
  - c. Having your client certify that, since January 2018, no other marketing materials exist for the Identified Products (as defined by Specification 5).
3. A partial response to Specification 8, limited to the period starting at January 2018 to the date of production.
4. An updated certification of the distribution of the order, including any additional order acknowledgements that your client has received, as well as a supplemental response to Specification 2 as requested in my May 21, 2018 letter.

I will review the materials immediately and let you know, no later than June 8, 2018, whether we need any of the additional requested materials. If so, those remaining materials will be due by June 25, 2018.

Please confirm that your client will agree to the above rolling production.



In addition, I will be out of the office and unavailable starting at noon on Friday, June 1, 2018, and will not return until June 5, 2018. Therefore, if you plan to produce materials on June 4 electronically, please let me know so that I can arrange for someone to send an SFTP link to whoever will be uploading the data. If you have any other questions or concerns, please be in touch some time tomorrow so that we can work out any additional logistics.

Best,  
Miriam

Miriam R. Lederer  
Attorney, Division of Enforcement  
Bureau of Consumer Protection  
Federal Trade Commission  
600 Pennsylvania Ave., N.W., CC-9528  
Washington, D.C. 20580  
Phone: 202.326.2975  
Fax: 202.326.3197

---

**From:** Lustigman, Andrew B. [<mailto:ALustigman@olshanlaw.com>]  
**Sent:** Tuesday, May 29, 2018 4:45 PM  
**To:** Lederer, Miriam  
**Cc:** DEbrief  
**Subject:** RE: FTC v. Health Research Laboratories, Case No. 2:12-cv-00467-JDL

Miriam –

Following up on our discussion, we offer the following proposal to address the concerns raised, and to balance the burden imposed on my client who has cooperated with the FTC over the course of its 3.5 year investigation.

As it relates to your inquiry, the company is marketing the products identified on an Ex B. to the report. Since the entry of the permanent injunction in January 2018, the company has marketing by mail 10 products, with the remainder of the products marketed online at the two URLs previously provided.

For those 10 products marketed by mail, we propose to provide by June 4, the mailers, telemarketing scripts, and labels. For the Internet-only products, I am advised that the Internet copy has not changed during this time period, and is already available for your inspection. My client does not include additional marketing materials on fulfillment.

We will also provide an updated certification of the distribution of the order, including any additional order acknowledgments that have been received.

I trust that the foregoing would be sufficient for you to confirm my clients' compliance with the order.

Please let me know if you have any questions.

Best,  
Andy

Andrew B. Lustigman

## OLSHAN

OLSHAN FROME WOLOSKY LLP  
1326 Avenue of the Americas  
(Entrance is on 53<sup>rd</sup> Street between Sixth and Seventh Avenues)  
New York, NY 10019  
Direct: 212.451.2258  
Facsimile: 212.451.2222  
Email: [ALustigman@olshanlaw.com](mailto:ALustigman@olshanlaw.com)  
Web: [www.olshanlaw.com](http://www.olshanlaw.com)

---

**From:** Lederer, Miriam [<mailto:mlederer@ftc.gov>]  
**Sent:** Monday, May 21, 2018 4:27 PM  
**To:** Lustigman, Andrew B. <[ALustigman@olshanlaw.com](mailto:ALustigman@olshanlaw.com)>  
**Cc:** DEbrief <[DEbrief@ftc.gov](mailto:DEbrief@ftc.gov)>  
**Subject:** FTC v. Health Research Laboratories, Case No. 2:12-cv-00467-JDL

Dear Andy:

Please see that attached correspondence.

Best,  
Miriam

Miriam R. Lederer  
Attorney, Division of Enforcement  
Bureau of Consumer Protection  
Federal Trade Commission  
600 Pennsylvania Ave., N.W., CC-9528  
Washington, D.C. 20580  
Phone: 202.326.2975  
Fax: 202.326.3197

---

Electronic transmissions by the law firm of Olshan Frome Wolosky LLP may contain information that is confidential or proprietary, or protected by the attorney-client privilege or work product doctrine. If you are not the intended recipient, be aware that any disclosure, copying, distribution or use of the contents hereof is strictly prohibited. If you have received this transmission in error, please notify Olshan Frome Wolosky LLP at once at 212.451.2300.

**Lewis Declaration**

**ATTACHMENT F**

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

FEDERAL TRADE COMMISSION and  
STATE of MAINE,

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

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.

**SUPPLEMENTAL STATEMENT OF COMPLIANCE**

I, Kramer Duhon, on behalf of myself and Health Research Laboratories, LLC (hereinafter, the “Company”), do hereby state as follows:

1. The following Supplemental Statement of Compliance is submitted in response to Ms. Miriam R. Lederer’s letter dated May 21, 2018, as modified by her email of June 1, 2018. The information in this Supplemental Statement of Compliance and certain attachments hereto are designated Confidential and should be given the level of confidential treatment accorded by the provisions of 15 U.S.C. §§46(f) and 57b-2 and the Federal Trade Commission’s Rules of Practice as set forth at 16 C.F.R. §§4.10-4.11.

2. I have delivered or caused to be delivered a copy of the Stipulated Final Judgment And Order For Permanent Injunction And Other Equitable Relief (the “Order”) to the following persons and entities set forth at HRL004908. The Order Acknowledgements that were received are produced at Bates HRL004895-004907.

3. The Company's response to Specification No. 5 (listing of all products marketed since January 2018 and requested dates) is set forth at Bates HRL005223.

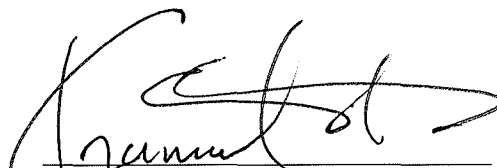
4. We have instituted a number of robust procedures at a significant investment cost to ensure reasonable compliance with the Order. For example, the products' efficacy claims have been reviewed by an independent scientific expert to confirm that they are supported by the appropriate level of scientific research. In addition, the Company's marketing materials that feature Dr. Richard Cohen are reviewed by him to confirm that the product claims are reasonably supported based on the current state of scientific literature. (A copy of his agreement, biography and approvals are produced at Bates HRL005207-5222). The mailers, Internet advertising and telemarketing scripts are submitted to the Olshan law firm for legal review. Moreover, the product labels have been reviewed by an independent scientific researcher.

5. With respect to Specification No. 6 (as modified), the company responds as follows. The Company marketed the following products by mail since January 2018: Betarol, Clear Colon Defense, Thyroid Essentials, BioStem, Neupathic, MaximumT, Black Garlic BG18, Black Garlic Botanicals, The Ultimate Heart Formula, Bladder Eze, and T-Plus. The labels for these products are produced at Bates HRL004909-4919; mailers are produced at Bates HRL004920-5101; and telemarketing scripts are produced at Bates HRL005102-5206. Since January 2018, I am unaware of the Company using any additional marketing channel or utilizing materially different marketing materials for the Identified Products (as defined by Specification 5).

6. With respect to Specification No. 8, I am unaware of any of the Identified Products or Essentially Equivalent Products being distributed by any authorized third-party retailer. As such, there are no advertisements responsive to Specification 8.

I certify that the foregoing is true and correct to the best of my knowledge and information based on my review of the books and records of the Company.

Executed on June 6, 2018



**KRAMER DUHON, individually  
and on behalf of Health Research  
Laboratories, LLC**

**Lewis Declaration**

**ATTACHMENT G**

**Nutritional Supplement**

**Suggested Use:** As a dietary supplement, adults take two (2) tablets daily, preferably with meals.

**KEEP OUT OF THE REACH OF CHILDREN**

**CONSULT YOUR DOCTOR PRIOR TO USE IF YOU HAVE OR SUSPECT A MEDICAL CONDITION, ARE TAKING PRESCRIPTION DRUGS, OR ARE PREGNANT OR LACTATING. NOT FOR USE BY INDIVIDUALS UNDER THE AGE OF 18 YEARS.**

**STORE PRODUCT AT 15 - 30°C (58 - 86°F)  
PROTECT FROM HEAT, LIGHT AND MOISTURE. DO NOT PURCHASE IF SEAL IS BROKEN**

**Manufactured Distributed by:  
Health Research Laboratories 165 Pleasant Ave.  
South Portland, ME 04106**

**TO REORDER, CALL TOLL-FREE 888-258-0339**

**THIS STATEMENT HAS NOT BEEN EVALUATED BY THE FDA. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE, OR PREVENT ANY DISEASE.**

MFP | WFLB - T57903 - 4246

# Betarol



**Helps Maintain Prostate Health  
and Sexual Well Being\*\***

## Dietary Supplement

60 Tablets

Supplement Facts		
Serving Size 2 Tablets Servings Per Container 30		
	Amount per serving	% Daily Value
Zinc (as Zinc Citrate)	10 mg	97%
Selenium (from Selenium Selenite)	25 mcg	50%
Pumpkin Seed Powder	100 mg	*
Beta Sterosterol Complex	300 mg	*
Beta Sterosterol	20 mg	*
Digoxin Sterol	15 mg	*
Cardosterol	15 mg	*
Brevisosterol	1.5 mg	*
Saw Palmetto (Serenoa repens) Extract (fruit, 25% fatty acids)	100 mg	*
Pygeol (Pygeum africanum/Phytosterol Complex (fruit, 25% phytosterols)	50 mg	*
Styrene Resin Extract (40% kaferones)	25 mg	*

Other ingredients: Dicalcium phosphate, silicon dioxide, vegetable stearic acid, hydroxypropyl cellulose, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, hypromellose, glycerin.

**PX 2**  
**HRL004909**



two (2) capsules daily, preferably with evening meal.

**KEEP OUT THE REACH OF CHILDREN.**

Consult your doctor prior to use if you have or suspect a medical condition, are taking prescription drugs, or are pregnant or lactating. Not for use by individuals under the age of 18 years.

STORE PRODUCT AS 15-30 °C (58-86 °F).  
PROTECT FROM HEAT, LIGHT AND MOISTURE.  
DO NOT PURCHASE IF SEAL IS BROKEN.

Manufactured for and distributed by  
**Health Research Labs**

165 Pleasant Avenue, South Portland, ME 04106

To Re-Order, Call Toll-Free 1-888-494-6187

**\*\*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.**

**CLEAR COLON DEFENSE**

**SUPPORTS COLON HEALTH\*\***

1 bln live cells per serving at the time of manufacture **60 CAPS**

**DIETARY SUPPLEMENT**

**Supplement Facts**

Serving Size: 2 capsules  
Servings Per Container: 30

	Amount Per Serving	% Daily Value
Flax seed ( <i>Linum usitatissimum</i> ) Powder	700 mg	*
Chlorella Broke Cells (2% chlorophyll)	200 mg	*
Apple Pectin ( <i>Pyrus malus</i> ) Powder	100 mg	*
Wheat Bran ( <i>Triticum aestivum</i> ) Powder	100 mg	*
Lactobacillus acidophilus	0.90 bln CFU	*
Bifidobacterium bifidum	0.10 bln CFU	*

\* Daily Value not established

**Other Ingredients:** Gelatin, Dicalcium Phosphate, Vegetable Magnesium Stearate, Silicon Dioxide.  
**Contains:** Wheat

**PX 2**  
HRL004910

Suggested Use: As a dietary supplement,  
adults take one (1) capsule daily preferably  
with a meal or as recommended by a  
physician.

KEEP OUT OF THE REACH OF CHILDREN.

Consult your doctor prior to use if you have  
or suspect a medical condition, are taking  
prescription drugs, or are pregnant or  
lactating.

STORE PRODUCT AT 15-30 °C (58-86 °F).  
PROTECT FROM HEAT, LIGHT AND  
MOISTURE.

\*\*This statement has not been evaluated  
by the Food and Drug Administration.  
This product is not intended to diagnose,  
treat, cure or prevent any disease.

# Thyroid Essentials

**FOR HEALTHY  
THYROID FUNCTION\*\***

**30 CAPSULES**

**DIETARY SUPPLEMENT**

## Supplement Facts

Serving Size: 4 capsules  
Servings Per Container: 30

	Amount Per Serving	% Daily Value
Vitamin E (as d-alpha tocopheryl succinate)	40 mg	268%
Iodine (from Seaceuticals™)	210 mcg	140%
Selenium (as L-selomethionine)	70 mcg	127%
Seaceuticals™ 3000 Sea Vegetation (whole thallus) powder (containing <i>Laminaria hyperborea</i> , <i>Ascophyllum nodosum</i> , <i>Laminaria digitata</i> )	75 mg	*

\* Daily Value not established.

Other Ingredients: Rice Flour, Gelatin, Vegetable Stearates & Silicates

Manufactured for and distributed by  
Health Research Labs, 165 Pleasant Ave, S Portland, ME 04106  
TO RE-ORDER, CALL TOLL-FREE 1-888-870-0533

**Suggested use:** Take two capsules daily preferably with meals as a dietary supplement.  
**KEEP OUT OF THE REACH OF CHILDREN**  
 STORE PRODUCT AT 15 - 30°C (58 - 86°F)

PROTECT FROM HEAT, LIGHT AND MOISTURE  
 TAMPER RESISTANT. DO NOT USE IF SEAL IS BROKEN.  
 DISCONTINUE USE IF YOU EXPERIENCE ADVERSE OR UNDESIRABLE SYMPTOMS.

**WARNING:** As with any dietary supplement, seek the advice of a health care professional before using this product.

Distributed by: **Health Research Labs**  
 165 Pleasant Ave.  
 South Portland, ME 04106  
 828-379-1431

This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

HEALTH RESEARCH LABS

**BioStem**

**Stem Cell Support<sup>+</sup>**  
**Liquid Biocaps**

**Dietary Supplement**  
**60 LIQUID BIOCAPS**

NPN# 80067382

**Supplement Facts**

Serving Size: 2 Capsules  
 Contains 60 Capsules

	Amount per serving	% Daily Value
Calories	8	
Calories from Fat	8	
Total Fat	0.8 g	1%*
Kleanth's Best® Blue Green Algae Powder (Aphanizomenon flos-aquae) (microalgae)	150 mg	**
Omega-3 Fish Oil (18 mg Eicosapentaenoic acid and 12 mg Docosahexaenoic acid)	50 mg	**
HyaMax® Non-GMO Hyaluronic acid (natural sodium hyaluronate from fermentation)	30 mg	**

\*Percent Daily Values are based on a 2,000 calorie diet.  
 \*\*Daily Value not established.

Other Ingredients: Rice bran oil, gelatin, vitamin E (D-alpha-tocopheryl acetate).

Contains Fish.

HyaMax® is a registered trademark of Feedherb Enterprises.

**Suggested Use:** As a dietary supplement, adults take two capsules daily preferably with meals.

**KEEP OUT THE REACH OF CHILDREN.**

**Consult your physician.**

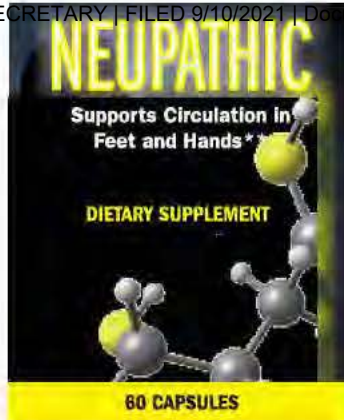
STORE PRODUCT AS 15-30 °C (58-86 °F). PROTECT FROM HEAT, LIGHT AND MOISTURE.

**Manufactured for and distributed by:**

Health Research Labs  
 165 Pleasant Ave.  
 South Portland, ME 04106.

**To Re-Order, Call Toll-Free 1-888-761-5490**

\*\*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.



**Supplement Facts**

Serving Size: 2 capsules  
 Servings Per Container: 30

	Amount Per Serving	% Daily Value
Vitamin E (as dl-alpha-tocopheryl acetate)	30 IU	100%
Vitamin B1 (as thiamine hydrochloride)	33.3 mg	2220%
Vitamin B6 (as pyridoxine hydrochloride)	33.3 mg	1665%
Folate (as folic acid)	766.7 mcg	87%
Vitamin B12 (as cyanocobalamin)	16.7 mcg	278%
Evening Primrose Oil (5% gamma linolenic acid)	866.7 mg	*

\* Daily Value not established  
**Other Ingredients:** Rice bran oil, gelatin (cassia), chlorophyll.

**Nutritional Supplement**

Suggested use: As a dietary supplement, adults should take 2 capsules daily with meals, or as recommended by a physician.

KEEP OUT OF THE REACH OF CHILDREN

STORE PRODUCT AT 15 - 30°C (58 - 86°F)  
 PROTECT FROM HEAT, LIGHT AND MOISTURE.

NOT FOR USE BY INDIVIDUALS UNDER THE AGE OF 18 YEARS.

DISCONTINUE USE IF YOU EXPERIENCE ADVERSE OR UNDESIRABLE SYMPTOMS.

TO REORDER, CALL TOLL-FREE 877-419-7679

Distributed by: Health Research Labs  
 165 Pleasant Ave.  
 South Portland, ME 04106

\* THIS STATEMENT HAS NOT BEEN EVALUATED BY THE FDA. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE, OR PREVENT ANY DISEASE.

# MAXIMUM!

Scientifically  
 Formulated  
 Testosterone Support

60 capsules

DIETARY SUPPLEMENT

NPN# 80067379

## Supplement Facts

	Amount per serving	% Daily Value
Vitamin B6 (as zinc monomethionine aspartate (ZMA) <sup>†</sup> )	0.0975 mg	5%
Magnesium (as zinc monomethionine aspartate (ZMA) <sup>†</sup> )	4.4 mg	1%
Zinc (as zinc monomethionine aspartate (ZMA) <sup>†</sup> )	0.295 mg	2%
Ginkgo (Ginkgo biloba) Powder (leaf)	250 mg	*
Tribulus (Tribulus terrestris) Powder (fruit)	250 mg	*
Asian ginseng (Panax ginseng) Powder (root)	150 mg	*
L-Arginine	100 mg	*
Chaste Berry (Vitis agnus-castus) Extract (berry 4:1)	62.5 mg	*
Fenugreek (Trigonotis foenum-graecum) Extract (seed, 4:1)	62.5 mg	*
Tongkat Ali (Eurycoma longifolia) Extract (root, 4:1)	62.5 mg	*
Oats (Avena sativa) Extract (aerial parts 10:1)	90 mg	*
Zinc monomethionine aspartate (ZMA) <sup>†</sup>	25 mg	*
Velvet Bean (Mucuna pruriens) Extract (seed, 20%)	75 mg	*
Chrysin (from Passion Flower Extract)	5 mg	*

\*Daily Value not established.

Other Ingredients: Gelatin, Magnesium Stearate, Silicon Dioxide, Maltodextrin

Suggested Use: As a dietary supplement, adults take two capsules daily, preferably with meals.  
KEEP OUT OF THE REACH OF CHILDREN.

Consult your doctor prior to use if you have or suspect a medical condition, are taking prescription drugs, or are pregnant or lactating. Not for use by individuals under the age of 18 years.

STORE PRODUCT AS 15-30 °C (58-86 °F). PROTECT FROM HEAT, LIGHT AND MOISTURE. DO NOT PURCHASE IF SEAL IS BROKEN.

Manufactured for and distributed by  
**Whole Body Supplements**  
165 Pleasant Ave, South Portland, ME 04106

To Re-Order, Call Toll-Free 1-888-493-8454

\*\*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.



SUPPLEMENT FACTS		
	Amount Per Serving	% Daily Value
Aged black garlic bulb powder (Allium sativum) (providing 3% polyphenols)	1200 mg *	
*Daily Value not established.		

Other Ingredients: Gelatin, Rice Flour, Vegetable Stearate, Silica.

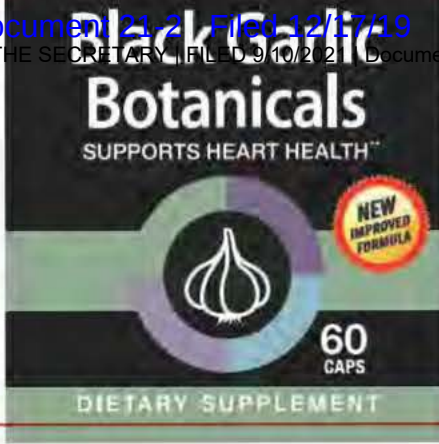
Suggested Use: As a dietary supplement, adults take two capsules daily preferably with meals.  
KEEP OUT THE REACH OF CHILDREN.

Consult your doctor prior to use if you have or suspect a medical condition, are taking prescription drugs, or are pregnant or lactating. Not for use by individuals under the age of 18 years.

STORE PRODUCT AS 15-30 °C (58-86 °F).  
PROTECT FROM HEAT, LIGHT AND MOISTURE.  
DO NOT PURCHASE IF SEAL IS BROKEN.

Manufactured for and distributed by  
**Health Research Labs**  
165 Pleasant Avenue, South Portland, ME 04106  
To Re-Order, Call Toll-Free 1-888-491-0724

\*\*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.



SUPPLEMENT FACTS		
	Amount Per Serving	% Daily Value
Aged black garlic bulb powder (allium sativum) (providing 3% polyphenols)	1200 mg	*
*Daily Value not established.		

Other Ingredients: Gelatin, Rice Flour, Vegetable Stearate, Silica.

<p><b>Suggested Use:</b>                  20 drops, 2-3 times daily. Well-tolerated. In each use. For liquid                  Supplement, adults take 20 drops, two times                  daily. For capsules, take 2 capsules, two times                  daily.</p> <p><b>KEEP OUT OF REACH OF CHILDREN.</b>                  Consult your doctor prior to use if you have or                  suspect a medical condition, are taking                  prescription drugs, or are pregnant or lactating.</p> <p>Manufactured for and distributed by:  <b>Health Research Laboratories</b>                  165 Pleasant Ave. South Portland, ME 04106                  To Re-Order, Call Toll-Free 1-866-493-2529</p> <p><small>**THIS STATEMENT HAS NOT BEEN EVALUATED                  BY THE FOOD AND DRUG ADMINISTRATION.                  THIS PRODUCT IS NOT INTENDED TO DIAGNOSE,                  TREAT, CURE OR PREVENT ANY DISEASE.</small></p>	<p>HEALTH RESEARCH LABS</p> <p><b>The                  Ultimate                  Heart                  Formula</b></p> <p>Multi-Ingredient Liquid Formula</p> <p>An Herbal Dietary Supplement                  For Optimal Heart Health**</p> <p>DIETARY SUPPLEMENT                  3.0 fl. oz. / 60 mL                  NPN# 80067236</p>	<p><b>Supplement Facts</b></p> <p>Serving Size: 1 mL (20 drops)                  Amount Per Serving % Daily Value*</p> <table border="1"> <tr> <td>Vitamin E (as Tocopheryl Acetate)</td> <td>55 IU</td> <td>&lt;2%</td> </tr> <tr> <td>Vitamin B12 (as Cyanocobalamin)</td> <td>100 mcg</td> <td>1887%</td> </tr> </table> <p><b>Proprietary Blend:</b>                  Aloe Vera Gel Juice (Aloe barbadensis),                  Resveratrol (EVA), Bilberry (Vaccinium                  myrtillus) Fruit Extract, Capsaicin (Capsicum                  frutescens) Fruit Extract, Garlic (Allium                  sativum) Bulb Extract, Ginger (Zingiber                  officinale) Root Extract, Kelp (Macrocystis                  perforata) Extract, Shiitake (Lentinula edodes)                  Leaf Extract, Orin (Ziziphus jujuba) Seed                  Extract, Propolis (Boraginaceae) Oil,                  Bromelain, Lactoferrin, Ubiquinol                  (Ubiquinol U3)</p> <p><small>*Percent Daily Values are based on a diet of other people's secrets.</small></p> <p><b>Other Ingredients:</b> Aqua (Distilled Water), Glycerin, Sorbitol,                  Gum, Natural Flavors, PEG-20 Hydrogenated Castor Oil, PEG-40                  Hydrogenated Castor Oil, Potassium Sorbate, Sodium Benzoate,                  Polysorbate-20, Acesulfame Potassium,                  Citric Acid, Soybean</p>	Vitamin E (as Tocopheryl Acetate)	55 IU	<2%	Vitamin B12 (as Cyanocobalamin)	100 mcg	1887%
Vitamin E (as Tocopheryl Acetate)	55 IU	<2%						
Vitamin B12 (as Cyanocobalamin)	100 mcg	1887%						



**SUGGESTED USE:**

As a dietary supplement, take 1-2 capsules with meals, 2-3 times daily.

KEEP OUT OF THE REACH OF CHILDREN.  
 STORE PRODUCT AT ROOM TEMPERATURE  
 DO NOT EXPOSE TO EXCESSIVE HEAT OR  
 MOISTURE.

NOT FOR USE BY INDIVIDUALS UNDER  
 THE AGE OF 18 YEARS. DO NOT USE IF  
 YOU ARE PREGNANT OR NURSING.

Manufactured for and distributed  
 to consumers by:  
**HEALTH RESEARCH LABS**  
 185 Pleasant Avenue  
 South Portland, ME 04106

TO REORDER CALL TOLL FREE:  
**1-866-955-0380**

THESE STATEMENTS HAVE NOT BEEN EVALUATED BY  
 THE FDA. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE,  
 TREAT, CURE OR PREVENT ANY DISEASE.

HEALTH RESEARCH LABS

**BLADDER SUPPORT FORMULA**



**60 CAPSULES**  
 DIETARY SUPPLEMENT

**Supplement Facts**

	per serving	Value
Vitamin D (as cholecalciferol)	800 IU	200%
Vitamin B12 (as cyanocobalamin)	12 mcg	200%
Magnesium (as magnesium citrate)	20 mg	5%
Pumpkin seed extract (10% fatty acids)	425 mg	*
Soybean Germ Extract	100 mg	*
Vitexinolin	7 mg	*
Cranberry fruit extract (1.0% proanthocyanidin)	50 mg	*

Daily Values not established  
 Other Ingredients: Gelatin, Cellulose, Silicon Dioxide, Magnesium Stearate

**PX2**  
 HRL004918

**Suggested use:** As a dietary supplement, adults take two (2) capsules daily, preferably with meals, or as recommended by a physician.

ZMA<sup>®</sup> is the original zinc-magnesium supplement and the only one validated by published clinical research.

**KEEP OUT OF THE REACH OF CHILDREN**

STORE PRODUCT AT 15 - 30°C (58 - 86°F)

PROTECT FROM HEAT, LIGHT AND MOISTURE.

NOT FOR USE BY INDIVIDUALS UNDER THE AGE OF 18 YEARS. DO NOT USE IF YOU ARE PREGNANT OR NURSING.

DISCONTINUE USE IF YOU EXPERIENCE ADVERSE OR UNDESIRABLE SYMPTOMS.

TO REORDER, CALL TOLL-FREE 877-657-0220

Distributed by: **Health Research Labs**  
 165 Pleasant Ave.  
 South Portland, ME 04106

\* THIS STATEMENT HAS NOT BEEN EVALUATED BY THE FDA. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE, OR PREVENT ANY DISEASE.

HEALTH RESEARCH LABS

# T-PLUS

Scientifically  
 Formulated  
 Testosterone Support

60 capsules

Dietary Supplement

### Supplement Facts

Serving size: 2 capsules  
 Servings per container: 30

	Amount per serving	% Daily Value
Vitamin B6 (as pyridoxine hydrochloride)	1.75mg	103%
Magnesium (as aspartate)	75mg	18%
Zinc (as zinc mono-L-methionine and aspartate)	8mg	48%
Oat Straw (Avena sativa) (from 10:1 extract)	500mg	*
Zinc Methylmethionine Aspartate (ZMA <sup>®</sup> )	400mg	*
Tribulus (fruit) Powder (Tribulus terrestris)	250mg	*
Ginkgo Biloba (leaf) Powder	250mg	*
Tongkat Ali (root) (Eurycoma longifolia) (from 4:1 extract)	250mg	*
Chaste Berry (Vitis agnus-castus) (from 4:1 extract)	250mg	*
Fenugreek (seed) (Trigonella foenum) (from 4:1 extract)	250mg	*
Korean Ginseng (root) Powder (Panax ginseng)	150mg	*
L-Arginine (base)	100mg	*
Mucuna Pruriens (seed) Extract (standardized to 20% L-Dopa)	25mg	*
Ghyslin	5mg	*
DHEA	1mg	*

\*Daily Value not established. Other Ingredients: Gelatin, Magnesium Silicate, Silicon Dioxide  
 ZMA<sup>®</sup> is a Federal trademark of SHAC System, Inc., San Carlos, CA 94070

**PX 3**

## **EXPERT REPORT OF FRANK M. SACKS, M.D.**

### **I. Credentials and Qualifications**

I am a Professor of Medicine at Harvard Medical School, a Professor of Cardiovascular Disease Prevention in the Department of Nutrition at Harvard T.H. Chan School of Public Health, and a Senior Physician at Brigham & Women's Hospital. In these roles, I engage in research and teaching related to hyperlipidemia, hypertension, and associated conditions in the prevention and treatment of cardiovascular disease (CVD).

My clinical field of expertise is lipidology. Clinical lipidology is the diagnosis and treatment of lipid disorders including hypercholesterolemia (high blood cholesterol), hypertriglyceridemia (high blood triglycerides), and low high-density lipoprotein (HDL) cholesterol. My clinical practice was in the Cardiology Division at Brigham and Women's Hospital from 1984 to 2010. I treated patients for the above-mentioned disorders, and often for additional conditions associated with cardiovascular disease, including hypertension, atherosclerosis, and type 2 diabetes.

I have substantial experience conducting randomized clinical trials, and my research has resulted in over 240 publications in peer-reviewed journals. I was the 2011 recipient of the American Heart Association (AHA)'s Research Achievement Award for lifetime research in cardiovascular disease. This was the top annual award of the AHA for research at the time.

I have held editorial positions with numerous publications in my fields of study. From 2007-2010, I was Associate Editor of *The American Journal of Clinical Nutrition*, the leading journal publishing research on nutrition and human disease. This position involved evaluating the quality and determining the acceptability of over 200 research manuscripts each year. I was

also an Associate Editor of the *Journal of Clinical Lipidology*.

Over the past ten years, I have peer-reviewed hundreds of papers submitted for publication to scientific journals. Many involved randomized, double-blind, and placebo-controlled clinical studies or other types of clinical studies. Nearly all involved the study of CVD or coronary heart disease (CHD) or related endpoints. Additional details about my credentials and qualifications are provided in my *curriculum vitae* (Attachment A). Based on my education, training and experience, I consider myself an expert in the fields of CVD, CHD, cholesterol disorders, hypertension, and atherosclerosis as well as the design, conduct, and analysis of clinical trials.

I previously testified as an expert in *FTC v. POM Wonderful*, FTC Docket No. 9344. I have also testified in other cases that are identified in Attachment A. I am being compensated for my work on this matter by the FTC at the rate of \$350 per hour.

## **II. Scope of Review and Summary of Conclusions**

In connection with this case, counsel for the FTC asked me to provide my expert opinion on several questions:

1. Are cardiovascular disease, atherosclerosis, and hypertension diseases?

Answer: Yes, all three are diseases.

2. Have the defendants, Health Research Laboratories and Kramer Duhon, provided competent and reliable scientific evidence substantiating the truth of their representations that Black Garlic Botanicals, BG18, and Ultimate Heart Formula cures, treats or mitigates cardiovascular disease, atherosclerosis, and hypertension? Specifically, did defendants have randomized, double-blind, and placebo-controlled human clinical testing, conducted by researchers qualified by training and experience to conduct such testing, of Black Garlic Botanicals, BG18, Ultimate Heart Formula or an Essentially Equivalent Product as that term is defined in the January 16, 2018 Order, that is sufficient in quality or quantity based on standards generally accepted by experts in cardiovascular disease, atherosclerosis, or hypertension, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the above representations are true?

Answer: No, the defendants do not have such human clinical testing to support claims that their products cure, mitigate, or treat cardiovascular disease, atherosclerosis, or hypertension.

3. What is your expert opinion as to whether Black Garlic Botanicals, BG18, and Ultimate Heart Formula or their ingredients, if properly tested with randomized, double-blind, placebo controlled human trials, could cure, mitigate, or treat cardiovascular disease, atherosclerosis, or hypertension?

Answer: Based on my 23 years of professional experience in the fields of cardiovascular disease, atherosclerosis, hypertension and hyperlipidemia, as well as my review of available evidence from human studies, there is no reason to believe that Black Garlic Botanicals, BG18, and Ultimate Heart Formula or their ingredients can cure, mitigate, or treat cardiovascular disease, atherosclerosis, or hypertension. It is much more likely that these products have no effect on these diseases.

### III. Materials Considered

In preparing this report and my conclusions, I considered the following documents provided to me by counsel for the FTC:

- (1) Letters from defendants' counsel to the FTC dated January 30, April 10, June 20, and September 27, 2019.
- (2) Purported substantiation and related documents submitted to the FTC by defendants' counsel.  
HRL005240-5435, HRL007714-7901, HRL007732-007749, HRL008150, HRL008151-008156, HRL008157-008162, HRL008164-008169, HRL008170-008231
- (3) Labels for Black Garlic Botanicals, BG18, and Ultimate Heart Formula.  
HRL004909-004919
- (4) Advertising for Black Garlic Botanicals and Ultimate Heart Formula.  
HRL004984-004999, HRL005068-005083
- (5) *Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief* entered in *FTC and Maine v. Health Research Laboratories, LLC, et al.*, No. 2:17-cv-00467-JDL (Jan. 16, 2018).

In developing my opinions, I also considered and performed an independent review of relevant materials that included searches of the PubMed, National Library of Medicine ("PubMed") database for human clinical trials on black garlic, nattokinase, EDTA chelation, and

Coenzyme Q10 (“CoQ10”). PubMed is a research database containing peer-reviewed biomedical literature and is the definitive, comprehensive resource used by research scientists to find articles that broadly pertain to medical and health science. I looked for, and was unable to find, any randomized, double-blind, and placebo-controlled human clinical trials involving products with the same combination of ingredients or the same doses of the purportedly active ingredients in BG18, Black Garlic Botanicals, or Ultimate Heart Formula. Such randomized, double-blind, placebo-controlled trials are the evidence-based standard to establish that an agent cures, mitigates, or treats a disease.

Randomization refers to a method by which study patients are assigned, randomly, to either the active product group or the control group. Randomization is important to help eliminate the possibility that a researcher may consciously or subconsciously employ a selection bias, for example, assign healthier or less healthy people to the treatment group, as compared to the control group. Randomization creates a likelihood that the make-up of the treatment and control groups will be similar on all relevant characteristics. A trial is double blind if neither the subject nor the investigator knows which subjects are receiving the placebo or the tested treatment. Double-blindness is important to avoiding inadvertent bias by the subject or the investigator. A trial is placebo-controlled if one group of subjects receives the treatment that is being tested, while another separate control group receives an inactive pill or treatment that has no therapeutic effect. This is important to account for a “placebo effect,” where a subject shows improvement even when receiving an ineffective treatment. It is also important because factors such as the passage of time and other environmental changes can result in changes to the endpoint being measured.

#### **IV. Cardiovascular Disease, Atherosclerosis, and Hypertension**

Cardiovascular disease refers to heart attack, angina pectoris (chest pain due to heart disease), heart failure, and stroke. Unquestionably, these are diseases, which, in fact, comprise by far the most prevalent life-threatening conditions, globally. Cardiovascular disease includes disease afflicting the large arteries that supply blood to the heart (coronary arteries) and brain (carotid and vertebral arteries and their branches). Blood flow through arteries can be reduced by blockages caused by cholesterol deposits from high levels of low density lipoprotein (“LDL”) and the resulting inflammatory and thrombotic reactions in the vessel wall, known as atherosclerosis. Atherosclerosis is a disease. High blood pressure and high LDL-cholesterol concentration in blood are the two most important causes of atherosclerosis, heart attack and stroke. (Grundy SM et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation 2018; pp.1-75.)

Hypertension, commonly referred to as high blood pressure, is also a disease. (Whelton PK, Carey RM. The 2017 Clinical Practice Guideline for High Blood Pressure. JAMA. 2017 Dec 5;318(21): 2073-2074.) High blood pressure damages the large blood vessels by making them stiff, fibrous and calcified. It also damages the kidneys causing them to secrete hormones that further increase blood pressure. High blood pressure also damages the small blood vessels which deliver arterial blood to the capillary beds of organs and tissues. The pressure in the small vessels increases causing higher resistance to the flow of blood to the organs, requiring still higher levels of blood pressure to compensate. High blood pressure damages the heart by thickening the muscular wall of the left ventricle. The heart undergoes chronic strain, leading to heart failure.



**V. Evaluation of Studies and Materials That Defendants Provided Related to Black Garlic and Aged Garlic Extract**

I reviewed all of the articles and materials related to garlic and black garlic that defendants submitted to the FTC prior to the date of this report in response to requests for substantiation of claims related to BG18, Black Garlic, and Ultimate Heart Formula. I also performed a literature search using PubMed with “black garlic” as the search term. A total of 221 citations were retrieved by PubMed. Limiting the search to humans yielded 103 citations, and limiting to clinical trials yielded 7 citations of which only two tested the effect of black garlic on endpoints related to cardiovascular disease, atherosclerosis, and hypertension. Therefore, clinical trials of black garlic (also known as aged black garlic) are few. None of the clinical trials of black garlic tested the same dose as found in BG18 and Black Garlic Botanicals.

Each capsule of BG18 and Black Garlic Botanicals contains 600 mg of black garlic. The recommended serving on the labels is two capsules for a total daily dose of 1200 mg (1.2g) (HRL004915, HRL004916). Thus, an important consideration in my evaluation of the studies involving black garlic is the amount of daily dose tested in comparison to the recommended daily serving size of BG18 and Black Garlic Botanicals. Because the tested products have higher doses of black garlic than do defendants’ products, they are not essentially equivalent to defendants’ products under the terms of the January 16, 2018 Order.

Composition and Bioequivalence

The particular form and preparation of garlic tested is critically important. Like products providing a different dose of black garlic than provided by defendants’ products, forms of garlic that differ chemically from black garlic are not essentially equivalent to defendants’ products because they are not identical ingredients or the same form of ingredient. As explained in more detail below, the substantiation submitted and relied upon by defendants to support their claims

related to BG18/Black Garlic Botanicals primarily consists of trials testing aged garlic extract, rather than black garlic.

Garlic has many chemical components that affect its sensory properties as well as its effects on biological systems. Black garlic is made by treating garlic cloves at high temperature, 70C, and 90% humidity for 35 days (HRL005272-005284: Choi IS, *Molecules* 2014;19:16811-16823). Lawson LD and Hunsaker SM (*Nutrients* 2018;10:1-49) tested garlic prepared in similar conditions, 60C-90C, 80-90% humidity, and 30-40 days. Since all black garlic is aged, the products are often called “aged black garlic.” The process causes the garlic cloves to turn purple or black and eliminates the pungent smell and taste of fresh garlic. This process greatly alters the chemical composition of garlic. Flavonoids and polyphenols increase; alliin, allicin, and glutamyl S-allyl cysteine (GSAC) decrease to near undetectable levels; and S-allyl cysteine (SAC), a conversion product of GSAC, is the only known compound remaining (Lawson and Hunsaker. *Nutrients* 2018;10:1-49). This distribution of bioactive compounds is unique among garlic preparations that have been studied in clinical trials.

Lawson and Hunsaker have hypothesized that other, uncharacterized sulfur-containing conversion and degradation products of alliin are produced during the aging process of black garlic. Noting these differences in composition between black garlic and fresh garlic, it is clear that black garlic is likely to have biological effects that differ from other garlic preparations, including aged garlic extract, powdered fresh garlic, and enteric coated garlic tablets. Harunobu Amagase, Ph.D., Institute of Pharmaceutical Sciences, Hiroshima University School of Medicine, and later at the Institute for Medical Research, Wakunaga Pharmaceuticals reviewed the constituents of various garlic preparations (Amagase H. Clarifying the real bioactive constituents of garlic. *J Nutr.* 2006 Mar;136(3 Suppl):716S-725S). Dr. Amagase published many

articles on bioactive compounds, including those in black garlic, in well-regarded biomedical sciences journals, such as *American Journal of Clinical Nutrition*, and *Journal of Nutrition*. He stated: “Because different garlic preparations consist of different constituents, the safety and effectiveness of each product must be examined through toxicological and pharmacological tests.” *Id.*

Lawson and Hunsaker (cited above) also have described an increase in anti-inflammatory and anti-oxidant properties of black garlic, possibly caused by polyphenols and flavonoids. However, largely to the contrary, Ryu and Kang describe recent studies that compared the biological activity and function of aged black garlic to those of raw garlic. Black garlic had lower anti-inflammatory, anti-coagulation, immunomodulatory, and anti-allergic effects but more antioxidant effects compared to raw garlic (Ryu JH, Kang D. *Molecules* 2017;22(6):1-14).

The studies of Budoff and colleagues cited by the defendants as purported substantiation for their claims for Black Garlic Botanicals and BG18 tested aged garlic extract, not black garlic (HRL007714-007901, HRL007732-007749, HRL008150, HRL008151-008156, HRL008157-008162). Aged garlic extract, which has been tested in many more trials than black garlic, is made from fresh garlic by a completely different method than that used to make aged black garlic. To make aged garlic extract, fresh raw garlic cloves are sliced, incubated in 20% ethyl alcohol for up to 20 months at ambient temperature. (Lawson and Hunsaker. *Nutrients* 2018;10:1-49). The product has GSAC, SAC, and a small amount of alliin, a chemical composition that differs from black garlic. *Id.* The studies of Budoff and colleagues reported favorable effects on coronary calcium scores. (HRL007732-007749, HRL008150, HRL008157-008162). However, he was not testing black garlic and his finding has not been confirmed in trials by other researchers and in other populations.

The study of Ried and colleagues cited by defendants as purported substantiation for their claims also tested aged garlic extract, not black garlic (HRL008170-008182). This study showed a favorable effect of aged garlic extract on systolic blood pressure. In general, no pattern of findings was evident across the disparate studies in the literature related to aged garlic extract that I have reviewed to support the conclusion that aged garlic extract is a therapeutic agent for cardiovascular disease or its causes, high blood pressure and LDL-cholesterol.

Given the unique chemical composition of different types of garlic preparations, it is not appropriate to generalize the effects of one garlic preparation to another. Indeed, for this reason, garlic preparations other than black garlic are not essentially equivalent to defendants' products Black Garlic Botanicals and BG18 because they are not identical ingredients or the same form of the ingredient. Therefore, for the purposes of this evaluation, I consider only studies that used black garlic.

#### Clinical Trials of Black Garlic

As described above, I conducted a thorough search of the relevant literature using PubMed and found only two human clinical trials testing the effect of black garlic on endpoints related to cardiovascular disease, atherosclerosis, and hypertension.

Jung et al. conducted a human clinical trial and reported that black garlic, administered in the amount of 6 grams per day, had no effect, compared to placebo, on LDL-cholesterol, triglyceride, or apolipoprotein A1 (Jung ES et al. Reduction of blood lipid parameters by a 12-wk supplementation of aged black garlic: A randomized controlled trial. *Nutrition* 2014;30:1034-1039). LDL-cholesterol is a fully established cause of atherosclerosis and cardiovascular disease that the FDA recognizes as a surrogate for cardiovascular disease in clinical trials. The results of this trial therefore suggest that black garlic does not affect atherosclerosis and cardiovascular

disease. Notably, the study of Jung et al. did not measure blood pressure, cardiovascular disease, or atherosclerosis outcomes. Because 6 g of black garlic per day had no effect, it is extremely unlikely that the smaller recommended daily dose of 1.2 g found in BG18 and Black Garlic Botanicals would. In any event, this study did not test an essentially equivalent product because it involved a dose of black garlic five times the dose provided by defendants' BG-18 and Black Garlic Botanicals products.

Liu et al. performed a clinical trial studying adults who had heart failure secondary to coronary heart disease. (Liu J, Zhang G, Cong X, Wen C. Black garlic improves heart function in patients with coronary heart disease by improving circulating antioxidant levels. *Frontiers in Physiology* 2018;9:1435.doi: 10.3389/fphys.2018.01435). The 120 participants were randomly allocated to receive black garlic in the amount of 20 g daily or an unspecified placebo for one month. All outcomes pertaining to cardiac function were improved in the black garlic group compared to the placebo control group. These outcomes included quality of life, walking distance, and left ventricular ejection fraction. Here again, as the dose of 20 g of black garlic administered in this trial is 17 times the recommended daily dose of 1.2 g found in Black Garlic Botanicals and BG18, this trial did not test an essentially equivalent product. Moreover, it is extremely unlikely that the low dose found in Black Garlic Botanicals and BG18 would be effective. The positive therapeutic findings in this study also need confirmation in additional trials and populations.

## **VI. Evaluation of Studies and Materials that Defendants Provided Related to Certain Ingredients in Ultimate Heart Formula**

There are no randomized, double-blind, placebo-controlled trials involving Ultimate Heart Formula or an essentially equivalent product with the same combination of active ingredients found in Ultimate Heart Formula. Such product-specific testing is important because even in cases where individual constituent ingredients have been shown to be efficacious in treating a particular condition in one particular formulation, that same ingredient may not have the same effect when combined with different ingredients.

Defendants have submitted to the FTC some studies and materials relating to only a few of the individual ingredients in Ultimate Heart Formula including: garlic, CoQ10, EDTA, and nattokinase. For the reasons explained below, none of these ingredient studies constitute competent and reliable evidence that Ultimate Heart Formula cures, mitigates, or treats cardiovascular disease, hypertension, or atherosclerosis. Defendants did not submit studies testing the other ingredients in Ultimate Heart Formula.

#### Garlic Extract

Ultimate Heart Formula contains garlic extract, 25 mg. This dose is very low compared with the doses that have been tested in clinical studies of various garlic products, e.g., 1200 mg of aged garlic extract in the studies of Budoff and Ried cited as purported substantiation by defendants. Defendants have provided no clinical studies showing that such a low dose of garlic extract or any other garlic preparation would be effective, and I did not find any in my review of literature related to various garlic preparations.

#### CoQ10

As part of my evaluation, I reviewed the articles and materials that defendants have provided to the FTC discussing CoQ10. In addition, I performed a PubMed literature search for CoQ10 that was restricted to systematic reviews and meta-analyses of trials, in an effort to

confirm whether there was any additional support for claims that the dosage of CoQ10 in Ultimate Heart Formula cures, treats, or mitigates cardiovascular disease, atherosclerosis, or high blood pressure. The search identified 73 citations, which I evaluated.

Ultimate Heart Formula has 5 mg of CoQ10 per capsule. (Letter from Andrew Lustigman, Esq. to Robert Frisby, Esq. dated Apr. 10, 2019). All of the studies that defendants have submitted to the FTC, and those I found in my literature review, tested doses of CoQ10 much higher than the 5 mg provided by defendants' Ultimate Heart Formula product. Therefore, these trials did not test a product essentially equivalent to Ultimate Heart Formula. Moreover, each study also suffers from other flaws, such as faulty statistical analysis as described below, or did not find evidence that CoQ10 conferred a health benefit. The articles that the defendants provided to the FTC related to CoQ10 included the following:

**HRL005342-5435: Singh U, Devaraj S, Jialal I. Coenzyme Q10 supplementation and heart failure, Nutrition Reviews 2007;65:6.** This article is a review on CoQ10 to treat heart failure. The authors included and discussed the meta-analysis of Sander S et al. (J Cardiac Failure 2006;12:464) that covered the literature through 2003. The main finding was a significant increase in left ventricular ejection fraction (a critical measure of the pumping action of the heart) in the CoQ10 group. The doses were 60-200 mg per day, significantly higher than the 5 mg dose found in Ultimate Heart Formula.

**HRL005299-005308: Tran et al. Pharmacotherapy 2001;21(7):797–806.** This article is a non-quantitative narrative review discussing the use of CoQ10 in patients with cardiovascular disease. It is not a critical evaluation of the merits of studies, and it is not a randomized, controlled trial. Notably, the authors conclude: “Coenzyme Q10 therapy in angina

and hypertension cannot be substantiated until additional clinical trials demonstrate consistent beneficial effects.”

**HRL005309-005316: Langsjoen P, et al. Molec Aspects of Med 1994;15**

**(Supplement): S265.** This is a case series in 109 patients, in which CoQ10 was added to blood pressure lowering drugs. A case series is a group of patients with a disease who are treated in one or more clinical practices. There is no control group. Thus, changes in disease over time in the case series could be the result of many influences and not specific to the CoQ10. A case series does not have reliability as in a randomized, controlled trial.

**HRL005317-005321:** This is the PDR for supplements. It is a non-quantitative, non-systematic narrative review on CoQ10. It reports positive results in heart failure and other diseases. It is not a critical evaluation of the merits of studies, and it is not a randomized, controlled trial.

**HRL005322-005326: Langsjoen P et al. Clin Investig (1993) 71:S 140-S 144.** This is a case series in which patients who had diastolic dysfunction (impaired pumping of the heart) were given CoQ10. It is not a randomized, controlled trial.

**HRL005327-005334: Baggio et al. Molec. Aspects Med 1994;15 (Supplement):S287.** This is a multicenter post-marketing study in 2664 heart failure patients who were given CoQ10 together with drug treatments. It is a case series with no control group. It is not a randomized, controlled trial.

**HRL005335-005341: Singh RB et al. CV Drugs Therapy 1998;12:347.** This article reported the results from a placebo-controlled study of CoQ10 involving 144 patients after acute myocardial infarction. The dose was 120 mg of CoQ10 per day which is much higher than the 5 mg dose in Ultimate Heart Formula. The authors reported significant (63-67%) reductions in



arrhythmia, non-fatal myocardial infarction, and angina. These are very large reductions that are highly unusual in clinical trials in cardiovascular disease. I also recognize that the first author, RB Singh, is the same individual who purportedly found reductions in cardiovascular disease in a controlled trial of a Mediterranean diet to patients in India. The study was published in *British Medical Journal* (“BMJ”), one of the world’s highest quality medical journals, in 1992. However, the BMJ subsequently published a letter expressing concern about possible scientific misconduct and data fabrication that cast doubt on the validity of Singh’s 1992 paper. *See* BMJ. 2005 July 30; 331 (7511): 266 (expression of concern), 281-288 (describing investigation of Singh). Although I did not find a similar expression of concern pertaining to the 1998 publication of Singh et al. related to the CoQ10 trial, the outsized reductions in cardiac events and the irregularities in Singh’s earlier work lead me to doubt the reliability of reported results in Singh’s CoQ10 trial.

**HRL005350-005356: Lei L, Liu Y. BMC Cardiovasc Disorders 2017;17:196.** This is a systematic review and meta-analysis focusing on CoQ10 and heart failure. The review included only placebo-controlled, randomized trials. Analysis of the results of included trials suggested that there was a reduction in mortality of 31%, improved exercise tolerance, and no effect on left ventricular ejection fraction associated with CoQ10. The results were largely driven by a single study, which contributed 43% of the fatalities (Mortensen SA, Rosenfeldt F, Kumar A, Dolliner P, Filipiak KJ, Pella D, Alehagen U, Steurer G, Littarru GP. The effect of coenzyme Q10 on morbidity and mortality in chronic heart failure: results from Q-SYMBIO: a randomized double-blind trial. *JACC Heart failure*. 2014; 2(6):641–649). The dose in that study was 100 mg three times a day for a total daily dose of 300 mg, which is much higher than the 5 mg of CoQ10 in Ultimate Heart Formula.

The trials relied upon by the defendants and discussed above, other than the favorable Mortensen study, were not randomized and double-blind. Furthermore, all of the trials tested doses of CoQ10 far exceeding the dose in Ultimate Heart Formula. I also considered a number of systematic reviews and meta-analyses of trials involving CoQ10 described below, that I independently identified in my PubMed searches.

**Jorat M et al., (Lipids in Health and Disease 2018;17:230).** This review found no effect of CoQ10 on LDL-cholesterol and triglycerides. LDL-cholesterol is a prime cause of atherosclerosis and cardiovascular disease because it brings cholesterol into the artery wall and causes inflammation. Triglycerides is literally the fat transported in the bloodstream, and it too promotes atherosclerosis and cardiovascular disease.

**Madmani ME et al. (Cochrane Database Syst Rev. 2014 Jun 2;(6):CD008684. doi: 10.1002/14651858.CD008684.pub2).** This was a Cochrane review looking at the effects of CoQ10 on heart failure. (A Cochrane review is a structured review with meta-analysis that adheres to widely accepted methodology for evaluating a topic across many studies.) There were no effects on left ventricular ejection fraction or exercise capacity. The authors' conclusion was: "No conclusions can be drawn on the benefits or harms of coenzyme Q10 in heart failure at this time as trials published to date lack information on clinically relevant endpoints. Furthermore, the existing data are derived from small, heterogeneous trials that concentrate on physiological measures: their results are inconclusive."

**Flowers N et al. (Cochrane Database Syst Rev. 2014;(12):CD010405. doi: 10.1002/14651858.CD010405.pub2. Epub 2014 Dec 4. 2014).** This Cochrane review also found no clear evidence for an effect of CoQ10 when administered at a dosage of 100-200 mg per day on primary prevention of cardiovascular disease, blood pressure or blood lipids.

**Ho MJ et al. (Cochrane Database of Systematic Reviews 2016, Issue 3. Art. No.: CD007435. DOI: 10.1002/14651858.CD007435.pub3).** This Cochrane review concluded: “This review provides moderate-quality evidence that coenzyme Q10 does not have a clinically significant effect on blood pressure.”

This group of systematic reviews and meta-analyses had data from only a few randomized controlled trials to work with. The findings did not show conclusive evidence for beneficial effects of CoQ10 on blood pressure, LDL-cholesterol or heart failure. Furthermore, the doses used in the studies included in the meta-analyses, 100-200 mg daily, are 20-40 times greater than the 5 mg contained in Ultimate Heart Formula. Therefore, as noted above, these studies did not test a product essentially equivalent to Ultimate Heart Formula. Given how weak the evidence is for a beneficial effect in published trials involving higher doses of CoQ10, it is even more unlikely that the small amount of CoQ10 in Ultimate Heart Formula produces any effect.

#### EDTA

Ultimate Heart Formula contains 40 mg of EDTA, formulated for oral administration. (HRL004917 and Letter from Andrew Lustigman, Esq. to Robert Frisby dated Apr. 10, 2019). None of the materials submitted by defendants to the FTC discuss randomized, double-blind, placebo-controlled clinical trials involving the oral administration of 40 mg of EDTA to study participants. Instead, the materials provided by defendants to the FTC discuss EDTA chelation therapy, which is not comparable. EDTA chelation therapy is used to cause excretion from the body of potentially toxic metals such as cadmium, and calcium, which accumulates in atherosclerosis. EDTA that is used for chelation therapy is administered intravenously (IV), and at a much higher dose, such as 3 grams, 75 times that found in Ultimate Heart Formula. (Lamas

GA et al. Effect of Disodium EDTA Chelation Regimen on Cardiovascular Events in Patients with Previous Myocardial Infarction The TACT Randomized Trial. JAMA. 2013;309(12):1241-1250). Because these studies tested a much higher dose of EDTA, and administered it to subjects through IV instead of orally, they did not test a product that is essentially equivalent to Ultimate Heart Formula.

I also searched the literature using PubMed for any studies that administered EDTA orally rather than intravenously. Although practitioners of chelation therapy advocate oral use, especially when IV is not tolerated (*e.g.*, HRL05421 - Gerber), I could not find even a mention of oral administration in articles that reported randomized clinical trials of EDTA chelation.

#### Nattokinase

Nattokinase is a component of natto, which is produced by fermentation of soybeans. Nattokinase has clot-dissolving properties, called fibrinolytic activity, demonstrated in humans (HRL005373-005377, Sumi et al.). There is a sparse literature on the effects of nattokinase. Defendants submitted a few articles discussing nattokinase to the FTC which I have reviewed (HRL005368-005400). I also independently searched the literature using PubMed and retrieved 150 citations using the search term “nattokinase.” I did not find any randomized, double-blind, placebo-controlled trials testing dosages of nattokinase that were the same as the dosage found in Ultimate Heart Formula.

Ultimate Heart Formula contains 10 mg of nattokinase per capsule. The dose of nattokinase used in human studies is expressed in terms of fibrinolytic units (FU). Doses tested in human clinical trials are typically 100 mg, having 2000 FU. Ultimate Heart Formula has only 200 FU. All of the studies I reviewed and discuss below tested doses much higher than provided

by Ultimate Heart Formula, and therefore none of the studies involved products that were essentially equivalent to the Ultimate Heart Formula.

**HRL005373-005377, Sumi et al. (Act Haematol 1990; 84: 139-143).** In this study, the researchers compared the effect of natto (200 g) to boiled soybeans (200 g) in 22 healthy adults. There was no mention of a randomization procedure for allocation of research participants to natto or soybeans. The changes after a single morning intake of natto in fibrinolytic activity were significantly different from boiled soybeans. In a second experiment, the researchers gave participants two 650 mg enteric coated capsules of nattokinase three times a day after meals. There was no control group. Results were improved thrombolysis, which reached plateau at 8 days.

**HRL005383-005388: Kim JY et al. (Hypertes Res 2008; 31:1583)** at Yonsei University in Seoul, South Korea, reported the results of a randomized, double-blind, placebo-controlled trial of nattokinase in 73 participants with untreated hypertension for 8 weeks. In this trial, nattokinase significantly lowered systolic and diastolic blood pressure. However, the dose tested was 2000 FU per capsule per day, which is ten times the amount found in Ultimate Heart Formula, and therefore not essentially equivalent.

**Yoo HJ et al. (Food Funct., 2019; 10: 2888)** also working at Yonsei University reported results of a randomized, double-blind, placebo-controlled trial of nattokinase on circulating blood clotting proteins factors in 100 participants. The dose tested was 100 mg per day, equivalent to 2000 FU, again ten times the amount found in Ultimate Heart Formula. Nattokinase prolonged platelet aggregation time, representing reduced clot-forming ability. Nattokinase had no effect on blood pressure, LDL cholesterol, triglycerides, HDL cholesterol,

glucose, fibrinogen, or C-reactive protein (an indicator of inflammation). Thus, Yoo et al. did not confirm the effects on blood pressure reported by the earlier study by Kim et al.

**Jensen GS et al. (Integrated Blood Pressure Control 2016;9 95-104)** reported the results of an 8-week randomized, placebo-controlled, double blind trial administering 100 mg (2000 FU) of nattokinase per day to 74 patients with hypertension. Compared to placebo, nattokinase did not affect systolic blood pressure. Nattokinase lowered diastolic blood pressure by 3 mm compared to placebo. The dose of nattokinase tested in this trial was, again, much higher than in Ultimate Heart Formula.

**Kurasawa Y et al. (Sci Rep 2015; 5:11601 | DOI: 10.1038/srep11601)** reported the results of a single dose, placebo-controlled trial involving the administration of 2000 FU of nattokinase in 12 healthy young men during 8 hours. The dose tested in the trial was ten times the amount found in Ultimate Heart Formula, and therefore this trial did not test an essentially equivalent product.

Finally, **Hsia CH et al. (Nutrition Research 2009; 29:190–196)** reported the results of a placebo-controlled trial administering 4000 FU of nattokinase per day for 2 months in 45 participants. Compared to placebo, no significant changes occurred in the nattokinase group. However, the authors claimed an effect of nattokinase by considering only the change from baseline in the nattokinase group and not considering the changes in the control group. This is an erroneous type of analysis because it violates valid statistical procedures in analyzing randomized trials, which always must subtract the changes in outcomes in the placebo group from those in the treated group. There is no purpose to having a control group if the analysis does not utilize its data.

Collectively, this sparse group of trials do not yield consistent findings of any effects of nattokinase on blood clotting, fibrinolysis, blood pressure, or LDL-cholesterol. Moreover, the dosages administered in all of these trials were much higher than in Ultimate Heart Formula. Since the typical dose of nattokinase tested was 100 mg, it is safe to infer that the much lower amount in Ultimate Heart Formula, 10 mg, also has no effect. In any event, because the studies tested much higher doses of nattokinase, they did not test products essentially equivalent to Ultimate Heart Formula. Therefore, they do not constitute competent and reliable scientific evidence.

**VII. Opinion as to Whether It Is Likely That Black Garlic Botanicals/BG18 or Their Active Ingredient Cure, Mitigate, or Treat Cardiovascular Disease, Atherosclerosis, or Hypertension**

Having studied the scientific literature related to black garlic, I conclude that black garlic has no established effects on cardiovascular disease, hypertension, or atherosclerosis. The very few published randomized, placebo-controlled trials of black garlic that have been conducted, discussed above in Section V, administered doses of black garlic between 6-20 grams per day that are much higher than the daily dose of 1.2 grams in Black Garlic Botanicals and BG18. If a very large dose is not effective, a smaller dose is also very likely to be ineffective in curing, mitigating or treating cardiovascular disease, atherosclerosis, or hypertension. Thus, there is no reason to believe that a properly conducted human clinical trial of Black Garlic Botanicals/BG18 or an essentially equivalent product would show that they cure, mitigate or treat cardiovascular disease, hypertension, or atherosclerosis.

As discussed above, many of the studies that defendants provided in support of their product claims tested aged garlic extract, which is a different preparation from black garlic, with different biochemical properties. Defendants did not provide, and I did not independently find,

any studies that tested products with both the same dose and form of garlic found in Black Garlic Botanicals and BG18.

**VIII. Opinion as to Whether It Is Likely That Ultimate Heart Formula or Its Active Ingredients Cure, Mitigate, or Treat Cardiovascular Disease, Atherosclerosis, or Hypertension**

Ultimate Heart Formula contains garlic extract, 25 mg. This is much lower than doses of aged garlic extract and other garlic preparations that have been tested in clinical studies, which generally did not show an effect. Thus, it is very unlikely for 25 mg of garlic extract to have a clinical effect to cure, mitigate or treat cardiovascular disease, atherosclerosis, or hypertension. Ultimate Heart Formula also contains EDTA, CoQ10, and nattokinase. The doses of these ingredients in the product are also very low, compared to the amounts studied in randomized, controlled trials of these ingredients, as I explained earlier. Moreover, controlled trials have not established beneficial effects of high doses of EDTA, CoQ10 or nattokinase, and in fact yielded mostly negative findings (no effect). Thus, it is very unlikely that these three components of Ultimate Heart Formula can cure, mitigate or treat cardiovascular disease, hypertension, or atherosclerosis.

Defendants did not submit studies testing the other ingredients in Ultimate Heart Formula. However, based on my experience treating patients, conducting and reviewing clinical studies, and reviewing medical literature relating to these diseases, I have no reason to think that any of the other ingredients in Ultimate Heart Formula would cure, treat, or mitigate them. Moreover, there is no reason to believe that a properly conducted human clinical trial of Ultimate Heart Formula or an essentially equivalent product would show that the product is effective in curing, mitigating or treating cardiovascular disease, hypertension, or atherosclerosis.



I declare under penalty of perjury under the laws of the United States of America that this report is a true and correct statement of my opinions and expert testimony. If called to testify, I could and would testify to this expert opinion.



Frank M. Sacks, M.D.

Date: December 11, 2019  
Executed in Boston, Massachusetts

---

## **Expert Report of Frank M. Sacks**

### **ATTACHMENT A**

CURRICULUM VITAE

December 1, 2019

NAME: Frank M. Sacks

EDUCATION:

1970 Biology, Sc.B. Brown University  
1970-1972 Music, New England Conservatory of Music  
1977 M.D. Columbia University, College of Physicians and Surgeons

POSTDOCTORAL TRAINING:

Internship and Residency:

1977-1978 Resident in Surgery, University Hospital, Madison, Wisconsin

Research Fellowship:

1980-1982 Research Fellow in Medicine, Harvard Medical School and Brigham and Women's Hospital

LICENSURE:

1980 Massachusetts

CURRENT APPOINTMENTS:

2000- Professor of Cardiovascular Disease Prevention, Department of Nutrition, Harvard T.H. Chan School of Public Health  
2004- Professor of Medicine, Harvard Medical School  
2004- Senior Physician, Channing Division of Network Medicine, Department of Medicine, Brigham & Women's Hospital  
2015- Professor of Molecular Metabolism, Harvard T.H. Chan School of Public Health

PAST APPOINTMENTS

1992-2004 Associate Professor of Medicine, Harvard Medical School  
1992-2004 Physician, Brigham and Women's Hospital  
1993-2000 Associate Professor in the Department of Nutrition, Harvard School of Public Health  
1992-1993 Assistant Professor in the Department of Nutrition, Harvard School of Public Health

1982-1991 Associate Physician, Brigham and Women's Hospital  
1984-1993 Assistant in Medicine, Beth Israel Hospital, Boston  
1984-1992 Assistant Professor of Medicine, Harvard Medical School  
1982-1984 Instructor in Medicine, Harvard Medical School  
1980-1982 Research Fellow in Medicine, Harvard Medical School  
1979-1980 Clinical Assistant Professor of Family Practice, University of Wisconsin School of Medicine  
1978-1979 Staff Physician, Migrant Health Services, Wild Rose, Wisconsin  
1979-1980 Attending Physician, St. Mary's Hospital, Madison, Wisconsin

#### HONORS AND DISTINCTIONS:

1972 Rockefeller Foundation Award for teaching philosophy of science in the Department of Humanities, New England Conservatory of Music  
1974 Annual Prize for Predoctoral Research, Society for Epidemiologic Research  
1980-1982 Individual Postdoctoral Research Award, United States Public Health Service  
1982-87 Clinician Scientist Award, American Heart Association, Jan Breslow-Preceptor; Edward Kass-Sponsor  
1986 Travenol Award Lecture, American College of Nutrition  
1987-1992 Established Investigator Award, American Heart Association, Eugene Braunwald, Sponsor  
1999 Pierre Bois Lecturer, McGill University and the University of Montreal  
2002 Myant Lecturer, British Hyperlipidemia Society  
2011 2011 Research Achievement Award of the American Heart Association for lifetime research accomplishments  
2013 Kelly West memorial lecture, University of Oklahoma Medical School  
2014 Don Chapman memorial lectureship, Baylor College of Medicine, Houston  
2016 Michael G. Wohl Memorial Lecture, Temple U., Philadelphia  
2018 Rank Lecture on Nutrition, Royal College of Physicians, London  
2019 Robert I. Levy Memorial Lecture, American Heart Association, Scientific Sessions, Philadelphia, 2019

#### MAJOR PROFESSIONAL SERVICE

1993-97 National Heart, Lung and Blood Institute. Chair, Design and Analysis Committee, Dietary Approaches to Stop Hypertension (DASH) Trial, a multicenter trial on dietary patterns and blood pressure.  
1996-2000 National Institutes of Health. Nutrition Study Section  
1997-2001 National Heart, Lung, and Blood Institute. Chair, Steering Committee, the Dietary Patterns, Sodium Intake and Blood Pressure trial (DASH2), a multicenter trial.

- 2000-2017 Organizing Committee and Co-Chair, Lipoprotein Kinetics Conference, Satellite Meeting to the Arteriosclerosis, Thrombosis and Vascular Biology Council Meeting, American Heart Association.
- 2001 National Cholesterol Education Program, Adult Treatment Panel III, Reviewer of Year 2002 guidelines
- 2002 NIH, NHLBI: Speaker, Workshop on Lipoprotein (a)
- 2002 NIH, NHLBI: Workshop participant, Diet and Congestive Heart Failure
- 2003 NIH, NHLBI: Chair, Committee on 5-year nutrition research agenda
- 2003 NIH, NHLBI: Member, Committee on 5-year obesity research agenda
- 2003-07 NIH, NHLBI: Member, DSMB, Gene Environment Interaction Project
- 2004 NIH, NHLBI: Working group on future clinical research directions on omega-3 fatty acids and cardiovascular disease.
- 2006 NIH, NHLBI: Consultant group on clinical trial design for lipid drugs
- 2007-10 American Journal of Clinical Nutrition, Associate Editor
- 2000-14 American Heart Association, Nutrition Committee, Member
- 2010-12 American Heart Association, Nutrition Committee, Chair
- 2010-12 American Heart Association, Leadership Committee, Nutrition Physical Activity and Metabolism Council
- 2008-11 NCEP ATP-IV: NHLBI Clinical Guidelines for Cardiovascular Risk Reduction, National Cholesterol Education Program ATP-IV Expert Panel member
- 2008-2013 Lifestyle Working Group member, NHLBI Clinical Guidelines for Cardiovascular Risk Reduction.
- 2009 Institute of Medicine, National Academy of Sciences, consultant on dietary treatments for hypertension.
- 2009 Institute of Medicine, National Academy of Sciences, panel on salt reduction; presented position of the American Heart Association.

- 2009 United States Dietary Guidelines Panel, invited presentation on diet treatment of obesity and sodium reduction goals.
- 2009-12 Residual Risk Reduction Institute: Trustee
- 2010-12 Endocrine Society, Guidelines Panel on treatment of high triglycerides
- 2012-15 American Heart Association: Sodium Advisory Task Force, Co-Chair
- 2013 NIH, NHLBI: Co-Chair of Workshop on Diet and Heart Failure
- 2016 NIH, NHLBI: Co-Chair of Workshop on Mediterranean Diet trial
- 2016 American Society of Nutrition, Committee to select a new editor-in-chief of American Journal of Clinical Nutrition
- 2018 Chair, HDL Workshop at American Heart Association Vascular Discovery
- 2018-2020 Vice Chair, American Heart Association Council on Lifestyle and Cardiometabolic Health
- 2019 Co-Chair, HDL Workshop, International Society of Atherosclerosis, Valencia, Spain

#### EDITORIAL POSITIONS

- 2007-15 Journal of Clinical Lipidology (Associate Editor, Editorial Board)
- 2006-14 Journal of Lipid Research (Editorial Board)
- 2008-11 American Journal of Clinical Nutrition (Associate Editor)

#### MAJOR RESEARCH INTERESTS:

Human lipoprotein metabolism: Discovery and metabolism of protein-based HDL subspecies that protect against or promote atherosclerosis. Effects of diet, drugs, apolipoproteins CIII and E. Identification of dysfunctional HDL metabolism in humans.

Epidemiology of protein-based HDL subspecies as risk factors for cardiovascular disease: Studies of 15 new HDL subspecies, some having protective, others adverse associations with cardiovascular disease. Effects of diet and drugs on these HDL subspecies. These epidemiological studies are linked in scientific scope to the metabolism studies.

Nutritional control of blood pressure and lipid levels: multi-center NIH-NHLBI diet trials. Chair of the Design Committee of the DASH trial. Chair of the DASH-Sodium Steering Committee: “Effects of dietary patterns and sodium intake on blood pressure.” Co-Chair, “Macronutrients and Cardiovascular Risk” (OMNI Heart), a trial of protein, carbohydrate and unsaturated fat to optimize cardiovascular risk factors. Chair of Omni-CARB: “Carbohydrate, type and amount affecting risk of CVD and diabetes”.

Dietary treatment of obesity. PI of multicenter NIH trial (POUNDS LOST) that compared diets for weight loss.

Dietary effects on cognition in older people. A diet called MIND, similar to DASH or the Mediterranean Diet, is being tested to determine if it can slow age-related decline in cognition.

#### RESEARCH FUNDING

2003-2009, NIH: 1 UO1 HL073286, F Sacks, PI. Dietary macronutrients and weight loss.

2007-2012, NIH: 1R01 HL084568, F Sacks, PI. Carbohydrate amount and type affecting risk of CVD and diabetes.

2010-2015: NIH, Dietary Fat and HDL Metabolism in Humans. F Sacks, PI.

2009-2010: Harvard University Catalyst Program: CTSC NIH award for innovative and translational research: Human HDL metabolism in obesity and dyslipidemia

2009-2012: R3i Foundation grant for an international case-control study of dyslipidemia and both macrovascular and microvascular disease.

2011-2012: Harvard University Research Accelerator Program: To support human studies on differentiating HDL into protective and nonprotective components.

2012-2013: Harvard-Roche Academic Collaboration: Grant to continue research on HDL.

2014-2019: NIH-NHLBI, F Sacks PI. HDL proteins and cardiovascular disease

2016-2021: NIH NIA, F Sacks, PI, Harvard Study Center, MIND trial to prevent dementia

#### PRINCIPAL CLINICAL AND HOSPITAL SERVICE RESPONSIBILITIES:

1984-2010 Attending Physician, Hyperlipidemia Clinic, Cardiovascular Division, Brigham and Women's Hospital.

#### PROFESSIONAL SOCIETIES:

1983- Fellow, Council on Arteriosclerosis, American Heart Association

1983- Fellow, Council on Epidemiology, American Heart Association

1994- Fellow, American Society of Clinical Nutrition

2000- Fellow, Council on Lifestyle and Cardiometabolic Health, American Heart Association

## TEACHING

### HARVARD SCHOOL OF PUBLIC HEALTH

- 1998-2020 The Science of Human Nutrition; Nutritional Metabolism and Biochemistry (NUT202); Course director
- 2004-2016 Scientific Writing (IS 206), Course director

### HARVARD MEDICAL SCHOOL AND TEACHING HOSPITALS

(HMS = Harvard Medical School; BWH = Brigham & Women's Hospital)

- 1984-2010 Cardiovascular Division Clinic, BWH: clinical teaching of treatment of hyperlipidemia to students, house staff, cardiology fellows and endocrinology fellows
- 2004-2012 BWH General Internal Medicine residents and faculty: Lectures on hyperlipidemia
- 1986-2010 BWH CME: Office Practice of Primary Care; Lectures on hyperlipidemia
- 2005-09, 2012, 2015 Harvard School of Public Health and Culinary Institute of America, "World of Healthy Eating", workshop for management in the food industry, St. Helena, California
- 2008 BWH, Cardiovascular Grand Rounds: Apolipoproteins and CVD
- 2009 BWH, Cardiovascular Grand Rounds: Diet composition to treat obesity
- 2015-17 BWH, Nutrition Department, Lecture to interns on dietary evidence

### REGIONAL, NATIONAL, OR INTERNATIONAL TEACHING

#### 2019

- Cleveland Clinic, Lectures on diet to prevent cardiovascular disease; and on HDL subspecies
- Lipoprotein Kinetics Satellite Meeting, American Heart Association Vascular Discovery; lecture on kinetic modeling of HDL metabolic data.
- European Atherosclerosis Society, Conference on lipoproteins, Mainz, Germany; lecture on mechanisms pertaining to triglyceride-rich lipoproteins and HDL.
- HDL Workshop, International Society of Atherosclerosis; co-chair and lecture on HDL subspecies
- Tulane University, Lecture on HDL subspecies



American Heart Association Scientific Sessions, Robert Levy Memorial Lecture  
Georgetown University Italian Research and Culture Institute, lecture on healthful dietary patterns

## **2018**

Royal College of Physicians, London. 500<sup>th</sup> anniversary celebration. Rank Nutrition Lecture.  
National Lipid Association annual scientific meeting. Lecture on LDL and HDL subtypes

## **2017**

American Heart Association, ATVB Council Scientific Sessions, HDL workshop, invited presentation on HDL subspecies  
Shanghai Institute for Biological Sciences, International Conference on Precision Health and Precision Nutrition, Lecture on dietary fats and dietary patterns to prevent disease  
American Heart Association Scientific Session, Lecture and workshop on dietary fat.

## **2016**

American College of Cardiology scientific sessions, Lecture on triglycerides and HDL  
Temple U. Hospital, Philadelphia, Wohl annual lecture on diet and CVD  
American Heart Association, ATVB Council Scientific Sessions, Lecture on apoC3  
NHLBI, Co-Chair workshop on planning a trial of Mediterranean diet  
Gordon Research Seminar on Lipoproteins: Lecture on building an academic career in biomedical sciences  
Gordon Research Conference on Lipoprotein Metabolism: Lecture on HDL subspecies metabolism  
EASD meeting on dietary carbohydrate, Prague. Lecture on OmniCarb study and glycemic index  
Tufts Univeristy, conference on postprandial lipoproteins. Lecture on postprandial metabolism.  
American Heart Association, Scientific Sessions, Lecture on HDL metabolism  
American Heart Association, Scientific Sessions, Lecture on dietary controversies

## **2015**

National Lipid Association clinical conference, Lecture on apoC-III  
American Heart Association, Lipoprotein kinetics workshop, Lecture on HDL metabolism  
American Heart Association, ATVB Council Scientific Sessions, HDL workshop, Lecture on HDL subspecies and metabolism.  
International Symposium on Atherosclerosis, Amsterdam, Lecture on apoC-III

International Carbohydrate Quality Consortium, Toronto, Lecture on glycemic index  
Cardiometabolic Diseases Conference, Quebec City, Lecture on diet and obesity  
American Heart Association Scientific Sessions, Lecture on apoE and apoC-III controlling lipoprotein metabolism; and on apoC-III as a target for treatment.  
Tufts University Human Nutrition Research Center, lecture on glycemic index  
U. Connecticut, lecture on apoC-III  
Cardiometabolic Conference, Boston, Lecture on diet to prevent heart disease and obesity  
Translational Medicine Academy, HDL Science Workshop, Lecture on HDL metabolism  
Beaumont Hospital, Michigan, Medical Grand Rounds on dietary treatment

## **2014**

American Heart Association, Scientific Sessions, Lecture on diet for weight loss  
American Heart Association, Scientific Sessions, Lecture on dietary patterns for cardiovascular health: Mediterranean, Vegetarian, and Paleo  
American Heart Association, ATVB Council Scientific Sessions, Lecture on human HDL metabolism.  
Baylor College of Medicine, Don Chapman Memorial Lecture on apoC-III, lipoprotein metabolism, CVD

## **2013**

University of Utah, Pathology Grand Rounds, Lecture on apolipoproteins and CVD  
Utah Atherosclerosis and Lipid Society: Lecture on apolipoproteins  
University of Cincinnati Medical Center: Lecture on apolipoproteins and CVD  
University of Oklahoma Medical School: Kelly West Memorial Lecture on apolipoproteins and CVD  
American Heart Association Epidemiology-Nutrition Councils Scientific Sessions, Lecture on trial of carbohydrate and CVD and diabetes  
American Heart Association, Lipoprotein Kinetics Workshop, Lecture on HDL metabolism  
NIH, NHLBI, Workshop on Diet and Heart Failure, Lecture on sodium trials  
American Heart Association Workshop on Sodium and health, Lecture on sodium studies

## **2012**

Tokyo Medical and Dental University: Lecture on apoC-III and cardiovascular disease  
National Defense Medical University, Tokorozawa, Japan: Lecture on diet and CVD

Japan Hypertension Society, Nagoya, Japan: Lectures on diet and hypertension  
Great Wall Congress on Cardiology, Beijing, China: Lecture on lipids and vascular disease  
Singapore National University School of Public Health: Lecture on diet and CVD  
National University Hospital of Singapore: Lecture on lipids and CVD  
ASEAN Society of Cardiology meeting, Singapore: Lecture on lipids and CVD  
Oklahoma Medical Research Foundation: Lecture on apolipoproteins and CVD  
University of Massachusetts, Amherst: Lecture on diet and CVD  
American Heart Association, Industry Nutrition Advisory Panel meeting: Lecture on the scientific basis for the AHA sodium reduction goals.

## **2011**

Tokyo Medical and Dental University: Lecture on diet and cardiovascular disease  
National Defense Medical University, Tokorozawa, Japan: Lecture on apoC-III  
National Lipid Association, New York: Lecture on diet and weight loss  
Gordon Conference on Atherosclerosis, Newport, RI: Lecture on apoC-III  
Great Wall Cardiology Conference, Beijing. Lecture on lipoproteins.  
AHA Scientific Sessions, Lecture on HDL function  
AHA Scientific Sessions, Lecture on diet and vascular aging  
AHA Scientific Sessions, Lecture on global hypertension control

## **2010**

Keystone Conference on Triglycerides: Lecture on apolipoprotein C-III  
Quebec Lipidology Society: Lecture on dyslipidemia and residual risk  
Beaumont Hospital, Royal Oak, Michigan: Lecture on diet to prevent CVD  
American Heart Association Conference on Added Sugars: Lecture on added sugar  
Japan Diabetes Association, Okayama, Japan: Lecture on lipid risk factors in diabetes  
Karolinska Institute, Stockholm, Sweden: Lecture on diet and cardiovascular disease  
Nagoya University, Japan: Lecturer, Conference on Sodium and Hypertension

## **2009**

Medstar CRT symposium, Washington DC, lecture on hypertriglyceridemia  
MSDA conference, Berlin, Germany: lecture on apolipoproteins  
International Symposium on Atherosclerosis, Boston: lectures on nutrition and obesity

School of Medicine, Universidad de los Andes, Bogota, Columbia: visiting professor  
European Society of Cardiology, Barcelona: lecture on lipoprotein risk factors  
Metabolic Syndrome Institute conference, Joslin Diabetes Center, Boston  
Bari, Puglia, Italy: Conference on Mediterranean diet and health; Lecture on recent science  
The Heart.org: Roundtable on genetic markers of cardiovascular risk and response to therapy

**2008**

Northeast Lipid Association annual meeting, Lecture on hyperlipidemia  
American College of Cardiology annual meeting, Lecture on hyperlipidemia  
American Diabetes Association annual meeting, Lecture on hyperlipidemia  
University of Sydney, Australia, NHMRC clinical trials unit, Lecture on hyperlipidemia  
American Heart Association Scientific Sessions, Lecture on postprandial lipoproteins

**2007**

American Heart Association Scientific Sessions, presenter  
Australian Atherosclerosis Society annual meeting, Perth, visiting lecturer  
Drugs Affecting Lipid Metabolism conference, New York City, speaker  
Metabolic Syndrome Institute meeting, St Petersburg Russia, speaker  
University of Texas Southwestern, Dallas, visiting professor  
National Lipid Association annual meeting, speaker  
European Atherosclerosis Society meeting, Helsinki, speaker  
Metabolic Syndrome Diabetes and Atherosclerosis Congress, Lisbon, speaker  
American Heart Association, Arteriosclerosis Council meeting, abstract presentation  
Insulin Resistance conference, International Diabetes Federation, Barcelona, speaker  
American College of Cardiology, annual meeting, speaker  
American Heart Association, Epidemiology Council meeting, speaker  
Ottawa Heart Institute, grand rounds  
St. Michael's Hospital, Toronto, grand rounds  
University of California Davis, cardiology grand rounds  
National Institutes of Health, inter-institute endocrine grand rounds

**2006**

American Heart Association, Obesity Conference, 1/2006, speaker

IBC Life Sciences, Metabolic Syndrome Conference, Boston, 3/2006, speaker  
University of Washington, Seattle, Cardiovascular Grand Rounds, 4/2006  
Columbia University, conference on hypertriglyceridemia, speaker, 4/2006  
American Heart Association, Arteriosclerosis Council meeting, presenter, 4/2006  
International Atherosclerosis Society meeting, Rome, speaker, 6/2006  
European Society of Cardiology meeting, Barcelona, speaker, 9/2006  
Biomarkers conference, U Montreal and FDA, Bethesda, panel discussant, 9/2006  
NIH, NHLBI, Cardiovascular Knowledge Networks meeting, participant, 9/2006  
American Heart Association, Trans Fat conference, Washington, speaker, 10/2006  
Cleveland Clinic, conference on obesity, speaker, 10/2006  
Cardiometabolic Institute conference, Boston, speaker, 10/2006  
American Heart Association, Scientific Sessions, speaker, 11/2006  
NIH, NHLBI, Lipid Advisory Panel, participant, 11/2006  
American College of Cardiology conference, NYC, speaker, 12/2006  
New York Lipid and Vascular Biology Club annual meeting, speaker, 12/2006

## **BIBLIOGRAPHY:**

### **Peer-Reviewed Journals:**

1. Sacks FM, Rosner B, Kass EH. Blood pressure in vegetarians. *Am J Epidemiol* 1974;100:390-394.
2. Zinner SH, Martin LF, Sacks FM, Rosner B, Kass EH. A longitudinal study of blood pressure in childhood. *Am J Epidemiol* 1974;100:437-442.
3. Sacks FM, Castelli WP, Donner A, Kass EH. Plasma lipids and lipoproteins in vegetarians and controls. *New Engl J Med* 1975; 292:1148-1151.
4. Sacks FM, Donner A, Castelli WP, Gronemeyer J, Pletka P, Margolius HS, Landsberg L, Kass EH. Effect of ingestion of meat on plasma cholesterol of vegetarians. *JAMA* 1981;246:640-644.
5. Sacks FM, Breslow JL, Wood PG, Kass EH. Lack of an effect of dairy protein (casein) and soy protein on plasma cholesterol of strict vegetarians. An experiment and a critical review. *J Lipid Res* 1983; 24:1012-1020.
6. Sacks FM, Marais GE, Handysides G, Salazar J, Miller L, Foster JM, Rosner B, Kass EH. Lack of an effect of dietary saturated fat and cholesterol on blood pressure in normotensives. *Hypertension* 1984; 6:193-198.

7. Sacks FM, Wood PG, Kass EH. Stability of blood pressure levels in vegetarians receiving dietary protein supplements. *Hypertension* 1984; 6:199-201.
8. Sacks FM, Salazar J, Miller L, Foster JM, Sutherland M, Samonds KW, Albers JJ, Kass EH. Ingestion of egg raises plasma low density lipoproteins in free-living subjects. *Lancet* 1984;i:647-649.
9. Sacks FM, Ornish D, Rosner B, McLanahan S, Castelli W, Kass EH. Plasma lipoprotein levels in vegetarians. The effect of ingestion of fats from dairy products. *JAMA* 1985;254:1337-1341.
10. Sacks FM, Handysides GH, Marais GE, Rosner B, Kass EH. The effect of a low fat diet on plasma lipoproteins in normal adults. *Arch Intern Med* 1986;146:1573-1577.
11. Sacks FM, Breslow JL. Very low density lipoproteins stimulate cholesteryl ester formation in U937 macrophages. Heterogeneity and biologic variation among normal humans. *Arteriosclerosis* 1987;7:35-46.
12. Sacks FM, Stampfer MJ, Munoz A, McManus K, Canessa M, Kass EH. Effect of linoleic and oleic acids on blood pressure, blood viscosity and erythrocyte cation transport. *J Am College Nutr* 1987;6:179-185.
13. Sacks FM, Rouse IL, Stampfer MS, Bishop LM, Lenherr C, Walther RJ. Effect of dietary fats and carbohydrate on blood pressure of mildly hypertensive patients. *Hypertension* 1987;10:452-460.
14. Sacks FM, Kass EH. Low blood pressure in vegetarians. The effects of specific foods and nutrients. *Am J Clin Nutr* 1988;48:795-800.
15. Kushi LH, Samonds KW, Lacey JM, Brown PT, Bergan JG, Sacks FM. The association of dietary fat with serum cholesterol in vegetarians: the effect of dietary assessment on the correlation coefficient. *Am J. Epidemiol* 1988;128:1054-64.
16. Figge HL, Figge J, Souney PF, Sacks FM, Shargel L, Janosik J, Kaul AF. Comparison of excretion of nicotinuric acid after ingestion of two controlled release nicotinic acid preparations. *J Clin Pharmacol* 1988; 28:1136-40.
17. Sacks FM, Creager MA, Gallagher SJ, Loscalzo J, Dzau VJ. Effects of alpha- and beta-adrenergic antagonists on plasma apolipoproteins and forearm blood flow in patients with mild hypertension. *Am J Med* 1989;86(1B):8-13.
18. Alderman JD, Pasternak RC, Sacks FM, Smith HS, Monrad ES, Grossman W. Effect of a modified, well-tolerated niacin regimen on serum total cholesterol, high density lipoprotein cholesterol and the cholesterol to high density lipoprotein ratio. *Am J Cardiol* 1989;64:725-9.

19. Reis GJ, Boucher TM, Sipperly ME, Silverman DI, McCabe CH, Baim DS, Sacks FM, Grossman W, Pasternak RC. Fish oil for the prevention of restenosis after coronary angioplasty: results of a randomized placebo-controlled trial. *Lancet* 1989;2:177-181.
20. Witteman JC, Willett WC, Stampfer MJ, Colditz GA, Sacks FM, Rosner B, Speizer FE, Hennekens CH. Dietary calcium and magnesium and hypertension; a prospective study. *Circulation* 1989;80:1320-1327.
21. Hankinson SE, London SJ, Chute CG, Barbieri RL, Jones L, Kaplan LA, Sacks FM, Stampfer MJ. Effect of transport conditions on the stability of biochemical markers in blood. *Clin Chem* 1989;35:2313-2316.
22. Swain JF, Rouse IL, Curley CB, Sacks FM. Comparison of the effects of oat bran and low fiber wheat on serum lipoproteins and blood pressure. *New Engl J Med* 1990;332:147-152.
23. Witteman JC, Willett WC, Stampfer MJ, Colditz GA, Sacks FM, Rosner B, Speizer FE, Hennekens CH. Relation of moderate alcohol consumption and risk of systemic hypertension in women. *Am J Cardiol* 1990;65:633-637.
24. Reis GJ, Silverman DI, Boucher TM, Sipperly ME, Horowitz GL, Sacks FM, Pasternak RC. Effects of two types of fish oil supplements on serum lipids and plasma phospholipid fatty acids in coronary artery disease. *Am J Cardiol* 1990; 66:1171-1175.
25. Silverman DI, Reis GJ, Sacks FM, Boucher TM, Pasternak RC. Usefulness of plasma phospholipid n-3 fatty acid levels in predicting dietary fish intake in patients with coronary artery disease. *Am J Cardiol* 1990;66:860-862.
26. Silverman DI, Ware JA, Sacks FM, Pasternak RC. Comparison of the absorption and effect of platelet function of a single dose of n-3 fatty acids given as fish or fish oil. *Am J Clin Nutr* 1991;53:1165-70.
27. Stampfer MJ, Sacks FM, Salvini S, Willett WC, Hennekens CH. A prospective study of lipids, apolipoproteins and risks of myocardial infarction. *New Engl J Med* 1991;325:373-81.
28. Walsh BW, Schiff I, Rosner B, Greenberg L, Ravnikar V, Sacks FM. Effects of postmenopausal estrogen replacement on the concentrations and metabolism of plasma lipoproteins. *New Engl J Med* 1991;325:1196-1204.
29. London SJ, Sacks FM, Caesar J, Stampfer MJ, Siguel E, Willett WC. Fatty acid composition of subcutaneous adipose tissue and diet in postmenopausal US women. *Am J Clin Nutr* 1991;54:340-345.
30. Sacks FM, Pfeffer MA, Moya L, Brown LE, Hamm P, Cole TG, Hawkins CM, Braunwald E. Rationale and design of a secondary prevention trial of lowering normal plasma cholesterol levels after acute myocardial infarction. The Cholesterol and Recurrent Events Trial (CARE). *Am J Cardiol* 1991;68:1436-46.

31. Hunter DJ, Rimm EB, Sacks FM, Stampfer MJ, Colditz GA, Litin LB, Willett WC. Comparison of measures of fatty acid intake by subcutaneous fat aspirate, food frequency questionnaire, and diet records. *Am J Epidemiol* 1992;135:418-427.
32. Gibson CM, Sandor T, Stone PH, Pasternak RC, Rosner B, Sacks FM. Quantitative angiographic and statistical methods to assess serial changes in coronary luminal diameter and implications for atherosclerosis regression trials. *Am J Cardiol* 1992;69:1286-1290.
33. Caine YG, Bauer KA, Barzegar S, ten Cate H, Sacks FM, Walsh BW, Schiff I, Rosenberg RD. Coagulation activation following estrogen administration to postmenopausal women. *Thrombosis Haemostasis* 1992;68:392-395.
34. Ascherio A, Rimm EB, Giovannucci EL, Colditz GA, Rosner B, Willett WC, Sacks FM, Stampfer MJ. A prospective study of nutritional factors and hypertension among US men. *Circulation* 1992;86:1475-1484.
35. Morris MC, Taylor JO, Stampfer MJ, Rosner B, Sacks FM. The effect of fish oil on blood pressure in mild hypertensives: a randomized clinical trial. *Am J Clin Nutr* 1993;57:59-64.
36. Gibson CM, Diaz L, Kandarpa K, Sacks FM, Pasternak RC, Sandor T, Feldman C, Stone PH. The relationship of vessel wall shear stress to atherosclerosis progression in coronary arteries. *Arteriosclerosis and Thrombosis* 1993;13:310-315.
37. Stone PH, Gibson CM, Pasternak RC, McManus K, Diaz L, Boucher T, Spears JR, Sandor T, Rosner B, Sacks FM. The natural history of coronary atherosclerosis using quantitative angiography: implications for clinical trials of coronary regression. *Am J Cardiol* 1993;71:766-772.
38. Campos H, Sacks FM, Walsh BW, Schiff I, O'Hanesian MA, Krauss RM. Differential effects of estrogen on low density lipoprotein subclasses in healthy postmenopausal women. *Metabolism* 1993;42:1153-1158.
39. Walsh BW, Sacks FM. The effect of low dose oral contraceptives on very low density and low density lipoprotein metabolism. *J Clin Invest* 1993;91:2126-2132.
40. London SJ, Sacks FM, Stampfer MJ, Henderson IC, Maclure M, Tomita A, Wood WC, Remine S, Robert NJ, Dmochowski JR, Willett WC. Fatty acid composition of the subcutaneous adipose tissue and risk of proliferative benign breast disease and breast cancer. *J Nat Cancer Inst* 1993;85:785-793.
41. Morris MC, Sacks FM, Rosner B. Does fish oil lower blood pressure? A meta-analysis of controlled trials. *Circulation* 1993;88:523-533.
42. Ridker PM, Vaughan DE, Stampfer MJ, Sacks FM, Hennekens CH. A cross-sectional study of endogenous tissue plasminogen activator, total cholesterol, HDL cholesterol, and apolipoproteins A-I, A-II, and B-100. *Arterioscler Thromb* 1993;13:1587-1592.



43. Sacks FM, McPherson R, Walsh BW. Effect of postmenopausal estrogen replacement on plasma lipoprotein(a) concentrations. *Arch Intern Med* 1994;154:1106-1110.
44. Sacks FM, Hebert P, Appel LJ, Borhani NO, Applegate WB, Cohen JD, Cutler JA, Kirchner KA, Kuller LH, Roth KJ, Taylor JO, Hennekens CH for the TOHP Collaborative Research Group. The effect of fish oil on blood pressure and high density lipoprotein cholesterol levels in Phase I of the Trials of Hypertension Prevention (TOHP). *J Hypertens* 1994;12:209-213.
45. Gann PH, Hennekens CH, Sacks FM, Grodstein F, Giovanucci E, Stampfer MJ. A prospective study of plasma fatty acids and risk of prostate cancer. *J Nat Cancer Inst* 1994;86:281-286.
46. Walsh BW, Li HJ, Sacks FM. The effect of postmenopausal estrogens on the metabolism of apolipoprotein A-I. *J Lipid Res* 1994;35:2083-93.
47. Sacks FM, Pasternak RC, Gibson CM, Rosner B, Stone PH for the Harvard Atherosclerosis Reversibility Project (HARP) Group. The effect on coronary atherosclerosis of decrease in plasma cholesterol concentrations in normocholesterolemic patients. *Lancet* 1994;344:1182-86.
48. Sacks FM, Obarzanek E, Windhauser MM, Svetkey LP, Vollmer WM, McCullough M, Karanja N, Lin PH, Steele P, Proschan MA, Evans MA, Appel LJ, Bray GA, Vogt TM, and Moore TJ for the DASH Investigators. Rationale and design of the dietary approaches to stop hypertension trial (DASH): A multicenter controlled feeding study of dietary patterns to lower blood pressure. *Ann Epidemiol* 1995;5:108-18.
49. Whelton PK, Buring J, Borhani NO, Cohen JD, Cook N, Cutler JA, Kiley JE, Kuller LH, Satterfield S, Sacks FM, Taylor JO for the TOHP Collaborative Research Group. The effect of potassium supplementation in persons with a high normal blood pressure: Results from the Phase I of the Trials of Hypertension Prevention (TOHP). *Ann Epidemiol* 1995;5:85-95.
50. Yamamoto ME, Applegate WB, Klag MJ, Borhani NO, Cohen JD, Kirchner KA, Lakatos E, Sacks FM, Taylor JO, Hennekens CH for the TOHP Collaborative Research Group. *Ann Epidemiol* 1995;5:96-107.
51. Sacks FM, Rouleau JL, Moye LA, Pfeffer MA, Warnica JW, Arnold MJ, Nash DT, Brown LE, Sestier F, Rutherford J, Davis BR, Hawkins CM, Braunwald E for the CARE investigators. Baseline characteristics in the Cholesterol and Recurrent Events (CARE) trial of secondary prevention in patients with average serum cholesterol levels. *Am J Cardiol* 1995;75:621-623.
52. Sacks FM, Stone PH, Gibson CM, Silverman DI, Rosner B, Pasternak RC for the Harvard Atherosclerosis Reversibility Project (HARP) Group. Controlled trial of fish oil for regression of human coronary atherosclerosis. *J Am Coll Cardiol* 1995;25:1492-8.

53. Guallar E, Hennekens CH, Sacks FM, Willett WC, Stampfer MJ. A prospective study of plasma fish oil levels and incidence of myocardial infarction in U.S. male physicians. *J Am Coll Cardiol* 1995;25:387-394.
54. Sacks FM, Brown LE, Appel L, Borhani N, Evans D, Whelton P. The effect of combinations of dietary potassium, calcium and magnesium on blood pressure in mildly hypertensive patients. *Hypertension* 1995;26:950-956.
55. Sacks FM, Gibson CM, Rosner B, Pasternak RC, Stone PH. The influence of pretreatment LDL cholesterol concentrations on the effect of hypocholesterolemic therapy on coronary atherosclerosis in angiographic trials. *Am J Cardiol* 1995;76:78C-85C.
56. Sacks FM, Krukonis GP. The influence of apolipoprotein E on the interactions between normal human VLDL and U937 macrophages: heterogeneity among persons. *Vascular Medicine* 1996;1:9-18.
57. Wilt TJ, Davis BR, Meyers DG, Rouleau JL, Sacks FM. Prevalence and correlates of symptomatic peripheral atherosclerosis in individuals with coronary heart disease and cholesterol levels less than 240 mg/dl: Baseline results from the Cholesterol and Recurrent Events (CARE) study. *Angiology* 1996; 47:533-40.
58. O'Hanesian MA, Rosner B, Bishop LM, Sacks FM. Inherent dietary responsiveness of plasma lipoproteins, and the contribution of random dietary variation to day to day variations of plasma lipoproteins. *Am J Clin Nutr* 1996;64:53-59.
59. Ascherio A, Hennekens CH, Willett WC, Sacks FM, Rosner B, Manson J, Witteman J, Stampfer MJ. A prospective study of nutritional factors, blood pressure, and hypertension among US women. *Hypertension* 1996; 27:1065-72.
60. Stampfer MJ, Krauss RM, Ma J, Blanche PJ, Holl LG, Sacks FM, Hennekens CH. A prospective study of triglycerides, LDL particle diameter, and risk of myocardial infarction. *JAMA* 1996;276:882-8.
61. Moye LA, Davis BR, Sacks FM, Cole T, Brown L, Crawford B, Hawkins CM. Decision rules for predicting future values in a cholesterol reduction clinical trial. *Controlled Clin Trials* 1996;17:536-46.
62. de Oliveira e Silva E, Seidman CE, Tian J, Sacks FM, Breslow JL. Shrimp consumption does not adversely affect the plasma lipoprotein profile. *Am J Clin Nutr* 1996;64:712-7.
63. Pasternak RC, Brown LE, Stone PH, Silverman DI, Sacks FM. Combined hypolipidemic drug therapy in normocholesterolemic patients with coronary heart disease: a stepped-care algorithm with four agents. *Ann Intern Med* 1996;125:529-40.
64. Sacks FM, Pfeffer MA, Moye LA, Rouleau JL, Rutherford JD, Cole T, Brown L, Theroux P, Warnica JW, Arnold JM, Nash DT, Wun CC, Davis BR, Hawkins CM, Braunwald E. The effect of pravastatin on coronary events after myocardial infarction in patients with average cholesterol levels. *N Engl J Med* 1996;335:1001-9.

65. Appel LJ, Moore TJ, Obarzanek E, Vollmer WM, Svetkey LP, Sacks FM, Bray GA, Vogt TM, Cutler JA, Simons-Morton D, Lin PH, Karanja N. The effect of dietary patterns on blood pressure: Results from the Dietary Approaches to Stop Hypertension trial. *N Engl J Med* 1997;336:1117-24.
66. Campos H, Walsh BW, Judge H, Sacks FM. Effect of estrogen on VLDL and LDL subclass metabolism in postmenopausal women. *J Clin Endocrinol Metab* 1997;82:3955-63.
67. Sacks FM, Willett WC, Smith A, Brown LE, Rosner B, Moore TJ. Effect on blood pressure of potassium, calcium, magnesium in women with low habitual intake. *Hypertension* 1998;31:131-8.
68. Garland M, Sacks FM, Colditz GA, Rimm EB, Sampson LA, Willett WC, Hunter DJ. The relation between dietary intake and adipose tissue composition of selected fatty acids in US women. *Am J Clin Nutr* 1998;67:25-30.
69. Sacks FM, Moye LA, Davis BR, Cole TG, Rouleau JL, Nash D, Pfeffer MA, Braunwald E. Relationship between plasma LDL concentrations during treatment with pravastatin and recurrent coronary events in the Cholesterol and Recurrent Events trial. *Circulation* 1998;97:1446-52.
70. Lewis SJ, Sacks FM, Mitchell JS, East C, Glasser S, Kell S, Letterer R, Limacher M, Moye LA, Rouleau JL, Pfeffer MA, Braunwald E. Effect of pravastatin on cardiovascular events in women after myocardial infarction: The Cholesterol and Recurrent Events trial. *J Am Coll Cardiol* 1998;32:140-146.
71. Su W, Campos H, Judge H, Walsh BW, Sacks FM. Metabolism of apo(a) and apoB100 of lipoprotein(a) in women: effect of postmenopausal estrogen replacement. *J Clin Endocrinol Metab* 1998;83:3267-3276.
72. Goldberg RB, Mellies MJ, Sacks FM, Moye LA, Howard BV, Howard WJ, Davis BR, Cole TG, Pfeffer MA, Braunwald E. Cardiovascular events and their reduction with pravastatin in diabetic and glucose intolerant myocardial infarction survivors with average cholesterol levels: subgroup analysis in the CARE trial. *Circulation* 1998;98:2515-2519.
73. Ridker PM, Rifai N, Pfeffer MA, Sacks FM, Moye LA, Goldman S, Flaker GC, Braunwald E. Inflammation, pravastatin, and the risk of coronary events after myocardial infarction in patients with average cholesterol levels. *Circulation* 1998;98:839-844.
74. Lewis SJ, Moye LA, Sacks FM, Johnstone DE, Timmis G, Mitchell J, Limacher J, Kell S, Glasser SP, Grant J, Davis BR, Pfeffer MA, Braunwald E. Effect of pravastatin on cardiovascular events in post-myocardial infarction patients aged 65-75 with cholesterol levels in the average range: results from the Cholesterol and Recurrent Events trial. *Ann Intern Med* 1998;129:681-689.
75. Gebara OC, Mittleman MA, Walsh BW, Lipinska I, Welty FK, Bellotti G, Muller JE, Sacks FM, Tofler TH. Fibrinolytic potential is significantly increased by estrogen therapy in postmenopausal women with mild dyslipidemia. *Heart* 1998;80:235-9.

76. Plehn JF, Davis BR, Sacks FM, Rouleau JL, Pfeffer MA, Bernstein V, Cuddy TE, Moye LA, Piller LB, Rutherford J, Simpson LM, Braunwald E. Reduction in stroke incidence following myocardial infarction with pravastatin: The Cholesterol and Recurrent Events Study. *Circulation* 1999;99:216-223.
77. Brown L, Rosner B, Willett WC, Sacks FM. Cholesterol lowering effects of dietary fiber: a meta-analysis. *Am J Clin Nutr* 1999;69:30-42.
78. Pfeffer MA, Sacks FM, Moye LA, East C, Goldman S, Nash DT, Rouleau J, Rouleau JL, Sussex BA, Theroux P, VandenBelt RJ, Braunwald E. Influence of baseline lipids on effectiveness of pravastatin in the CARE trial. *J Am Coll Cardiol* 1999;33:125-130
79. Khoo C, Campos H, Judge H, Sacks FM. Effects of estrogenic oral contraceptives on the lipoprotein B particle system defined by apolipoproteins E and CIII. *J Lipid Res* 1999;40:202-212.
80. Walsh BW, Spiegelman D, Morrissey M, Sacks FM. The relationship between serum estradiol levels and the increases in high-density lipoprotein levels in postmenopausal women treated with oral estradiol. *J Clin Endocrinol Metab* 1999;84:985-989.
81. Hu FB, Stampfer MJ, Rimm EB, Manson JE, Ascherio A, Colditz GA, Rosner BA, Spiegelman D, Speizer FE, Sacks FM, Hennekens CH, Willett WC. A prospective study of egg consumption and risk of cardiovascular disease in men and women. *JAMA* 1999;281:1387-94.
82. Gann PH, Ma J, Giovannucci E, Willett W, Sacks FM, Hennekens CH, Stampfer MJ. Lower prostate cancer risk in men with elevated plasma lycopene levels: results of a prospective analysis. *Cancer Research* 1999;59:1225-1230.
83. Flaker GC, Warnica JW, Sacks FM, Moye LA, Davis BR, Rouleau JL, Webel RR, Pfeffer MA, Braunwald E. Pravastatin prevents clinical events in revascularized patients with average cholesterol concentrations. *J Am Coll Cardiol* 1999;34:106-112.
84. Moore TJ, Vollmer WM, Appel LJ, Sacks FM, Svetkey LP, Vogt TM, Conlin PR, Simons-Morton DG, Carter-Edwards L, Harsha DW. Effect of dietary patterns on ambulatory blood pressure: results from the Dietary Approaches to Stop Hypertension (DASH) Trial. *Hypertension* 1999;34:472-7.
85. Ridker PM, Rifai N, Pfeffer MA, Sacks F, Braunwald E. Long-term effects of pravastatin on plasma concentration of C-reactive protein. *Circulation* 1999;100:230-235.
86. Cook NR, Stampfer MJ, Ma J, Manson JE, Sacks FM, Buring JE, Hennekens CH. Beta-carotene supplementation for patients with low baseline levels and decreased risks of total and prostate carcinoma. *Cancer* 1999;86:1783-92.
87. Svetkey LP, Sacks FM, Obarzanek E, Vollmer WM, Appel LJ, Lin PH, Karanja NM, Harsha DW, Bray GA, Aickin M, Proschan MA, Windhauser MM, Swain JF, McCarron

- PB, Rhodes DG, Laws RL. The DASH diet, Sodium Intake and Blood Pressure Trial (DASH-Sodium): rationale and design. *J Am Diet Assoc* 1999;8 Suppl: S96-104.
88. Conlin PR, Chow D, Miller ER, Svetkey LP, Lin PH, Harsha DW, Moore TJ, Sacks FM, Appel LJ. The effect of dietary patterns on blood pressure control in hypertensive patients: results from the DASH trial. *Am J Hypertens* 2000;13:949-55
89. Sacks FM, Alaupovic P, Moye LA, Cole TG, Sussex B, Stampfer MJ, Pfeffer MA, Braunwald E. Very Low Density Lipoproteins, Apolipoproteins B, CIII, and E and Risk of Recurrent Coronary Events in the Cholesterol and Recurrent Events (CARE) Trial. *Circulation* 2000;102:1886-1892.
90. Sacks FM, Tonkin AM, Shepherd J, Braunwald E, Cobbe S, Hawkins CM, Keech A, Packard C, Simes J, Byington R, Furberg CD, for the The Prospective Pravastatin Pooling Project Investigators Group. The Effect of Pravastatin on Coronary Disease Events in Subgroups Defined by Coronary Risk Factors. The Prospective Pravastatin Pooling Project. *Circulation* 2000;102:1893-1900.
91. Ridker PM, Rifai N, Pfeffer M, Sacks F, Lepage S, Braunwald E. Elevation of tumor necrosis factor-alpha and increased risk of recurrent coronary events after myocardial infarction. *Circulation* 2000;101:2149-53.
92. Tsevat J, Kuntz KM, Orav EJ, Weinstein MC, Sacks FM, Goldman L. Cost-effectiveness of pravastatin therapy for survivors of myocardial infarction with average cholesterol levels. *Am Heart J* 2001;141:727-34.
93. Sacks FM, Svetkey LP, Vollmer WM, Appel LJ, Bray GA, Harsha D, Obarzanek E, Conlin PR, Miller ER, Simons-Morton D, Karanja N, Lin PH. Effects on blood pressure of reduced dietary sodium and the Dietary Approaches to Stop Hypertension (DASH) diet. *N Engl J Med* 2001;344:3-10.
94. Hines LM, Stampfer MJ, Ma J, Gaziano JM, Ridker PM, Hankinson SE, Sacks F, Rimm EB, Hunter DJ. Genetic variation in alcohol dehydrogenase and the beneficial effect of moderate alcohol consumption on myocardial infarction. *N Engl J Med* 2001;344:549-55.
95. Obarzanek E, Sacks FM, Vollmer WM, Bray GA, Miller ER, Lin PH, Karanja NM, Most-Windhauser M, Moore TJ, Swain JF, Bales CW, Proschan MA. Effects on blood lipids of a blood pressure lowering diet: the Dietary Approaches to Stop Hypertension (DASH) Trial. *Am J Clin Nutr* 2001;74: 80-89.
96. Lai D, Moye LA, Davis BR, Brown LE, Sacks FM. Brownian motion and long-term clinical trial recruitment. *J Statist Planning Inference* 2001;93:239-46.
97. Bray PF, Cannon CP, Goldschmidt-Clermont P, Moye LA, Pfeffer MA, Sacks FM, Braunwald E. The platelet PI(A2) and angiotensin-converting enzyme (ACE) D allele polymorphisms and the risk of recurrent events after acute myocardial infarction. *Am J Cardiol* 2001;88:347-52.

98. Vollmer W, Sacks FM, Ard J, Appel LJ, Bray GA, Simons-Morton DG, Conlin PR, Svetkey LP, Erlinger TP, Moore TJ, Karanja N. Effects of dietary patterns and sodium intake on blood pressure: subgroup analysis of the DASH-Sodium trial. *Ann Intern Med* 2001;135:1019-28.
99. McManus K, Antinoro L, Sacks F. A randomized controlled trial of a moderate-fat, low-energy diet compared with a low fat, low-energy diet for weight loss in overweight adults. *Int J Obesity* 2001; 25: 1503-11.
100. Campos H, Perlov D, Khoo C, Sacks FM. Distinct patterns of lipoproteins with apoB defined by presence of apoE or apoC-III in hypercholesterolemia and hypertriglyceridemia. *J Lipid Res* 2001; 42: 1239-49.
101. Tomiyasu K, Walsh BW, Ikewaki K, Judge H, Sacks FM. Differential metabolism of human VLDL according to content of apolipoprotein E and CIII. *Arterioscler Thromb Vasc Biol* 2001; 21:1494-1500.
102. Svetkey LP, Moore TJ, Simons-Morton DG, Appel L, Bray GA, Sacks FM, Ard J, Mortensen RM, Mitchell SR, Conlin PR, Kesari M. Angiotensinogen Genotype and BP Response in the Dietary Approaches to Stop Hypertension (DASH) study. *J Hypertension* 2001; 19:1949-56.
103. Campos H, Moye L, Glasser S, Sacks FM. Low density lipoprotein size, pravastatin treatment, and coronary events. *JAMA* 2001; 286:1468-74.
104. Lin YS, Smith TJ, Wypij D, Kelsey KT, Sacks FM. Association of the blood/air partition coefficient of 1,3 butadiene with blood lipids and albumin. *Environ Health Perspective* 2002; 110:165-8.
105. Sacks FM, Tonkin AM, Craven T, Pfeffer MA, Shepherd J, Keech A, Furberg CD, Braunwald E. Coronary heart disease in patients with low LDL cholesterol: benefit of pravastatin in diabetics and enhanced role of HDL-cholesterol and triglycerides as risk factors. *Circulation* 2002; 105:1424-8.
106. Liu S, Schmitz C, Stampfer MJ, Sacks F, Hennekens CH, Lindpaintner K, Ridker PM. A prospective study of Taq1B polymorphism in the gene coding for cholesteryl ester transfer protein and risk of myocardial infarction in men. *Atherosclerosis* 2002;161:469-79.
107. Pfeffer MA, Keech A, Sacks FM, Cobbe SM, Tonkin A, Byington RP, Davis BR, Friedman CP, Braunwald E. Safety and tolerability of pravastatin in long-term clinical trials. Prospective Pravastatin Pooling (PPP) Project. *Circulation* 2002;105; 2341-6.
108. Sacks FM, Alaupovic P, Moye LA. Effect of pravastatin on apolipoproteins B and C-III in very-low-density lipoproteins and low-density lipoproteins. *Am J Cardiol* 2002;90:165-7.
109. Jehn M, Appel LJ, Sacks FM, Miller ER. The effect of ambient temperature and barometric pressure on ambulatory blood pressure variability. *Am J Hypertens* 2002;15:941-5.

110. Tonelli M, Moye L, Sacks FM, Kiberd B, Curhan G. Pravastatin for secondary prevention of cardiovascular events in persons with mild chronic renal insufficiency. *Ann Intern Med* 2003;138:98-104.
111. Lin PH, Aickin M, Champagne C, Craddock S, Sacks FM, McCarron P, Rukenbrod F, Haworth L. Food group sources of nutrients in the dietary patterns of the Dash-Sodium Trial. *J Am Diet Assoc* 2003;103:488-96.
112. Lee SJ, Campos H, Moye LA, Sacks FM. LDL particles containing apolipoprotein CIII are independent risk factors for coronary events in diabetic patients. *Arterioscl Thromb Vasc Biol* 2003;23:853-8.
113. Akita S, Sacks FM, Svetkey LP, Conlin PR, Kimura G. Effects of the Dietary Approaches to Stop Hypertension (DASH) diet on pressure-natriuresis relationship. *Hypertension* 2003; 42:8-13.
114. Lee SJ, Campos H, Williams GH, Moye LA, Sacks FM. Hypertriglyceridemia but not diabetes status is associated with VLDL containing apolipoprotein CIII in patients with coronary heart disease. *Atherosclerosis* 2003;167:293-302.
115. Tonelli M, Moye LA, Sacks FM, Cole T, Curhan G. The effect of pravastatin on loss of renal function in patients with moderate chronic renal insufficiency and cardiovascular disease. *J Am Soc Nephrol* 2003;14:1605-13.
116. Obarzanek E, Proschan MA, Vollmer WM, Moore TJ, Sacks FM, Appel LJ, Svetkey LP, Most-Windhauser MM, Cutler JA. Individual blood pressure responses to changes in salt intake: results from the DASH-Sodium trial. *Hypertension* 2003;42:459-67.
117. Lee SJ, Sacks FM. Effect of pravastatin on intermediate-density and low-density lipoproteins containing apolipoprotein CIII in patients with diabetes mellitus. *Am J Cardiol* 2003;92:121-124.
118. Lewis EF, Moye LA, Rouleau JL, Sacks FM, Arnold JM, Warnica JW, Flaker GC, Braunwald E, Pfeffer MA. Predictors of late development of heart failure in stable survivors of myocardial infarction. The CARE study. *J Am Coll Cardiol* 2003;42:1446-53.
119. Seeger JD, Walker AM, Williams PL, Saperia GM, Sacks FM. A propensity score-matched cohort study of the effect of statins, mainly fluvastatin, on the occurrence of acute myocardial infarction. *Am J Cardiol* 2003;92:6-10.
120. Harsha DW, Sacks FM, Obarzanek, E, Svetkey LP, Lin PH, Bray GA, Aickin M, Conlin PR, Miller ER, Appel LJ. Effect of dietary sodium intake on blood lipids. Results from the DASH-Sodium Trial. *Hypertension* 2004;43[part 2]:393-8.
121. Hennekens CH, Sacks FM, Tonkin A, Jukema JW, Byington RP, Pitt B, Berry DA, Berry SM, Ford NF, Walker AJ, Natarajan K, Sheng-Lin C, Fiedorek FT, Belder R. Additive benefits of pravastatin and aspirin to decrease risks of cardiovascular disease: randomized

- and observational comparisons of secondary prevention trials and their meta-analyses. *Arch Intern Med* 2004;164:40-4.
122. De Grooth GJ, Zerba KE, Huang SP, Tsuchihashi Z, Kirchgessner T, Belder R, Vishnupad P, Hu B, Klerkx AH, Zwinderman AH, Jukema JW, Sacks FM, Kastelien JJ, Kuivenhoven JA. The cholesteryl ester transfer protein (CETP) Taq1B polymorphism in the Cholesterol and Recurrent Events study: no interaction with the response to pravastatin therapy and no effects on cardiovascular outcome. *J Am Coll Cardiol* 2004;43:854-7.
  123. Chiuve S, Martin LA, Campos H, Sacks FM. Effect of the combination of methyltestosterone and esterified estrogens compared with esterified estrogens alone on apolipoprotein CIII and other apolipoproteins in VLDL, LDL, and HDL in surgically postmenopausal women. *J Clin Endocr Metab* 2004; 89:2207-2213.
  124. Svetkey LP, Simons-Morton DG, Proschan MA, Sacks FM, Conlin PR, Harsha D, Moore TJ. Effects of the Dietary Approaches to Stop Hypertension (DASH) diet and reduced sodium intake on blood pressure control. *J Clin Hypertens* 2004;6:373-381.
  125. Bray GA, Vollmer WM, Sacks FM, Appel LJ, Svetkey LP, Obarzanek E. A further subgroup analysis of the effects of the DASH diet and three dietary sodium levels on blood pressure. *Am J Cardiol* 2004; 94:222-227.
  126. Rifai N, Ma J, Sacks FM, Ridker PM, Hernandez WJ, Stampfer MJ, Marcovina SM. Apolipoprotein (a) size and lipoprotein(a) concentration and future risk of angina pectoris with evidence of severe coronary atherosclerosis in men: The Physicians Health Study. *Clin Chem* 2004; 50:1364-71.
  127. Tonelli M, Isles C, Curhan GC, Tonkin A, Pfeffer MA, Shepherd J, Sacks FM, Furbur C, Cobbe SM, Simes J, Craven T, West M. Effect of pravastatin on cardiovascular events in people with chronic kidney disease. *Circulation* 2004;110:1557-63.
  128. Boekholdt SM, Sacks FM, Jukema JW, Shepherd J, Freeman DJ, McMahon AD, Cambien F, Nicaud V, de Grooth GJ, Talmud PJ, Humphries SE, Miller GJ, Eiriksdottir G, Gudnason V, Kauma H, Kakko S, Savolainen MJ, Arca M, Montali A, Liu S, Lanz HJ, Zwinderman AH, Kuivenhoven JA, Kastelein JJ. Cholesteryl ester transfer protein Taq1B variant, high-density lipoprotein cholesterol levels, cardiovascular risk, and efficacy of pravastatin treatment: individual patient meta-analysis of 13,677 subjects. *Circulation*. 2005 111:278-87.
  129. Campos H, Khoo C, Sacks FM. Diurnal and Acute Patterns of Postprandial Apolipoprotein B-48 in VLDL, IDL, and LDL from Normolipidemic Humans. *Atherosclerosis* 2005;181:345-51.
  130. Miller ER, Erlinger TP, Sacks FM, Svetkey LP, Charleston J, Lin PH, Appel LJ. A dietary pattern that lowers oxidative stress increases antibodies to oxidized LDL: Results from a randomized controlled feeding study. *Atherosclerosis* 2005;183:175-82.



131. Ray KK, Cannon CP, McCabe CH, Cairns R, Tonkin AM, Sacks FM, Jackson G, Braunwald E. Early and late benefits of high-dose atorvastatin in patients with acute coronary syndromes: results from the PROVE IT-TIMI 22 trial. *J Am Coll Cardiol* 2005;46:1405-10.
132. Ranade K, Kirschgessner TG, Iacobova OA, Devlin JJ, DelMonte T, Vishnupad P, Hui L, Tsuchihashi Z, Sacks FM, Sabatine MS, Braunwald E, White TJ, Shaw PM, Dracopoli NC. Evaluation of the paraoxonases as candidate genes for stroke: Gln192Arg polymorphism in the paraoxonase 1 gene is associated with increased risk of stroke. *Stroke* 2005;36:2346-50.
133. Tonelli M, Isles C, Craven T, Tonkin A, Pfeffer MA, Shepherd J, Sacks FM, Furberg C, Cobbe S, Simes J, West M, Packard C, Curhan G. Effect of pravastatin on rate of kidney function loss in people with or at risk for coronary disease. *Circulation* 2005;112:171-8.
134. Tonelli M, Sacks F, Pfeffer M, Gao Z, Curhan G. Relation between serum phosphate level and cardiovascular event rate in people with coronary disease. *Circulation* 2005;112:2627-33.
135. Tonelli M, Keech A, Shepherd J, Sacks F, Tonkin A, Packard C, Pfeffer M, Simes J, Isles C, Furberg C, West M, Craven T, Curhan G. Effect of pravastatin in people with diabetes and chronic kidney disease. *J Am Soc Nephrol* 2005;16:3748-54.
136. Van den Elzen P, Garg S, Leon L, Brigl M, Leadbetter EA, Gumperz JE, Dascher CC, Cheng TY, Sacks FM, Illarionov PA, Besra GS, Kent SC, Moody DB, Brenner MB. Apolipoprotein-mediated pathways of lipid antigen presentation. *Nature* 2005;437:906-10.
137. Carey VJ, Bishop L, Charleston J, Conlin P, Erlinger T, Laranjo N, McCarron P, Miller E, Rosner B, Swain J, Sacks FM, Appel LJ. Rationale and design of the Optimal Macro-Nutrient Intake Heart Trial to prevent heart disease (OMNI-Heart). *Clin Trials* 2005;2:529-37.
138. Appel LJ, Sacks FM, Carey VJ, Obarzanek E, Swain JF, Miller ER, Conlin PR, Erlinger TP, Rosner B, Laranjo NM, Charleston J, McCarron P, Bishop LM. Effects of Protein, Monounsaturated Fat, and Carbohydrate Intake on Blood Pressure and Serum Lipids: Results of the OmniHeart Randomized Trial. *JAMA* 2005;294:2455-64.
139. Pischon T, Girman CJ, Sacks FM, Rifai N, Stampfer MJ, Rimm EB. Non-high-density lipoprotein cholesterol and apolipoprotein B in the prediction of coronary heart disease in men. *Circulation* 2005;112:3375-83.
140. Zheng CY, Murdoch SJ, Brunzell JD, Sacks FM. Lipoprotein lipase bound to apolipoprotein B lipoproteins accelerates clearance of postprandial lipoproteins in humans. *Arterioscler Thromb Vasc Biol* 2006;26:891-6.
141. Kawakami A, Aikawa M, Libby P, Alcaide P, Luscinskas FW, Sacks FM. Apolipoprotein CIII in apoB lipoproteins enhances the adhesion of human monocytic cells to endothelial cells *Circulation* 2006;113:691-700.

142. Tonelli M, Sacks F, Pfeffer M, Lopez-Jimenez, Jhangri GS, Curhan G. Effect of pravastatin on blood pressure in people with cardiovascular disease. *J Human Hypertens* 2006;20:560-5.
143. Tonelli M, Jose P, Curhan G, Sacks F, Braunwald E, Pfeffer M. Proteinuria, impaired kidney function, and adverse outcomes in people with coronary disease: analysis of a previously conducted clinical trial. *BMJ* 2006;332:1426.
144. Chiuve SE, McCullough ML, Sacks FM, Rimm EB. Healthy lifestyle factors in the primary prevention of CHD among men: benefits among users and non-users of lipid-lowering and antihypertensive medications. *Circulation* 2006; 114:160-7.
145. Kawakami A, Aikawa M, Alcaide P, Luscinskas FW, Libby P, Sacks FM. Apolipoprotein CIII induces expression of vascular cell adhesion molecule-1 in vascular endothelial cells and increases adhesion of monocytic cells. *Circulation* 2006;114:681-7.
146. Zheng CY, Ikewaki K, Walsh BW, Sacks FM. Metabolism of apoB lipoproteins of intestinal and hepatic origin during constant feeding of small amounts of fat. *J Lipid Res* 2006; 47:1171-9.
147. Iakoubova OA, Tong CH, Chokkalingam AP, Rowland CM, Kirchgessner TG, Louie JZ, Ploughman LM, Sabatine MS, Campos H, Catanese JJ, Leong DU, Young BA, Lew D, Tsuchihashi Z, Luke MM, Packard CJ, Zerba KE, Shaw PM, Shepherd J, Devlin JJ, Sacks FM. Asp92Asn polymorphism in the myeloid IgA Fc receptor is associated with myocardial infarction in two disparate populations, CARE and WOSCOPS. *Arterioscler Thromb Vasc Biol* 2006; 26:2763-8.
148. Kawakami A, Aikawa M, Nitta N, Yoshida M, Libby P, Sacks FM. Apolipoprotein CIII-induced THP-1 cell adhesion to endothelial cells involves pertussis toxin-sensitive G-protein- and protein kinase C $\alpha$ -mediated nuclear factor- $\kappa$ B activation. *Arterioscler Thromb Vasc Biol* 2007; 27:219-25.
149. Zheng CY, Khoo C, Ikewaki K, Sacks FM. Rapid turnover of apolipoprotein C-III-containing triglyceride-rich lipoproteins contributing to the formation of LDL subfractions. *J Lipid Res.* 2007;48:1190-203.
150. Bansal S, Buring JE, Rifai N, Mora S, Sacks FM, Ridker PM. Fasting compared with nonfasting triglycerides and risk of cardiovascular events in women. *JAMA* 2007;298:309-16.
151. Karanja N, Lancaster KJ, Vollmer WM, Lin PH, Most MM, Ard JD, Swain JF, Sacks FM, Obarzanek E. Acceptability of sodium-reduced research diets, including the Dietary Approaches To Stop Hypertension diet, among adults with prehypertension and stage 1 hypertension. *J Am Diet Assoc* 2007;107:1530-8.
152. Tonelli M, Sacks F, Arnold M, Moye L, Davis B, Pfeffer M. Relation between red blood cell distribution width and cardiovascular event rate in people with coronary disease. *Circulation* 2008;117:163-8.

153. Sabatine MS, Ploughman L, Simonsen KL, Iakoubova OA, Kirchgessner TG, Ranade K, Tsuchihashi A, Zerba KE, Long DU, Tong CH, Packard DJ, Pfeffer MA, Dracopoli NC, Devlin JJ, Shepherd J, Campos H, Sacks FM, Braunwald E. Association Between ADAMTS1 Matrix Metalloproteinase Gene Variation, Coronary Heart Disease, and Benefit of Statin Therapy. *Arterioscler Thromb Vasc Biol.* 2008;28:562-7.
154. Iakoubova OA, Tong CH, Rowland CM, Kirchgessner TG, Young BA, Arellano AR, Shiffman D, Sabatine MS, Campos H, Packard CJ, Pfeffer MA, White TJ, Braunwald E, Shepherd J, Devlin JJ, Sacks FM. Association of the Trp719Arg polymorphism in kinesin-like protein 6 with myocardial infarction and coronary heart disease in 2 prospective trials: the CARE and WOSCOPS trials. *J Am Coll Cardiol.* 2008; 29;51:435-43.
155. Swain JF, McCarron PB, Hamilton EF, Sacks FM, Appel LJ. Characteristics of the dietary patterns tested in the Optimal Macronutrient Intake Trial to Prevent Heart Disease (Omni Heart). Options for a heart-healthy diet. *J Am Diet Assoc* 2008;108:257-65.
156. Zheng C, Khoo C, Furtado J, Ikewaki K, Sacks FM. Dietary monounsaturated fat activates pathways for triglyceride-rich lipoproteins that involve apolipoproteins E and C-III. *Am J Clin Nutr* 2008;88:272-81.
157. DeSouza RJ, Swain JF, Appel LJ, Sacks FM. Alternatives for macronutrient intake and chronic disease: a comparison of OmniHeart diets with popular diets and with dietary recommendations. *Am J Clin Nutr* 2008;88:1-11.
158. Furtado JD, Campos H, Appel LJ, Miller ER, Laranjo N, Carey VJ, Sacks FM. Effect of protein, unsaturated fat, and carbohydrate intakes on plasma apolipoprotein B and VLDL and LDL containing apolipoprotein C-III: results from the OmniHeart trial. *Am J Clin Nutr* 2008;87:1623-30.
159. Ruiz-Narvaez EA, Sacks FM, Campos H. Abdominal obesity and hyperglycemia mask the effect of a common APOC3 haplotype on risk of myocardial infarction. *Am J Clin Nutr* 2008;87:1932-8.
160. Beasley JM, Ange BA, Anderson CA, Miller ER 3rd, Erlinger TP, Holbrook JT, Sacks FM, Appel LJ. Associations between macronutrient intake and self-reported appetite and fasting levels of appetite hormones: results from the Optimal Macronutrient Intake Trial to Prevent Heart Disease. *Am J Epidemiol* 2009;169:893-900.
161. Jacobs DR Jr, Gross MD, Steffen L, Steffes MW, Yu X, Svetkey LP, Appel LJ, Vollmer WM, Bray GA, Moore T, Conlin PR, Sacks F. The effects of dietary patterns on urinary albumin excretion: results of the Dietary Approaches to Stop Hypertension (DASH) Trial. *Am J Kidney Dis.* 2009;53:638-46.
162. Tonelli M, Curhan G, Pfeffer M, Sacks F, Thadhani R, Melamed ML, Wiebe N, Muntner P. Relation between alkaline phosphatase, serum phosphate, and all-cause or cardiovascular mortality. *Circulation.* 2009;120:1784-92...

163. Sacks FM, Rudel L, Connor A, Akeefe H, Kostner G, Baki T, Rothblat R, Llera-Moya M, Asztalos B, Perlman T, Zheng C, Alaupovic P, Maltais J, Brewer HB. Selective delipidation of plasma HDL enhances reverse cholesterol transport, in vivo. *J Lipid Res* 2009;50:894-907.
164. Sacks FM, Bray GA, Carey VJ, Smith SR, Ryan DH, Anton SD, McManus K, Champagne CM, Bishop LM, Laranjo N, Leboff MS, Rood JC, deJonge L, Greenway FL, Loria CM, Obarzanek E, Williamson DA. Comparison of weight-loss diets with different compositions of fat, protein, and carbohydrates. *N Engl J Med* 2009;360:859-73.
165. Mendivil C, Zheng C, Furtado J, Lel J, Sacks FM. Metabolism of VLDL and LDL containing apolipoprotein C-III and not other small apolipoproteins. *Arterioscler Thromb Vasc Biol* 2010;30:239-45.
166. Williamson DA, Anton SD, Han H, Champagne CM, Allen R, LeBlanc E, Ryan DH, McManus K, Laranjo N, Carey VJ, Loria CM, Bray GA, Sacks FM. Adherence is a multi-dimensional construct in the POUNDS LOST trial. *J Behav Med.* 2010;33:35-46.
167. Zheng C, Furtado J, Khoo C, Sacks FM. Apolipoprotein C-III and the metabolic basis for hypertriglyceridemia and the dense LDL phenotype. *Circulation* 2010;121:1722-34.
168. Williamson DA, Anton SD, Han H, Champagne CM, Allen R, Leblanc E, Ryan DH, Rood J, McManus K, Laranjo N, Carey VJ, Loria CM, Bray GA, Sacks FM. Early behavioral adherence predicts short and long-term weight loss in the POUNDS LOST study. *J Behav Med.* 2010;33:305-14
169. Micha R, King IB, Lemaitre RN, Rimm EB, Sacks F, Song X, Siscovick DS, Mozaffarian D. Food sources of individual plasma phospholipid trans fatty acid isomers: the Cardiovascular Health Study. *Am J Clin Nutr.* 2010;91:883-93.
170. Shiffman D, Sabatine MS, Louie JZ, Kirchgessner TG, Iakoubova OA, Campos H, Devlin JJ, Sacks FM. Effect of pravastatin therapy on coronary events in carriers of the KIF6 719Arg allele from the cholesterol and recurrent events trial. *Am J Cardiol.* 2010;105:1300-5.
171. Carey VJ, Bishop L, Laranjo N, Harshfield BJ, Kwiat C, Sacks FM. Contribution of high plasma triglycerides and low high-density lipoprotein cholesterol to residual risk of coronary heart disease after establishment of low-density lipoprotein cholesterol control. *Am J Cardiol.* 2010;106:757-63.
172. Furtado JD, Campos H, Sumner AE, Appel LJ, Carey VJ, Sacks FM. Dietary interventions that lower lipoproteins containing apolipoprotein C-III are more effective in whites than in blacks: results of the OmniHeart trial. *Am J Clin Nutr.* 2010;92:714-22.
173. Bare LA, Ruiz-Narvaez EA, Tong CH, Arellano AR Rowland CM, Catanese JJ, Sacks FM, Devlin JJ, Campos H. Investigation of KIF6 Trp719Arg in a case-control study of myocardial infarction: a Costa Rican population. *PLoS One* 2010; Sep 29;5(9).pii:e13081.

174. Hermans MP, Sacks FM, Ahn SA, Rousseau MF. Non-HDL-cholesterol as valid surrogate to apolipoprotein B100 measurement in diabetes: Discriminant Ratio and unbiased equivalence. *Cardiovasc Diabetol* 2011;10:20.
175. Mozaffarian D, Lemaitre RN, King IB, Song X, Spiegelman D, Sacks FM, Rimm EB, Siscovick DS. Circulating long-chain omega-3 fatty acids and incidence of congestive heart failure in older adults : The Cardiovascular Health Study : a cohort study. *Ann Intern Med* 2011;155 :160-70
176. van der Velde M, Matsushita K, Coresh J, Astor BC, Woodward M, Levey A, de Jong P, Gansevoort RT; Chronic Kidney Disease Prognosis Consortium, van der Velde M, Matsushita K, Coresh J, Astor BC, Woodward M, Levey AS, de Jong PE, Gansevoort RT, Levey A, El-Nahas M, Eckardt KU, Kasiske BL, Ninomiya T, Chalmers J, Macmahon S, Tonelli M, Hemmelgarn B, Sacks F, Curhan G, Collins AJ, Li S, Chen SC, Hawaii Cohort KP, Lee BJ, Ishani A, Neaton J, Svendsen K, Mann JF, Yusuf S, Teo KK, Gao P, Nelson RG, Knowler WC, Bilo HJ, Joosten H, Kleefstra N, Groenier KH, Auguste P, Veldhuis K, Wang Y, Camarata L, Thomas B, Manley T. Lower estimated glomerular filtration rate and higher albuminuria are associated with all-cause and cardiovascular mortality. A collaborative meta-analysis of high-risk population cohorts. *Kidney Int.* 2011;79:1341-52.
177. Qi Q, Bray GA, Smith SR, Hu FB, Sacks FM, Qi L. Insulin receptor substrate 1 gene variation modifies insulin resistance response to weight-loss diets in a 2-year randomized trial : The Preventing Overweight Using Novel Dietary Strategies (POUNDS LOST)\_ Trial. *Circulation* 2011;124 :563-71.
178. Bray GA, Smith SR, Delonge L, de Souza R, Rood J, Champagne CM, Laranjo N, Carey V, Obarzanek E, Loria CM, Anton SD, Ryan DH, Greenway FL, Williamson D, Sacks FM. Effect of diet composition on energy expenditure during weight loss : the POUNDS LOST Study. *Int J Obes* 2011 ;36:448-455. PMID: 21946707.
179. Trompet S, de Craen AJ, Postmus I, Ford I, Sattar N, Caslake M, Stott DJ, Buckley BM, Sacks F, Devlin JJ, Slagboom PE, Westendorp RG, Jukema JW. Replication of LDL GWAs hits in PROSPER/PHASE as validation for future (pharmaco)genetic analyses. *BMC Med Genet* 2011 ;12 :131 epub ahead of print.
180. Mendivil CO, Rimm EB, Furtado J, Chiuve SE, Sacks FM. Low-density lipoproteins containing apolipoprotein C-III and the risk of coronary heart disease. *Circulation* 2011;124 : 2065-72.
181. Qi Q, Bray GA, Hu FB, Sacks FM, Qi L. Weight-loss diets modify glucose-dependent insulinotropic polypeptide receptor rs2287019 genotype effects on changes in body weight, fasting glucose, and insulin resistance: the Preventing Overweight Using Novel Dietary Strategies trial. *Am J Clin Nutr.* 2012;95:506-13.
182. de Souza RJ, Bray GA, Carey VJ, Hall KD, Leboff MS, Loria CM, Laranjo NM, Sacks FM, Smith SR. Effects of 4 weight-loss diets differing in fat, protein, and carbohydrate on fat

- mass, lean mass, visceral adipose tissue, and hepatic fat: results from the POUNDS LOST trial. *Am J Clin Nutr* 2012;95:614-25.
183. Furtado JD, Wedel MK, Sacks FM. Antisense inhibition of apoB synthesis with mipomersen reduces plasma apoC-III and apoC-III-containing lipoproteins. *J Lipid Res* 2012;53:784-91.
  184. Wu JH, Lemaitre RN, King IB, Song X, Sacks FM, Rimm EB, Heckbert SR, Soscovick DS, Mozaffarian D. Association of plasma phospholipid long-chain n-3 fatty acids with incident atrial fibrillation in older adults: the Cardiovascular Health Study. *Circulation* 2012;125:1084-93.
  185. Mahajan N, Ference BA, Arora N, Madhavan R, Bhattacharya P, Sudhakar R, Sagar A, Want Y, Sacks F, Afonso L. Role of non-high-density lipoprotein cholesterol in predicting cerebrovascular events in patients following myocardial infarction. *Am J Cardiol* 2012; 109:1694-9.
  186. Jensen MK, Rimm EB, Furtado JD, Sacks FM. Apolipoprotein C-III as a potential modulator of the association between HDL-cholesterol and incident coronary heart disease. *J Am Heart Assoc* 2012;1:e000232.
  187. De Jongh L, Bray GA, Smith SR, Ryan DH, de Souza RJ, Loria CM, Champagne CM, Williamson DA, Sacks FM. Effect of diet composition and weight loss on resting energy expenditure in the POUNDS LOST Study. *Obesity* 2012;20:2384-9.
  188. Shiffman D, Trompet S, Jouie JZ, Rowland CM, Catanese JJ, Iakoubova OA, Kirchgessner TG, Westendorp RG, de Craen AJ, Slagboom PE, Buckley BM, Stott DJ, Sattar N, Devlin JJ, Packard CJ, Ford I, Sacks FM, Jukema JW. Genome-wide study of gene variants associated with differential cardiovascular event reduction by pravastatin therapy. *PLoS One* 2012;7:e38240
  189. Lemaitre FM, Sitlani C, Song X, King IB, McKnight B, Spiegelman D, Sacks FM, Djousse L, Rimm EB, Soscovick DS, Mozaffarian D. Circulating and dietary alpha-linolenic acid and incidence of congestive heart failure in older adults: the Cardiovascular Health Study. *Am J Clin Nutr* 2012;96:269-74.
  190. Zhang X, Qi Q, Zhang C, Hu FB, Sacks FM, Qi L. FTO genotype and two-year change in body composition and fat distribution in response to weight-loss diets: the POUNDS LOST trial. *Diabetes* 2012;61:3005-11.
  191. Zhang X, Qi Q, Bray GA, Hu FB, Sacks FM, Qi L. APOA5 genotype modulates 2-y changes in lipid profile in response to weight-loss diet intervention : the PoundsLost Trial. *Am J Clin Nutr* 2012 ;96 :917-22.
  192. Zheng C, Azcutia V, Aikawa E, Figueiredo JL, Croce K, Sonoki H, Sacks FM, Lusinskas FW, Aikawa M. Statins suppress apolipoprotein CIII-induced vascular endothelial cell activation and monocyte adhesion. *Eur Heart J* 2012 ; Aug 26 epub.

193. Mattei J, Qi Q, Hu FB, Sacks FM, Qi L. TCF7L2 genetics variants modulate the effect of dietary fat intake on changes in body composition during a weight-loss intervention. *Am J Clin Nutr* 2012 ;96 :1129-36.
194. Anton SD, Leblanc E, Allen HR, Karabetian C, Sacks F, Bray G, Williamson DA. Use of a computerized tracking system to monitor and provide feedback on dietary goals for calorie-restricted diets : The POUNDS LOST Study. *J Diabetes Sci Technol* 2012 ;6 :1216-25.
195. Anton SD, Gallagher J, Carey VJ, Laranjo N, Cheng J, Champagne DM, Ryan DH, McManus K, Loria CM, Bray GA, Sacks FM, Williamson DA. Diet type and changes in food cravings following weight loss : findings from the PoundsLost trial. *Eat Weight Disord* 2012;17:3101-8
196. Zhang X, Qi Q, Liang J, Hu FB, Sacks FM, Qi L. Neuropeptide Y promoter polymorphism modifies effects of a weight-loss diet on 2-year changes of blood pressure. *Hypertension* 2012 ;60 :1169-75.
197. Gadgil MD, Appel LJ, Yeung E, Anderson CA, Sacks FM, Miller ER. The effects of carbohydrate, unsaturated fat, and protein intake on measures of insulin sensitivity : Results from the OmniHeart trial. *Diabetes Care* 2013 ; 36 :1132-7.
198. Xu M, Qi Q, Liang J, Bray GA, Hu FB, Sacks FM, Qi L. Genetic determinant for amino acid metabolites and changes in body weight and insulin resistance in response to weight-loss diets : the preventing overweight using novel dietary strategies (POUNDS LOST) trial. *Circulation* 2013 ;127 :1283-9.
199. McCausland FR, McMullan CJ, Sacks FM, Forman JP. Race, plasma renin activity, and morning blood pressure surge – Results from the Dietary Approaches to Stop Hypertension Trial. *Am J Hypertens* 2013 ;Mar 9, epub.
200. Fretts AM, Mozaffarian D, Siscovick DS, Heckbert SR, McKnight B, King IB, Rimm EG, Psaty BM, Sacks FM, Song X, Spiegelman D, Lemaitre RN. Associations of plasma phospholipid and dietary alpha linolenic acid with incident atrial fibrillation in older adults : the Cardiovascular Health Study. *J Am Heart Assoc* 2013 ;2 :e003814.
201. Mozaffarian D, Lemaitre RN, King IB, Song X, Huang H, Sacks FM, Rimm EB, Wang M, Siscovick DS. Plasma phospholipid long-chain omega-3 fatty acids and total and cause-specific mortality in older adults : a cohort study. *Ann Intern Med* 2013 ;158 :515-25.
202. Mendivil CO, Rimm EB, Furtado J, Sacks FM. Apolipoprotein E in VLDL and LDL with apolipoprotein C-III is associated with a lower risk of coronary heart disease. *J Am Heart Assoc* 2013 ; May 14 ;2 :e000130. PMID: 23672999
203. Nicklas JM, Sacks FM, Smith SR, Leboff MS, Rood JC, Bray GA, Ridker PM. Effect of dietary composition of weight loss diets on high-sensitivity C-reactive protein : The randomized POUNDS LOST trial. *Obesity* 2013; 21:681-9.

204. Qi Q, Xu M, Wu H, Liang L, Champagne CM, Bray GA, Sacks FM, Qi L. IRS1 genotype modulates metabolic syndrome reversion in response to 2-year weight-loss diet intervention: The PoundsLost trial. *Diab Care* 2013;36:520-7.
205. O'Donoghue M, Morrow DA, Tsimikas S, Sloan S, Ren AF, Hoffman EB, Desai NP, Solomon SD, Domanski M, Arai K, Chiuve SE, Cannon CP, Sacks FM, Sabatine M. Lipoprotein (a) For Risk Assessment in Patients with Established Coronary Artery Disease. *J Am Coll Cardiol*. 2014;63:520-527. PMID: 24161323
206. Mirzaei K, Xu M, Qi Q, de Jonge L, Bray GA, Sacks F, Qi L. Variants in glucose- and circadian rhythm-related genes affect the response of energy expenditure to weight-loss diets: the POUNDS LOST Trial. *Am J Clin Nutr*. 2014;99:392-399. PMID: 24335056
207. Sacks FM, Hermans MP, Fioretto P, Valensi P, Davis T, Horton E, Wanner C, Al-Rubeaan K, Aronson R, Barzon I, Bishop L, Bonora E, Bunnag P, Chuang LM, Deerochanawong C, Goldenberg R, Harshfield B, Hernández C, Herzlinger-Botein S, Itoh H, Jia W, Jiang YD, Kadowaki T, Laranjo N, Leiter L, Miwa T, Odawara M, Ohashi K, Ohno A, Pan C, Pan J, Pedro-Botet J, Reiner Z, Rotella CM, Simo R, Tanaka M, Tedeschi-Reiner E, Twum-Barima D, Zoppini G, Carey VJ. Association Between Plasma Triglycerides and HDL-Cholesterol and Microvascular Kidney Disease and Retinopathy in Type 2 Diabetes: A Global Case-Control Study in 13 Countries. *Circulation*. 2014;129:999-1008.
208. Sumner AE, Furtado JD, Courville AB, Ricks M, Younger-Coleman N, Tulloch-Reid MK, Sacks FM. ApoC-III and visceral adipose tissue contribute to paradoxically normal triglyceride levels in insulin-resistant African-American women. *Nutr Metab (Lond)*. 2013;10:73. PMID: 24365086
209. Cousland FR, Sacks FM, Forman JP. Marital status, dipping and nocturnal blood pressure: results from the Dietary Approaches to Stop Hypertension trial. *J Hypertens*. 2014;32:756-61. PMID: 24509120
210. Huang T, Qi Q, Li Y, Hu FB, Bray GA, Sacks FM, Williamson DA, Qi L. FTO genotype, dietary protein, and change in appetite: the Preventing Overweight Using Novel Dietary Strategies trial. *Am J Clin Nutr*. 2014;99:1126-30. PMID: 24622803
211. Miyazaki T, Chiuve S, Sacks FM, Ridker PM, Libby P, Aikawa M. Plasma pentraxin 3 levels do not predict coronary events but reflect metabolic disorders in patients with coronary artery disease in the CARE trial. *PLoS One*. 2014;9:e94073. PMID: 24705587
212. Ha V, Sievenpiper JL, de Souza RJ, Jayalath VH, Mirrahimi A, Agarwal A, Chiavaroli L, Mejia SB, Sacks FM, Di Buono M, Bernstein AM, Leiter LA, Kris-Etherton PM, Vuksan V, Bazinet RP, Josse RG, Beyene J, Kendall CW, Jenkins DJ. Effect of dietary pulse intake on established therapeutic lipid targets for cardiovascular risk reduction: a systematic review and meta-analysis of randomized controlled trials. *CMAJ*. 2014;186:E252-62. PMID: 24710915



213. Barte JC, Veldwijk J, Teixeira PJ, Sacks FM, Bemelmans WJ. Differences in Weight Loss Across Different BMI Classes:A Meta-analysis of the Effects of Interventions with Diet and Exercise. *Int J Behav Med.* 2014;21:784-793.
214. Postmus I, Johnson PC, Trompet S, de Craen AJ, Slagboom PE, Devlin JJ, Shiffman D, Sacks FM, Kearney PM, Stott DJ, Buckley BM, Sattar N, Ford I, Westendorp RG, Jukema JW. In search for genetic determinants of clinically meaningful differential cardiovascular event reduction by pravastatin in the PHarmacogenetic study of Statins in the Elderly at risk (PHASE)/PROSPER study. *Atherosclerosis.* 2014;235:58-64
215. Talayero B, Wang L, Furtado JD, Carey VJ, Bray GA, Sacks FM. Obesity Favors Apolipoprotein E and CIII-containing High-density Lipoprotein Subfractions Associated with Risk of Heart Disease. *J Lipid Res.* 2014;55:2167-2177. PMC4174008
216. Fretts AM, Mozaffarian D, Siscovick DS, Djousse L, Heckbert SR, King IB, McKnight B, Sitlani C, Sacks FM, Song X, Sotoodehnia N, Spiegelman D, Wallace ER, Lemaitre RN. Plasma phospholipid saturated Fatty acids and incident atrial fibrillation: the cardiovascular health study. *J Am Heart Assoc.* 2014 Jun 26;3:e000889. PMID: 24970268
217. Huang T, Huang J, Qi Q, Li Y, Bray GA, Rood J, Sacks FM, Qi L. PCSK 7 genotype modifies effect of a weight-loss diet on 2-year changes of insulin resistance; The POUNDS LOST trial. *Diabetes Care* 2015 ;38 :439-444. PMID: 25504030
218. Haring B, Wyler von Ballmoos MC, Appel LJ, Sacks FM. Healthy dietary interventions and lipoprotein(a) plasma levels; results from the OmniHeart trial. *PLOS One* 2014;9:e114859. PMID: 25506933
219. Sacks FM, Carey VJ, Anderson CA, Miller ER 3rd, Copeland T, Charleston J, Harshfield BJ, Laranjo N, McCarron P, Swain J, White K, Yee K, Appel LJ. Effects of high vs low glycemic index of dietary carbohydrate on cardiovascular disease risk factors and insulin sensitivity: the OmniCarb randomized clinical trial. *JAMA* 2014;312:2531-2541. PMID: 25514303
220. Wang L, Sacks FM, Furtado JD, Ricks M, Courville AB, Sumner AE. Racial differences between African-American and white women in insulin resistance and visceral adiposity are associated with differences in apoCIII containing apoAI and apoB lipoproteins. *Nutr Metab (Lond)* 2014;11:56. PMID: 25553059
221. Qi Q, Durst R, Schwarzfuchs D, Leitersdorf E, Shpitzen S, Li Y, Wu H, Champagne CM, Hu FB, Stampfer MJ, Bray GA, Sacks FM, Shai I, Qi L. CETP genotype and changes in lipid levels in response to weight-loss diet intervention in the POUNDS LOST and DIRECT randomized trials. *J Lipid Res.* 2015;56:713-21. PMID: 25548261
222. Morris MC, Tangney CC, Wang Y, Sacks FM, Bennett DA, Aggarwal NT. MIND diet associated with reduced incidence of Alzheimer's disease. *Alzheimers Dement.* 2015;11:1007-1014. PMID: 25681666

223. Thomas DM, Ivanescu AE, Martin CK, Heymsfield SB, Marshall K, Bodrato VE, Williamson DA, Anton SD, Sacks FM, Ryan D, Bray GA. Predicting successful long-term weight loss from short-term weight-loss outcomes: new insights from a dynamic energy balance model (the POUNDS Lost study). *Am J Clin Nutr.* 2015;101:449-54. PMID: 25733628
224. Mega JL, Stitzel NO, Smith JG, Chasman DI, Caulfield MJ, Devlin JJ, Nordio F, Hyde CL, Cannon CP, Sacks FM, Poulter NR, Sever PS, Ridker PM, Braunwald E, Melander O, Kathiresan S, Sabatine MS. Genetic risk, coronary heart disease events, and the clinical benefit of statin therapy: an analysis of primary and secondary prevention trials. *Lancet.* 2015;385:2264-71. PMID: 25748612
225. Zheng Y, Huang T, Zhang X, Rood J, Bray GA, Sacks FM, Qi L. Dietary Fat Modifies the Effects of FTO Genotype on Changes in Insulin Sensitivity. *J Nutr.* 2015;145:977-82. PMID: 25761503
226. Xu M, Ng SS, Bray GA, Ryan DH, Sacks FM, Ning G, Qi L. Dietary Fat Intake Modifies the Effect of a Common Variant in the LIPC Gene on Changes in Serum Lipid Concentrations during a Long-Term Weight-Loss Intervention Trial. *J Nutr.* 2015;145:1289-94. PMID: 25926410
227. Tirosh A, de Souza RJ, Sacks F, Bray GA, Smith SR, LeBoff MS. Sex Differences in the Effects of Weight Loss Diets on Bone Mineral Density and Body Composition: POUNDS LOST Trial. *J Clin Endocrinol Metab.* 2015;100:2463-71. PMID: 25825948
228. Desai NK, Ooi EM, Mitchell PD, Furtado J, Sacks FM. Metabolism of apolipoprotein A-II containing triglyceride rich ApoB lipoproteins in humans. *Atherosclerosis.* 2015;241:326-33. PMID: 26071654
229. Morris MC, Tangney CC, Wang Y, Sacks FM, Barnes LL, Bennett DA, Aggarwal NT. MIND diet slows cognitive decline with aging. *Alzheimers Dement.* 2015 ;11:1015-1022.
230. Lin X, Qi Q, Zheng Y, Huang T, Lathrop M, Zelenika D, Bray GA, Sacks FM, Liang L, Qi L. Neuropeptide Y genotype, central obesity, and abdominal fat distribution: the POUNDS LOST trial. *Am J Clin Nutr.* 2015;102:514-9. PMID: 26156739
231. Wyler von Ballmoos MC, Haring B, Sacks FM. The risk of cardiovascular events with increased apolipoprotein CIII : a systematic review and meta-analysis. *J Clin Lipidol* 2015;498-510. PMID: 26228667
232. Qi Q, Zheng Y, Huang T, Rood J, Bray GA, Sacks FM, Qi L. Vitamin D metabolism-related genetic variants, dietary protein intake and improvement of insulin resistance in a 2 year weight-loss trial: POUNDS Lost. *Diabetologia.* 2015;58:2791-9. PMC4631625
233. Mendivil CO, Furtado J, Morton AM, Wang L, Sacks FM. Novel Pathways of Apolipoprotein A-I Metabolism in High-Density Lipoprotein of Different Sizes in Humans. *Arterioscler Thromb Vasc Biol.* 2016;36:156-165. PMC4690755

234. Juraschek SP, McAdams-Demarco M, Gelber AC, Sacks FM, Appel LJ, White KJ, Miller ER 3rd. Effects of Lowering Glycemic Index of Dietary Carbohydrate on Plasma Uric Acid Levels: The OmniCarb Randomized Clinical Trial. *Arthritis Rheumatol.* 2016;68:1281-9. PMC5532800
235. Fretts AM, Mozaffarian D, Siscovick DS, King IB, McKnight B, Psaty BM, Rimm EB, Sitlani C, Sacks FM, Song X, Sotoodehnia N, Spiegelman D, Lemaitre RN. Associations of Plasma Phospholipid SFAs with Total and Cause-Specific Mortality in Older Adults Differ According to SFA Chain Length. *J Nutr.* 2016;146:298-305. PMC4870839
236. Zheng Y, Ceglarek U, Huang T, Li L, Rood J, Ryan DH, Bray GA, Sacks FM, Schwarzfuchs D, Thiery J, Shai I, Qi L. Weight-loss diets and 2-y changes in circulating amino acids in 2 randomized intervention trials. *Am J Clin Nutr.* 2016;103:505-511. PMC4733257
237. Singh SA, Andraski AB, Pieper B, Goh W, Mendivil CO, Sacks FM, Aikawa M. Multiple apolipoprotein kinetics measured in human HDL by high-resolution/accurate mass parallel reaction monitoring. *J Lipid Res.* 2016;57:714-28. PMC4808760
238. Ma W, Huang T, Zheng Y, Wang M, Bray GA, Sacks FM, Qi L. Weight-Loss Diets, Adiponectin, and Changes in Cardiometabolic Risk in the 2-Year POUNDS Lost Trial. *J Clin Endocrinol Metab.* 2016;101:2415-22. PMC4891796
239. Wang T, Huang T, Zheng Y, Rood J, Bray GA, Sacks FM, Qi L. Genetic variation of fasting glucose and changes in glycemia in response to 2-year weight-loss diet intervention: the POUNDS LOST trial. *Int J Obes (Lond).* 2016; 40:1164-1169. PMC4935586
240. Huang T, Ley SH, Zheng Y, Wang T, Bray GA, Sacks FM, Qi L. Genetic susceptibility to diabetes and long-term improvement of insulin resistance and  $\beta$  cell function during weight loss: the Preventing Overweight Using Novel Dietary Strategies (POUNDS LOST) trial. *Am J Clin Nutr.* 2016; 104:198-204. PMC4919524
241. Vadiveloo M, Sacks FM, Champagne CM, Bray GA, Mattei J. Greater Healthful Dietary Variety Is Associated with Greater 2-Year Changes in Weight and Adiposity in the Preventing Overweight Using Novel Dietary Strategies (POUNDS Lost) Trial. *J Nutr.* 2016;146:1552-1559. PMC4958287
242. Ma W, Huang T, Wang M, Zheng Y, Wang T, Heianza Y, Sun D, Smith SR, Bray GA, Sacks FM, Qi L. Two-year changes in circulating adiponectin, ectopic fat distribution and body composition in response to weight-loss diets: the POUNDS Lost Trial. *Int J Obes (Lond).* 2016;40:1723-1729
243. Zheng Y, Ceglarek U, Huang T, Wang T, Heianza Y, Ma W, Bray GA, Thiery J, Sacks FM, Qi L. Plasma Taurine, Diabetes Genetic Predisposition, and Changes of Insulin Sensitivity in response to weight-loss diets. *J Clin Endocrinol Metab.* 2016;101:3820-3826. PMC5052340

244. Heianza Y, Ma W, Huang T, Wang T, Zheng Y, Smith SR, Bray GA, Sacks FM, Qi L. Macronutrient Intake-Associated FGF21 Genotype Modifies Effects of Weight-Loss Diets on 2-Year Changes of Central Adiposity and Body Composition: The POUNDS Lost Trial. *Diabetes Care*. 2016;39:1909-1914. PMC5079612
245. Livingstone KM, Celis-Morales C, Papandonatos GD, Erar B, Florez JC, Jablonski KA, Razquin C, Marti A, Heianza Y, Huang T, Sacks FM, Svendstrup M, Sui X, Church TS, Jääskeläinen T, Lindström J, Tuomilehto J, Uusitupa M, Rankinen T, Saris WH, Hansen T, Pedersen O, Astrup A, Sørensen TI, Qi L, Bray GA, Martinez-Gonzalez MA, Martinez JA, Franks PW, McCaffery JM, Lara J, Mathers JC. FTO genotype and weight loss: systematic review and meta-analysis of 9563 individual participant data from eight randomised controlled trials. *BMJ*. 2016;354:i4707; PMID: 27650503
246. Ma W, Huang T, Heianza Y, Wang T, Sun D, Tong J, Williamson DA, Bray GA, Sacks FM, Qi L. Genetic variations of circulating adiponectin levels modulate changes in appetite in response to weight-loss diets. *J Clin Endocrinol Metab*. 2016;102:316-325. PMC5413100
247. Lee LH, Andraski AB, Pieper B, Higashi H, Sacks FM, Aikawa M, Singh SA. Automation of PRM-dependent D3-Leu tracer enrichment in HDL to study the metabolism of apoA-I, LCAT and other apolipoproteins. *Proteomics*. 2017;17(1-2). PMCID: PMC5572145
248. Juraschek SP, Miller ER, Selvin E, Carey VJ, Appel LJ, Christenson RH, Sacks FM. Effect of type and amount of dietary carbohydrate on biomarkers of glucose homeostasis and C reactive protein in overweight or obese adults: results from the OmniCarb trial. *BMJ Open Diabetes Research and Care* 2016;4:e000276. PMC5128999
249. Morton AM, Furtado JD, Lee J, Amerine W, Davidson MH, Sacks FM. The effect of omega-3 carboxylic acids on apolipoprotein CIII-containing lipoproteins in severe hypertriglyceridemia. *J Clin Lipidol* 2016;10:1442-1451. PMID: 27919362
250. Liu G, Liang L, Bray GA, Qi L, Hu FB, Rood J, Sacks FM, Sun Q. Thyroid hormones and changes in body weight and metabolic parameters in response to weight-loss diets: The POUNDS LOST trial. *Int J Obes (Lond)*. 2017;41:878-886. PMC5461198
251. Huang T, Zheng Y, Hruby A, Williamson DA, Bray GA, Shen Y, Sacks FM, Qi L. Dietary Protein Modifies the Effect of the *MC4R* Genotype on 2-Year Changes in Appetite and Food Craving: The POUNDS Lost Trial. *J Nutr*. 2017;147:439-444. PMC5320402
252. Bray GA, Ryan DH, Johnson W, Champagne CM, Johnson CM, Rood J, Williamson DA, Sacks FM. Markers of dietary protein intake are associated with successful weight loss in the POUNDS Lost trial. *Clin Obes*. 2017;7:166-175. PMCID: PMC5517018
253. Koch M, Furtado JD, Jiang GZ, Gray BE, Cai T, **Sacks F**, Tjønneland A, Overvad K, Jensen MK. Associations of anthropometry and lifestyle factors with HDL subspecies according to apolipoprotein C-III. *J Lipid Res*. 2017;58:1196-1203. PMCID: PMC5454517

254. Melchior JT, Street SE, Andraski AB, Furtado JD, Sacks FM, Shute RL, Greve EI, Swertfeger DK, Li H, Shah AS, Lu LJ, Davidson WS. Apolipoprotein A-II alters the proteome of human lipoproteins and enhances cholesterol efflux from ABCA1. *J Lipid Res.* 2017;58:1374-1385. PMID: PMC5496035
255. He H, Sun D, Zeng Y, Wang R, Zhu W, Cao S, Bray GA, Chen W, Shen H, Sacks FM, Qi L, Deng HW. A Systems Genetics Approach Identified GPD1L and its Molecular Mechanism for Obesity in Human Adipose Tissue. *Sci Rep.* 2017 May 11;7(1):1799. PMID: PMC5431993
256. Aroner SA, Yang M, Li J, Furtado JD, Sacks FM, Tjønneland A, Overvad K, Cai T, Jensen MK. Apolipoprotein C-III and High-Density Lipoprotein Subspecies Defined by Apolipoprotein C-III in Relation to Diabetes Risk. *Am J Epidemiol.* 2017;186:736-744. PMID: 28520887
257. Juraschek SP, Miller ER 3rd, Appel LJ, Christenson RH, Sacks FM, Selvin E. Effects of dietary carbohydrate on 1,5-anhydroglucitol in a population without diabetes: results from the OmniCarb trial. *Diabet Med.* 2017;34:1407-1413. PMID: PMC5603394
258. Kakarmath SS, Zack RM, Leyna GH, Fahimi S, Liu E, Fawzi WW, Lukmanji Z, Killewo J, Sacks F, Danaei G. Dietary determinants of serum total cholesterol among middle-aged and older adults: a population-based cross-sectional study in Dar es Salaam, Tanzania. *BMJ Open.* 2017 Jun 6;7(5):e015028. PMID: PMC5663012
259. Apolzan JW, Myers CA, Champagne CM, Beyl RA, Raynor HA, Anton SA, Williamson DA, Sacks FM, Bray GA, Martin CK. Frequency of Consuming Foods Predicts Changes in Cravings for Those Foods During Weight Loss: The POUNDS Lost Study. *Obesity.* 2017;25:1343-1348. PMID: 28618170
260. Heianza Y, Sun D, Wang T, Huang T, Bray GA, Sacks FM, Qi L. Starch Digestion-Related Amylase Genetic Variant Affects 2-Year Changes in Adiposity in Response to Weight-Loss Diets: The POUNDS Lost Trial. *Diabetes.* 2017;66:2416-2423. PMID: PMC5566300
261. Han L, Ma W, Sun D, Heianza Y, Wang T, Zheng Y, Huang T, Duan D, Bray JGA, Champagne CM, Sacks FM, Qi L. Genetic variation of habitual coffee consumption and glycemic changes in response to weight-loss diet intervention: the Preventing Overweight Using Novel Dietary Strategies (POUNDS LOST) trial. *Am J Clin Nutr.* 2017;106:1321-1326. PMID: 28931532
262. Juraschek SP, Woodward M, Sacks FM, Carey VJ, Miller ER 3rd, Appel LJ. Time Course of Change in Blood Pressure From Sodium Reduction and the DASH Diet. *Hypertension.* 2017 Nov;70(5):923-929. PMID: 28993451
263. Goni L, Sun D, Heianza Y, Wang T, Wang T, Cuervo M, Martinez JA, Shang X, Bray GA, Sacks FM, Qi L. Macronutrient-specific effect of the MTNR1B genotype on lipid levels in response to 2-year weight-loss diets. *J Lipid Res.* 2018;59:155-161. PMID: 29089366

264. Jensen MK, Aroner SA, Mukamal KJ, Furtado JD, Post WS, Tsai MY, Tjønneland A, Polak JF, Rimm EB, Overvad K, McClelland RL, Sacks FM. HDL Subspecies Defined by Presence of Apolipoprotein C-III and Incident Coronary Heart Disease in Four Cohorts. *Circulation*. 2018;137:1364-1373. PMID: 29162611
265. Heianza Y, Sun D, Smith SR, Bray GA, Sacks FM, Qi L. Changes in Gut Microbiota-Related Metabolites and Long-term Successful Weight Loss in Response to Weight-Loss Diets: The POUNDS Lost Trial. *Diabetes Care*. 2018;41:413-419. PMID: 29305401
266. Yamamoto R, Sacks FM, Hu FB, Rosner B, Furtado JD, Aroner SA, Ferrannini E, Baldi S, Kozakova M, Balkau B, Natali A, Jensen MK; RISC Investigators. High density lipoprotein with apolipoprotein C-III is associated with carotid intima-media thickness among generally healthy individuals. *Atherosclerosis*. 2018;269:92-99. PMID: 29351856
267. Huang T, Wang T, Heianza Y, Sun D, Ivey K, Durst R, Schwarzfuchs D, Stampfer MJ, Bray GA, Sacks FM, Shai I, Qi L. HNF1A variant, energy-reduced diets and insulin resistance improvement during weight loss: The POUNDS Lost trial and DIRECT. *Diabetes Obes Metab*. 2018;20:1445-1452. PMID: 29424957
268. Morton AM, Koch M, Mendivil CO, Furtado JD, Tjønneland A, Overvad K, Wang L, Jensen MK, Sacks FM. Apolipoproteins E and CIII interact to regulate HDL metabolism and coronary heart disease risk. *JCI Insight* 2018; Feb 22;3(4). PMC5916256
269. Goni L, Sun D, Heianza Y, Wang T, Huang T, Martínez JA, Shang X, Bray GA, Smith SR, Sacks FM, Qi L. A circadian rhythm-related MTNR1B genetic variant modulates the effect of weight-loss diets on changes in adiposity and body composition: the POUNDS Lost trial. *Eur J Nutr*. 2018 Mar 7. PMID: 29516223
270. Heianza Y, Sun D, Ma W, Zheng Y, Champagne CM, Bray GA, Sacks FM, Qi L. Gut-microbiome-related LCT genotype and 2-year changes in body composition and fat distribution: the POUNDS Lost Trial. *Int J Obes (Lond)*. 2018 Feb 26. PMID: 29568104
271. Sun D, Heianza Y, Li X, Shang X, Smith SR, Bray GA, Sacks FM, Qi L. Genetic, epigenetic, and transcriptional variations at NFATC2IP locus with weight loss in response to diet interventions: The POUNDS Lost Trial. *Diabetes Obes Metab*. 2018 Apr 24. PMID: 29693310
272. Heianza Y, Sun D, Li X, DiDonato JA, Bray GA, Sacks FM, Qi L. Gut microbiota metabolites, amino acid metabolites and improvements in insulin sensitivity and glucose metabolism: the POUNDS Lost trial. *Gut*. 2018 Jun 2. PMID: 29860242 [Epub ahead of print]
273. Zhou T, Sun D, Heianza Y, Li X, Champagne CM, LeBoff MS, Shang X, Pei X, Bray GA, Sacks FM, Qi L. Genetically determined vitamin D levels and change in bone density during a weight-loss diet intervention: the Preventing Overweight Using Novel Dietary Strategies (POUNDS Lost) Trial. *Am J Clin Nutr* 2018;108:1129-1134. PMID: 30475961

274. Furtado JD Yamamoto R, Melchior JT, Andraski AB, Gamez-Guerrero M, Mulcahy P, He Z, Cai T, Davidson WS, Sacks FM. Distinct proteomic signatures in 16 HDL (High-Density Lipoprotein) subspecies. *Arterioscler Thromb Vasc Biol* 2018;38:2827-2842. PMID: 30571168.
275. Hjorth MF, Bray GA, Zohar Y, Urban L, Miketinas DC, Williamson DA, Ryan DH, Rood J, Champagne CM, Sacks FM, Astrup A. Pretreatment fasting glucose and insulin as determinants of weight loss on diets varying in macronutrients and dietary fibers – The POUNDS LOST Study. *Nutrients*. 2019 Mar 11;11(3). PMC6470525
276. Morton AM, Furtado JD, Mendivil CO, Sacks FM. Dietary unsaturated fat increases HDL metabolic pathways involving apoE favorable to reverse cholesterol transport. *JCI Insight* 2019;4(7): e124620. PMID: 30944249
277. Aroner SA, Furtado JD, Sacks FM, Tsai MY, Mukamal KJ, McClelland RL, Jensen MK. Apolipoprotein C-III and its defined lipoprotein subspecies in relation to incident diabetes: the Multi-Ethnic Study of Atherosclerosis. *Diabetologia*. 2019;62(6):981-992. PMID: 30949716
278. Miketinas DC, Bray GA, Beyl RA, Ryan DH, Sacks FM, Champagne CM. Fiber Intake Predicts Weight Loss and Dietary Adherence in Adults Consuming Calorie-Restricted Diets: The POUNDS Lost (Preventing Overweight Using Novel Dietary Strategies) Study. *J Nutr*. 2019;149(10):1742-1748. PMID: 31174214
279. Cahill LE, Sacks FM, Rimm EB, Jensen MK. Cholesterol Efflux Capacity, HDL Cholesterol, and Risk of Coronary Heart Disease: a Nested Case-Control Study in Men. *J Lipid Res*. 2019;60:1457-64. PMID: 31142574
280. Satija A, Malik V, Rimm EB, Sacks F, Willett W, Hu FB. Changes in intake of plant-based diets and weight change: results from 3 prospective cohort studies. *Am J Clin Nutr*. 2019;110(3):574-582. PMID: 31127828
281. Zhou T, Heianza Y, Chen Y, Li X, Sun D, DiDonato JA, Pei X, LeBoff MS, Bray GA, Sacks FM, Qi L. Circulating Gut Microbiota Metabolite Trimethylamine N-Oxide (TMAO) and Changes in Bone Density in Response to Weight Loss Diets: The POUNDS Lost Trial. *Diabetes Care*. 2019;42(8):1365-1371. PMID: 31332027
282. Ding M, Zeleznik OA, Guasch-Ferre M, Hu J, Lasky-Su J, Lee IM, Jackson RD, Shadyab AH, LaMonte MJ, Clish C, Eliassen AH, Sacks F, Willett WC, Hu FB, Rexrode KM, Kraft P. Metabolome-Wide Association Study of the Relationship Between Habitual Physical Activity and Plasma Metabolite Levels. *Am J Epidemiol*. 2019;188(11):1932-1943. PMID: 31364705
283. Ardisson Korat AV, Li Y, Sacks F, Rosner B, Willett WC, Hu FB, Sun Q. Dairy fat intake and risk of type 2 diabetes in 3 cohorts of US men and women. *Am J Clin Nutr*. 2019;110(5):1192-1200. PMID: 31414137

284. Andraski AB, Singh SA, Lee LH, Higashi H, Smith N, Zhang B, Aikawa M, Sacks FM. Effects of Replacing Dietary Monounsaturated Fat With Carbohydrate on HDL (High-Density Lipoprotein) Protein Metabolism and Proteome Composition in Humans. *Arterioscler Thromb Vasc Biol.* 2019;39(11):2411-2430. PMID: 31554421
285. Ardisson Korat AV, Malik VS, Furtado JD, Sacks F, Rosner B, Rexrode KM, Willett WC, Mozaffarian D, Hu FB, Sun Q. Circulating Very-Long-Chain SFA Concentrations Are Inversely Associated with Incident Type 2 Diabetes in US Men and Women. *J Nutr.* 2019 Oct 16. [Epub ahead of print]. PMID: 31618417
286. Lian Z, Perrard XD, Peng X, Raya JL, Hernandez AA, Johnson CG, Lagor WR, Pownall HJ, Hoogeveen RC, Simon SI, Sacks FM, Ballantyne CM, Wu H. Replacing Saturated Fat With Unsaturated Fat in Western Diet Reduces Foamy Monocytes and Atherosclerosis in Male *Ldlr*<sup>-/-</sup> Mice. *Arterioscler Thromb Vasc Biol.* 2019 Oct 17:ATVBAHA119313078. doi: 10.1161/ATVBAHA.119.313078. [Epub ahead of print] PMID: 31619061
287. Sun D, Zhou T, Li X, Heianza Y, Liang Z, Bray GA, Sacks FM, Qi L. Genetic Susceptibility, Dietary Protein Intake, and Changes of Blood Pressure: The POUNDS Lost Trial. *Hypertension.* 2019 Dec;74(6):1460-1467. doi: 10.1161/HYPERTENSIONAHA.119.13510. Epub 2019 Oct 28. PMID: 31656094

#### Books and Monographs

1. Sacks FM ed. Dietary fats and coronary heart disease. *J Cardiovasc Risk* 1994;1:1-70.
2. Sacks FM, Pfeffer MA, Braunwald E, eds. Cholesterol-lowering trials: new results and emerging issues (monograph). *Am J Cardiol* 1995;76:1C-126C.
3. Sacks FM, editor. Dietary fat, the Mediterranean diet and health: reports from scientific exchanges, 1998, 2000. *Am J Med* 2002;113 Suppl 9B: 1S – 89S.

#### Reviews, case reports, letters, and editorials

1. Sacks FM. A literature review of *Phaseolus angularis* - the adsuki bean. *Econ Bot* 1977; 31:9-15.
2. Sacks FM. Vegetarian diets and cardiovascular risk factors. In: Anderson J, ed. *Vegetarianism*. Chapel Hill: Health Sciences Consortium, 1982, pp 134-142.
3. Sacks FM, Dzau VJ. Adrenergic effects on plasma lipoprotein metabolism: speculation on mechanisms of action. *Am J Med* 1986; 80 (2A):71-81.
4. Dzau VJ, Sacks FM. Regulation of lipoprotein metabolism by adrenergic mechanisms. *J. Cardiovasc. Pharmacol.* 1987; 10 (suppl 9):52-56



5. Stone PH, Sacks FM, Smith TW. Use of hypolipidemic strategies to halt atherosclerosis: evidence for alteration in clinical course. In, Grundy SM, Bearn AG eds, *The role of cholesterol in atherosclerosis: New therapeutic opportunities*. Philadelphia, PA, Hanley and Belfus 1988; 83-103.
6. Figge HL, Figge J, Souney PF, Mutnick AH, Sacks FM. Nicotinic acid: A review of clinical use in the treatment of lipid disorders. *Pharmacotherapy* 1988;8:287-94.
7. Sacks, FM. Dietary fats and blood pressure: a critical review of the evidence. *Nutr Rev* 1989;47:291-300.
8. Sacks FM, Walsh BW. The effects of reproductive hormones on blood lipoproteins and blood pressure. Unresolved issues in biology and clinical practice. *Ann NY Acad Sci* 1990;592:272-285.
9. [NIH authorship]. Lipoproteins and childhood antecedents of adult cardiovascular disease. [FM Sacks, author of this chapter]. In, *Nutrition, An Evaluation and Assessment of the State of the Science*, National Institute of Child Health and Human Development, National Institutes of Health, Public Health Service, U.S. Department of Health and Human Services, 1991, pp.159-176.
10. Willett WC, Sacks FM. Chewing the fat; how much and what kind. *New Engl J Med* 1991;324:121-123.
11. Sacks FM, Willett WC. More on chewing the fat; the good fat and the good cholesterol. *New Engl J Med* 1991;325:1740-1742.
12. Sacks FM. Desirable serum total cholesterol with low HDL cholesterol levels. An undesirable situation in coronary heart disease. *Circulation* 1992;86:1341-1344.
13. Working Group, National High Blood Pressure Education Program. Report on primary prevention of hypertension. *Arch Intern Med* 1993;153:186-208.
14. Sacks FM. Dietary fiber and cardiovascular disease. Directly protective or an indicator of a healthy lifestyle? *Am J Prev Med* 1993;9:259-260.
15. Sacks FM. Hyperlipidemia. In Braunwald E, Rose BD, eds, *Intensive Review of Internal Medicine*, 4th Ed, Boston, Nimrod Press, 1993:393-405.
16. Eaker ED, Chesebro JH, Sacks FM, Wenger NK, Whisnant JP (Members, American Heart Association Special Writing Group). AHA Medical/Scientific Statement, Special Report, Cardiovascular Disease in Women. *Circulation* 1993;88:1999-2009.

17. Sacks FM. Macronutrients and blood pressure. In Izzo JL, Black HR, eds. Hypertension Primer. The Essentials of High Blood Pressure. Dallas, Texas, Council for High Blood Pressure Research, American Heart Association 1993:178-179.
18. Morris MC, Sacks FM. Dietary fats and blood pressure. In Swales JD ed, Textbook of hypertension, Oxford, Blackwell, 1994:605-618.
19. Sacks FM. Hyperlipidemia. In Branch WT, ed, Office practice of medicine, 3rd edition. NY, Saunders, 1994:87-100.
20. Sacks FM, Walsh BW. Sex hormones and lipoprotein metabolism. Current Opinion in Lipidology 1994;5:236-240.
21. Sacks FM. Dietary fats and CHD; Overview and effects on serum lipoproteins. J Cardiovasc Risk 1994;1:3-8.
22. Stone PH, Sacks FM. Strategies for secondary prevention. In Manson J, Ridker P, Gaziano M, Hennekens CH, eds, Prevention of Myocardial Infarction. Oxford University Press 1995.
23. Sacks FM, Gerhart M, Walsh BW. Sex hormones, lipoproteins, and vascular reactivity. Current Opinion in Lipidology 1995;6:161-166.
24. Willett WC, Sacks F, Trichopoulou A, Drescher G, Ferro-Luzzi A, Helsing E, Trichopoulos D. Mediterranean diet pyramid: a cultural model for healthy eating. Am J Clin Nutr 1995;61(6 Suppl):1402S-1406S.
25. Pfeffer MA, Sacks F, Moye LA, Brown L, Rouleau JL, Hartley LH, Rouleau J, Grimm R, Sestier F, Wickemeyer W, Cole TG, Braunwald E. Cholesterol and Recurrent Events: A secondary prevention trial for normolipidemic patients. Am J Cardiol 1995;76:98C-112C.
26. Sacks FM, Campos H, Judge H, Walsh BW. Estrogen treatment and human lipoprotein metabolism. In Forte TM ed. Hormonal, metabolic, and cellular influences on cardiovascular disease in women. Armonk, NY: Futura, 1997;229-246.
27. Shepherd J, Olsson AG, Sacks FM, Black DM, Orloff DG, Bilheimer DW. Should separate endpoint trials be required for all lipid-lowering drugs acting by the same mechanism? Am J Cardiol 1998; 81:88F-94F.
28. Sacks FM. Why cholesterol as a central theme in coronary artery disease? In Esselstyn CB ed, A Symposium: Summit on cholesterol and coronary disease. Am J Cardiol 1998;82:14T-17T.
29. Sacks FM. Dietary prevention trials. In Hennekens CH, Buring JE, Manson JE, Ridker PM eds. Clinical trials in cardiovascular disease: A companion to Braunwald's Heart Disease. Philadelphia, WB Saunders Co, 1999; 423-431.

30. Sacks FM. The overall dietary pattern and blood pressure. In Izzo JL, Black HR, eds. Hypertension Primer. The Essentials of High Blood Pressure. Dallas, Texas, Council for High Blood Pressure Research, American Heart Association. Baltimore, Maryland: Lippincott, Williams and Wilkins 1999: 244-246.
31. Sacks FM, Ridker PM. Lipid lowering and beyond: results from the CARE study on lipoproteins and inflammation. *Herz* 1999;24:51-56.
32. Sacks FM, Appel LJ, Moore TJ, Obarzanek E, Vollmer WM, Svetkey LP, Bray GA, Vogt TM, Cutler JA, Windhauser MM, Lin PH, Karanja N. A dietary approach to prevent hypertension: a review of the Dietary Approaches to Stop Hypertension (DASH) study. *Clin Cardiol* 1999;22 (7 Suppl): III-6-10).
33. Sacks FM, Pfeffer MA, Moye LA, Hawkins CM, Davis BR, Rouleau JL, Cole TG, Braunwald E. Cholesterol and Recurrent Events Trial (CARE): The effect of pravastatin on coronary events after myocardial infarction in patients with average cholesterol levels. In Grundy SM editor: Cholesterol lowering therapy: evaluation of clinical trial evidence. New York, Marcel Dekker, 2000: 63-90.
34. Sacks FM. Lipid-lowering therapy in acute coronary syndromes (editorial on MIRACL trial results). *JAMA* 2001;285:1758-60.
35. Vollmer WM, Sacks FM, Svetkey LP. New insights into the effects on blood pressure of diets low in salt and high in fruits and vegetables and low-fat dairy products. (Published as a "commentary"). *Curr Control Trials Cardiovasc Med* 2001, 2:71-74.
36. Sacks FM, Appel LJ. Lifestyle therapy for hypertension. In Antman E ed. Cardiovascular Therapeutics. 2nd Edition. Companion to Braunwald's Heart Disease. Saunders. 2001.
37. Barter PJ, Sacks FM. Threshold level or not for low density lipoprotein cholesterol. *Am J Managed Care* 2001; 7(5 Suppl):S125-31.
38. Kris-Etherton P, Daniels SR, Eckel RH, Engler M, Howard BV, Krauss RM, Lichtenstein AH, Sacks F, St Jeor S, Stampfer M, et al. Summary of the scientific conference on dietary fatty acids and cardiovascular health: conference summary from the nutrition committee of the American Heart Association. *Circulation* 2001;103:1034-9.
39. Sacks FM. The relative role of low-density lipoprotein cholesterol and high-density lipoprotein cholesterol in coronary artery disease: evidence from large-scale statin and fibrate trials. *Am J Cardiol* 2001;88(12A):14N-18N.
40. Sacks FM. Dietary treatment to prevent cardiovascular disease, Part 1: Effects on Hypertension. *Cardiology Rounds* 2001; 5 (6). [CME publication of Cardiovascular Division, BWH].

41. Sacks FM. Dietary treatment to prevent cardiovascular disease, Part 2: Effects on hyperlipidemia. *Cardiology Rounds* 2001; 5 (7). [CME publication of Cardiovascular Division, BWH].
42. Sacks FM for the HDL Expert Group on HDL cholesterol. The role of high-density lipoprotein (HDL) cholesterol in the prevention and treatment of coronary heart disease: expert group recommendations. *Am J Cardiol* 2002;90:139-43.
43. Sacks FM. Adherence to statin therapy: why aren't we doing better? Editorial. *Am J Med* 2002;113:685-6.
44. Sacks FM. Low-Density Lipoprotein lowering therapy: an analysis of the options. Editorial. *J Am Coll Cardiol* 2002;40:2135-8.
45. Sacks FM, Katan M. Randomized clinical trials on the effects of dietary fat and carbohydrate on plasma lipoproteins and cardiovascular disease. *Am J Med* 2002;113 Suppl 9B:13S-24S.
46. Sacks FM, Appel LJ. Lifestyle modification in the treatment of hypertension. In Antman EM, *Cardiovascular Therapeutics, A companion to Braunwald's Heart Disease*, 2<sup>nd</sup> Edition, WB Saunders, 2002:715-21.
47. Sacks FM, Appel LJ, Bray GA, Conlin PR, Moore TJ, Svetkey LP, Vollmer WM. Sodium and blood pressure: no data dredging, please! (Editorial). *Am J Hypertens* 2003;16:614-616.
48. Sacks FM. Dietary patterns and blood pressure. In: Izzo JL, Black HR, editors. *Hypertension Primer, Third Edition*. From the Council on High Blood Pressure Research, American Heart Association. Philadelphia, Lippincott, 2003, p. 274-6.
49. Sacks FM, Campos H. Low density lipoprotein size and cardiovascular disease: a reappraisal. (Clinical Review 163). *J Clin Endocrinol Metab* 2003;88:4525-32.
50. Sacks FM. High-intensity statin treatment for coronary heart disease (Editorial on REVERSAL trial). *JAMA* 2004;291:1132-4.
51. Sacks FM. Metabolic syndrome: epidemiology and consequences. *J Clin Psychiatry* 2004;65[supple 18]:3-12.
52. Byington RP, Sacks FM. Lessons learned from the prospective pravastatin pooling project. *Curr Atheroscler Rep* 2004;6:366-74.
53. Sacks FM. Dietary phytoestrogens to prevent cardiovascular disease: early promise unfulfilled. (Editorial). *Circulation* 2005;111: 385-7.

54. Goff DC, Cather C, Evins AE, Henderson DC, Freudenreich O, Copeland PM, Bierer M, Duckworth K, Sacks FM. Medical Morbidity and Mortality in Schizophrenia: Guidelines for Psychiatrists. *J Clin Psychiatry*. 2005;66:183-194.
55. Sacks FM, Skerret PJ. Your health in the 21<sup>st</sup> century. Fine-tuning heart health. *Newsweek*. 2005. Summer;145(26A):22-3.
56. Sacks FM, Campos H. Polyunsaturated fatty acids, inflammation and cardiovascular disease: time to widen our view of the mechanisms. Editorial. *J Clin Endocrinol Metab* 2006; 91:398-400.
57. Sacks FM, Lichtenstein A, Van Horn L, Harris W, Kris-Etherton P, Winston M for the American Heart Association Nutrition Committee. Soy protein, isoflavones, and cardiovascular health. An American Heart Association Science Advisory for Professionals from the Nutrition Committee. *Circulation* 2006;113:1034-44.
58. Appel LJ, Brands DW, Daniels SR, Karanja N, Elmer PJ, Sacks FM. Dietary approaches to prevent and treat hypertension: a scientific statement from the American Heart Association. *Hypertension* 2006;47:296-308.
59. Lichtenstein AH, Appel LJ, Brands M, Carnethon M, Daniels S, Franch HA, Kris-Etherton P, Harris WS, Howard B, Karanja N, Lefevre M, Rudel L, Sacks F, Van Horn L, Winston M, Wylie-Rosett J, and the American Heart Association Nutrition Committee. Diet and lifestyle recommendations revision 2006: a scientific statement from the American Heart Association Nutrition Committee. *Circulation* 2006;114:82-96.
60. Sacks FM. The apolipoprotein story. *Atherosclerosis Suppl* 2006;7:23-7.
61. Sacks FM, Campos H. Polyunsaturated fatty acids, inflammation, and cardiovascular disease: time to widen our view of the mechanisms. *J Clin Endocrinol Metab* 2006;91:398-400.
62. Sacks FM, McManus K. Diet and exercise therapy. Chapter 28 in Antman EM, *Cardiovascular Therapeutics, A companion to Braunwald's Heart Disease, 3<sup>rd</sup> Edition*, WB Saunders, 2006.
63. Sacks FM. Dietary patterns and blood pressure. In: Izzo JL, Sica DA, Black HR, editors. *Hypertension Primer, Fourth Edition*. From the Council on High Blood Pressure Research, American Heart Association. Philadelphia, Lippincott, 2008, p. 297-300.
64. Sacks FM. Major potential for diet treatment for type 2 diabetes. *Curr Diab Rep* 2008;8:249-50.
65. Fruchart JC, Sacks FM, Hermans MP, Assmann G, Brown WV, Ceska R, Chapman MJ, Dodson PM, Fioretto P, Ginsberg HN, Kadowaki T, Lablanche JM, Marx N, Plutzky J, Reiner Z, Rosenson RS, Staels B, Stock JK, Sy R, Wanner C, Zambon A, Zimmet P. The

- Residual Risk Reduction Initiative: a call to action to reduce residual vascular risk in dyslipidaemic patients. *Diab Vasc Dis Res* 2008;5:319-25.
66. Pfeffer MA, Sacks FM. Leapfrogging data: no shortcuts for safety or efficacy information. Editorial. *Circulation* 2008;118:2491-4.
  67. Harris WS, Mozaffarian D, Rimm E, Kris-Etherton P, Rudel LL, Appel LJ, Engler MM, Engler MB, Sacks F. Omega-6 fatty acids and risk for cardiovascular disease: a science advisory from the American Heart Association Nutrition Subcommittee of the Council on Nutrition, Physical Activity, and Metabolism; Council on Cardiovascular Nursing; and Council on Epidemiology and Prevention. *Circulation*. 2009;119:902-7.
  68. Johnson RK, Appel LJ, Brands M, Howard BV, Lefevre M, Lustig RH, Sacks F, Steffen LM, Wylie-Rosett J; on behalf of the American Heart Association Nutrition Committee of the Council on Nutrition, Physical Activity, and Metabolism and the Council on Epidemiology and Prevention. Dietary sugars intake and cardiovascular health: A scientific statement from the American Heart Association. *Circulation* 2009;120:1011-20.
  69. Fruchart JC, Sacks FM, Hermans MP. Implications of the ACCORD Lipid study: perspective from the Residual Risk Reduction Initiative (R(3)i). *Curr Med Res Opin*. 2010;26:1793-97.
  70. Cook NR, Sacks F, MacGregor G. Public policy and dietary sodium restriction (letter to editor). *JAMA*. 2010;303:1917
  71. Sacks FM, Campos H. Dietary therapy in hypertension. *N Engl J Med* 2010;362:2102-12.
  72. Sacks MF, Carey VJ, Fruchart JC. Combination lipid therapy in type 2 diabetes. *N Engl J Med* 2010;363:692-3. Letter to editor presenting original meta-analysis.
  73. Appel LJ, Frohlich ED, Hall JE, Pearson TA, Sacco RL, Seals DR, Sacks FM, Smith SC, Vafiadis DK, Van Horn LV. The importance of population-wide sodium reduction as a means to prevent cardiovascular disease and stroke: a call to action from the American Heart Association. *Circulation* 2011;124:1138-43.
  74. Sacks FM. Lipid and lipoprotein metabolism, and risk for cardiovascular disease. In Eckel RH, ed, *Metabolic risk for cardiovascular disease. The AHA clinical series*. Wiley-Blackwell, West Sussex, UK, 2011, pp. 18-40.
  75. Braunwald E, Sacks FM, Pfeffer MA, Ridker PM. HMG CoA reduction in patients with average cholesterol concentrations. *Clin Chem* 2011;57:1072-3.
  76. Sacks FM, Zheng C, Cohn JS. Complexities of plasma apolipoprotein C-III metabolism. *J Lipid Res* 2011;52:1067-70.

77. Talayero BG, Sacks FM. The role of triglycerides in atherosclerosis. *Curr Cardiol Rep* 2011;13:544-52.
78. Braunwald E, Sacks FM, Pfeffer MA, Ridker PM. HMG CoA reduction in patients with average cholesterol concentrations. *Clin Chem* 2011;57:1072-3.
79. Berglund L, Brunzell JD, Goldberg AC, Goldberg IJ, Sacks FM, Murad MH, Stalenhoef AF. Evaluation and treatment of hypertriglyceridemia: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab* 2012;97:2969-89.
80. Berglund L, Brunzell J, Sacks FM. Patient guide to the assessment and treatment of hypertriglyceridemia (high triglycerides). *J Clin Endocrinol Metab* 2012;97:31A-32A
81. Whelton PK, Appel LJ, Sacco RL, Anderson CA, Antman EM, Campbell N, Dunbar SB, Frohlich ED, Hall JE, Jessup M, Labarthe DR, MacGregor GA, Sacks FM, Stamler J, Vafiadis DK, Van Horn LV. Sodium, blood pressure and cardiovascular disease: further evidence supporting the American Heart Association sodium reduction recommendations. *Circulation* 2012;Nov 2.
82. Sacks FM, McManus K. Cardiovascular Disease and Lifestyle Modification. Chapter 26 in Antman EM, Sabatine ES eds. *Cardiovascular Therapeutics, A companion to Braunwald's Heart Disease*, 4th Edition, Elsevier Saunders, 2013:442-454.
83. Eckel RH, Jakicic JM, Ard JD, Hubbard VS, de Jesus JM, Lee IM, Lichtenstein AH, Loria CM, Millen BE, Miller NH, Nonas CA, Sacks FM, Smith SC Jr, Svetkey LP, Wadden TW, Yanovski SZ. 2013 AHA/ACC Guideline on Lifestyle Management to Reduce Cardiovascular Risk: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2013 Nov 12.
84. Sacks FM, Stanesa M, Hegele RA. Severe Hypertriglyceridemia With Pancreatitis: Thirteen Years' Treatment With Lomitapide. *JAMA Intern Med*. 2013 Dec 23
85. Sacks FM, Brewer HB. Petar Alaupovic: The father of lipoprotein classification based on apolipoprotein composition. *Arterioscler Thromb Vasc Biol*. 2014 Jun;34(6):1111-3.
86. Sacks FM. The crucial roles of apolipoproteins E and C-III in apoB lipoprotein metabolism in normolipidemia and hypertriglyceridemia. *Curr Opin Lipidol*. 2015 Feb;26(1):56-63.
87. Brown WV, Sacks FM, Sniderman AD. JCL roundtable: Apolipoproteins as causative elements in vascular disease. *J Clin Lipidol*. 2015;9:733-40. PMID: 26687693
88. Eljovich F, Weinberger MH, Anderson CA, Appel LJ, Bursztyrn M, Cook NR, Dart RA, Newton-Cheh CH, Sacks FM, Laffer CL; American Heart Association. Salt Sensitivity of Blood Pressure: A Scientific Statement From the American Heart Association. *Hypertension*. 2016;68:e7-e46. PMID: 27443572

89. Sacks FM, Lichtenstein AH, Wu JHY, Appel LJ, Creager MA, Kris-Etherton PM, Miller M, Rimm EB, Rudel LL, Robinson JG, Stone NJ, Van Horn LV; American Heart Association. Dietary Fats and Cardiovascular Disease: A Presidential Advisory From the American Heart Association. *Circulation*. 2017;136(3):e1-e23. PMID: 28620111
90. Rosenson RS, Brewer HB Jr, Barter PJ, Björkegren JLM, Chapman MJ, Gaudet D, Kim DS, Niesor E, Rye KA, Sacks FM, Tardif JC, Hegele RA. *Nat Rev Cardiol*. 2018;15:9-19. Review. PMID: 28795686
91. Sacks FM, Jensen MK. From high-density lipoprotein cholesterol to measurements of function. Prospects for the development of tests for high-density lipoprotein functionality in cardiovascular disease. *Arterioscl Thromb Vasc Dis* 2018;38:487-499. PMID:29371248
92. Qi L, Bray GA, Sacks FM. Low-Fat vs Low-Carbohydrate Diets and Weight Loss. Letter to editor. *JAMA*. 2018 Jul 10;320(2):202-203. PMID: 29998330
93. Cuchel M, Rohatgi A, Sacks FM, Guyton JR. JCL roundtable: High-density lipoprotein function and reverse cholesterol transport. *J Clin Lipidol* 2018;12:1086-1094. PMID: 3031480
94. Rodriguez A, Trigatti BL, Mineo C, Knaack D, Wilkins JT, Sahoo D, Asztalos BF, Mora S, Cuchel M, Pownall HJ, Rosales C, Bernatchez P, Ribeiro Martins da Silva A, Getz GS, Barber JL, Shearer GC, Zivkovic AM, Tietge UJF, Sacks FM, Connelly MA, Oda MN, Davidson WS, Sorci-Thomas MG, Vaisar T, Ruotolo G, Vickers KC, Martel C. Proceedings of the Ninth HDL (High-Density Lipoprotein) Workshop: Focus on Cardiovascular Disease. *Arterioscler Thromb Vasc Biol*. 2019 Dec;39(12):2457-2467
95. Bray GA, Krauss RM, Sacks FM, Qi L. Lessons Learned from the POUNDS Lost Study: Genetic, Metabolic, and Behavioral Factors Affecting Changes in Body Weight, Body Composition, and Cardiometabolic Risk. *Curr Obes Rep*. 2019 Sep;8(3):262-283. doi: 10.1007/s13679-019-00353-1.



## **Expert Report of Frank M. Sacks**

### **ATTACHMENT B**

**List of cases in which during the previous 4 years, I have testified as an expert at trial or in a deposition:**

*Coalition for Affordable Drugs VIII, LLC v. The Trustees of the University of Pennsylvania;* IPR2015-01836. (U.S. Patent Trial and Appeals Board) - Deposition August 12, 2016

*In Re: Lipitor (Atorvastatin Calcium) Marketing, Sales Practices And Products Liability Litigation,* MDL No. 2:14-mn-02502-RMG

*Brandeis University and GFA Brands, Inc. v. Voortman Cookies Ltd., et al.,* No. 1:12-cv-1508 (N.D. Ill.).

*In Re: Niaspan Antitrust Litigation,* MDL 2460, Master File No. 13-MD-2460

**PX 4**

## **EXPERT REPORT OF CHARLES F. BURANT, M.D., PH.D**

My name is Charles F. Burant. I have been retained by the Federal Trade Commission (FTC) to provide my expert opinion in evaluating whether there is competent and reliable scientific evidence to support advertising claims that the dietary supplement Neupathic cures, treats, or mitigates the diseases of diabetes or diabetic neuropathy.

### **I. Credentials and Qualifications**

I am a medical doctor, certified by the American Board of Internal Medicine in the fields of Endocrinology, Diabetes and Metabolism. As detailed in my *curriculum vitae*, which is included with this report as Attachment 1, I am the Director of the A. Alfred Taubman Medical Research Institute — a medical research institute at the University of Michigan dedicated to supporting medical doctors who also perform laboratory research in the quest for new treatments and cures.

I have served on the faculty at the University of Michigan since 1999. Currently, I am the Robert C. and Veronica Atkins Professor of Metabolism, a Professor of Internal Medicine in the Division of Metabolism, Endocrinology, and Diabetes, and a Professor of Molecular and Integrative Physiology. I am a member of the Cell and Molecular Biology Training Program. Prior to joining the University of Michigan, I was an Assistant Professor in the Endocrinology Section of the Department of Medicine at the University of Chicago and was employed by Warner-Lambert, a pharmaceutical company, as a Director for two years before returning to academics.

During my time at Warner-Lambert, I oversaw preclinical and clinical diabetes drug development, including drugs for diabetic neuropathy. I was also responsible for evaluating external research projects from individuals who were interested in developing potential products related to the treatment of diabetes and diabetes complications, including potential drugs for diabetic neuropathy.

I received a Bachelor of Science degree in Biochemistry from University of Wisconsin (Madison, Wisconsin) in 1979, a Master of Science degree in Environmental Toxicology from the University of Wisconsin in 1981, and a degree in Medicine from the Medical University of South Carolina (Charleston, S. Carolina) in 1987. I also received a Ph.D. in Molecular and Cellular Biology from the Medical University of South Carolina in 1987.

I am a member of the American Diabetes Association, the American Association of Clinical Endocrinology, and the American Society for Nutrition, among other professional societies. I have also been elected a Fellow of the American College of Endocrinology and the American Association of Physicians.

I serve on the Executive Committee for the NIH Common Fund program, “Molecular Transducers of Physical Activity.” Previously, I have served on the American Diabetes Association’s Research Policy and Marketing Committee, Research Foundation Board of Directors Committee, and Oversight Committee.

I have held several editorial positions relating to the publication of diabetes-related research. Currently, I am an associate editor for *Diabetes*, the American Diabetes Association’s journal that publishes peer-reviewed studies related to the physiology and pathophysiology of

diabetes. Previously, I have served as an associate editor for the *Journal of Lipid Research* and the *American Journal of Physiology, Endocrinology and Metabolism*.

I have authored, co-authored, or published numerous books, book chapters, abstracts and peer-reviewed journal articles related to the science of type 2 diabetes, including risk factors and treatment for the disease. I was the editor for several editions of the *American Diabetes Association's Medical Management of Type 2 Diabetes* as well as coauthor of the chapter "Type 2 Diabetes" for the *Williams Textbook of Endocrinology*, the preeminent endocrinology textbook. I have also served as principal or co-investigator on at least 15 clinical trials and studies of diabetic patients. Most of my publications and active or completed research support have been on subjects related to obesity, insulin resistance, and type 2 diabetes, including publications or trials studying its causes, prevention, consequences and treatment.

A complete list of all publications that I have authored, as well as the active, pending and completed research support I have provided, is included as part of my *curriculum vitae*, provided with this report as Attachment 1.

I am the recipient of several professional awards and honors, including the American Medical Association Award for Outstanding Research, the American Diabetes Association Award for Outstanding Research, and the Cure, Care and Commitment Award from the American Diabetes Association's Michigan Affiliate.

My clinical practice at the University of Michigan is almost exclusively focused on the care of individuals with type 1 and type 2 diabetes. Over my clinical career, I have also cared for hundreds of individuals with diabetic complications, including the disease of diabetic neuropathy.

My teaching at the University of Michigan consists of lectures in endocrinology, nutrition and diabetes, including complications of diabetes. I am well versed in the primary literature surrounding the care of individuals with diabetes and related complications, including the disease of diabetic neuropathy.

Based upon my education, training and experience, as summarized above, I consider myself an expert in the fields of: (1) type 2 diabetes and its complications (neuropathy, retinopathy, and nephropathy), including treatment, management, preventative care, causes, and risk or contributory factors; (2) the design, conduct, and analysis of clinical trials; and (3) statistical analyses of the results of such clinical trials. I have significant experience in the development and execution of clinical trials, and I have published numerous articles in peer-reviewed publications related to my diabetes research.

I have not testified as an expert at trial or by deposition in the last four years. The FTC is compensating me for my work on this case at the rate of \$350 per hour. I am also currently working for the FTC as a testifying expert in the case of *FTC v. Agora Financial*, 1:19-cv-03100-JMC (D. Md.).

## **II. Scope of Report and Review**

In connection with this case, the FTC asked me to provide my expert opinion on the following issues. First, are diabetes and diabetic neuropathy diseases? Second, did Health Research Laboratories, LLC and Kramer Duhon (collectively referred to as “Defendants”) have competent and reliable scientific evidence, as defined in Section II of the January 16, 2018 Order in *FTC and Maine v. Health Research Laboratories, LLC*, No. 2:17-cv-00467-JDL (“Final Order”), substantiating the truth of their advertising representations that Neupathic cures, mitigates, or treats diabetes or diabetic neuropathy? Specifically, did Defendants have

randomized, double-blind, and placebo-controlled human clinical testing, conducted by researchers qualified by training and experience to conduct such testing, of Neupathic or an Essentially Equivalent Product as that term is defined in the Final Order, that is sufficient in quality or quantity based on standards generally accepted by experts in diabetes and diabetic neuropathy, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that Neupathic will cure, mitigate, or treat diabetes or diabetic neuropathy? And finally, what is the likelihood that a properly conducted human clinical trial of Neupathic or an Essentially Equivalent Product would establish that it cures, mitigates, or treats diabetes or diabetic neuropathy?

In preparing this report, I reviewed the following documents provided to me by the FTC:

- (1) Letters from Defendants' counsel to the FTC dated January 30, 2019 and June 20, 2019;
- (2) Neupathic labeling (HRL004913);
- (3) Neupathic advertising (HRL004997-5051);
- (4) Purported substantiation and related documents Defendants submitted to the FTC (HRL005640-005680 and HRL007902-008131); and
- (5) *Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief* entered in *FTC and Maine v. Health Research Laboratories, LLC, et al.*, No. 2:17-cv-00467-JDL (Jan. 16, 2018).

In addition, I considered other scientific literature relating to diabetic neuropathy, alternative treatment approaches, and certain ingredients in Neupathic as general reference materials including:

- (1) Feldman EL, Callaghan BC, Pop-Busui R, Zochodne DW, Wright DE, Bennett DL, Bril V, Russell JW, Viswanathan V. *Nat Rev Dis Primers*. 2019. Diabetic neuropathy. Jun 13;5(1):41. doi: 10.1038/s41572-019-0092-1.
- (2) Iqbal Z, Azmi S, Yadav R, Ferdousi M, Kumar M, Cuthbertson DJ, Lim J, Malik RA, Alam U. Diabetic Peripheral Neuropathy: Epidemiology, Diagnosis, and



Pharmacotherapy. *Clin Ther.* 2018 Jun;40(6):828-849. doi: 10.1016/j.clinthera.2018.04.001.

- (3) American Diabetes Association. 2018. 10. Microvascular Complications and Foot Care: Standards of Medical Care in Diabetes-2018. *Diabetes Care.* Jan;41(Suppl 1):S105-S118. doi: 10.2337/dc18-S010.
- (4) Tajti J, Szok D, Majláth Z, Csáti A, Petrovics-Balog A, Vécsei L. 2016 Alleviation of pain in painful diabetic neuropathy. *Expert Opin Drug Metab Toxicol.* Jul;12(7):753-64. doi: 10.1080/17425255.2016.1184648. Epub 2016 May 25. Review.
- (5) Boyd A, Bleakley C, Hurley DA, Gill C, Hannon-Fletcher M, Bell P, McDonough S. 2019. Herbal medicinal products or preparations for neuropathic pain. *Cochrane Database Syst Rev.* Apr 2;4:CD010528. doi: 10.1002/14651858.CD010528.pub4.
- (6) Jayabalan B, Low LL. 2016 Vitamin B supplementation for diabetic peripheral neuropathy. *Singapore Med J.* Feb;57(2):55-9. doi: 10.11622/smedj.2016027.
- (7) Jiang DQ, Li MX, Ma YJ, Wang Y, Wang Y. 2016. Efficacy and safety of prostaglandin E1 plus lipoic acid combination therapy versus monotherapy for patients with diabetic peripheral neuropathy. *J Clin Neurosci.* May;27:8-16. doi: 10.1016/j.jocn.2015.07.028.
- (8) Hamel J, Logigian EL. 2018. Acute nutritional axonal neuropathy. *Muscle Nerve.* 57:33-39. doi: 10.1002/mus.25702.
- (9) Chaparro LE, Wiffen PJ, Gilron I. 2012. Combination pharmacotherapy for the treatment of neuropathic pain in adults. *Cochrane Database Syst. Rev.* Jul 11;(7): CD008943. doi: 10.1002/14651858.

### **III. Background about the Diseases of Diabetes and Diabetic Neuropathy**

Diabetes mellitus, more commonly known as diabetes, is a metabolic disease that is characterized by high blood glucose levels over a prolonged period (“hyperglycemia”). Diabetes occurs when a person’s blood glucose, sometimes referred to as blood sugar, is higher than what is considered safe. Diabetes is due to either the body’s failure to produce enough insulin or the body’s failure to effectively respond to the insulin produced. Insulin performs the critical job of removing glucose from the bloodstream to the body’s cells.

Diabetes most commonly arises by two different pathways<sup>1-3</sup>. Type 1 diabetes is due to the autoimmune destruction of beta cells, a type of cell found in the pancreas that is responsible

for producing insulin. This results in nearly complete loss of insulin and significant hyperglycemia. After diagnosis, type 1 diabetics must be treated with insulin. Only about 5% of all diabetes is due to type 1 diabetes. The more common form, type 2 diabetes, results primarily because of obesity. Obesity results in insulin resistance, leading to increased insulin production by beta cells to overcome the insulin resistance. Eventually, an individual's beta cells begin to fail, insulin secretion decreases, and blood glucose levels rise.

Diabetes can be treated effectively, but it cannot be cured in the sense that it cannot be permanently reversed or prevented as the loss of beta cells is not reversible.

Both type 1 and type 2 diabetes can give rise to microvascular complications of diabetes. Microvascular complications include eye disease (retinopathy), kidney damage (nephropathy) and nerve damage (neuropathy). Only a subset of diabetics develops microvascular complications. The development of such complications is primarily related to the degree and length of hyperglycemia and genetic susceptibility. Other factors, including hypertension, high blood lipid levels, vascular problems and smoking, can increase a person's risk for complications, including neuropathy.

Neuropathy is a disease of the functions of nerves<sup>4</sup>. Neuropathy can arise from more than 100 different conditions<sup>4,5</sup>. Most neuropathies arise because of another underlying condition. For example, severe vitamin deficiencies can cause neuropathy. Individuals with neuropathy associated with vitamin deficiencies have manifestations of malnutrition and other signs of vitamin deficiency that are not typical of diabetic neuropathy<sup>4</sup>.

The disease of diabetic neuropathy is neuropathy associated with persistent elevations of blood glucose in both type 1 and type 2 diabetes<sup>6</sup>. The most common type of diabetic

neuropathy is a symmetric, sensory neuropathy, which arises from the degeneration of small, unmyelinated nerve fibers (C-fibers) that conduct sensations of pain as well as heat and cold sensation. The condition, also known as peripheral neuropathy, affects the lower limbs first, gradually spreading from the toes to the foot and legs. When severe, it can also affect the hands and arms. Symptoms commonly include tingling, pricking, chilling, burning, or numbness. Some individuals with diabetic neuropathy experience burning and sharp lancinating pain that can be debilitating to patients. In addition, the autonomic nervous system can be affected, resulting in erectile dysfunction, low blood pressure, and digestive system problems.

There have been no interventions identified that can *cure* the disease of diabetic neuropathy. Prevention of neuropathy by strict blood glucose control once a patient is diagnosed with diabetes is therefore very important. The landmark Diabetes Complications and Control (DCCT) trial showed that the development of diabetic neuropathy can be prevented by good control of glucose<sup>7</sup>. Once it is established, diabetic neuropathy is not reversible. However, diabetic neuropathy progression can be stabilized or slowed by meticulous control of glucose levels, cessation of smoking, and control of blood pressure and lipid levels, all of which may contribute to the worsening of diabetic neuropathy. Some individuals with only small elevations in blood glucose can suffer from diabetic neuropathy, and it is thought that they have a genetic predisposition for neuropathy.

Recommended medical treatment for diabetic neuropathy consists of careful foot care to prevent ulcerations, which can lead to amputations. Topical products, such as capsaicin and oral medications such as anti-inflammatory medications, selective serotonin uptake inhibitors, anticonvulsants, pregabalin, and narcotics can be used to treat some symptoms of diabetic neuropathy by relieving pain<sup>6</sup>.

It is important to note that no FDA-approved treatments have been shown to cure or reverse the underlying pathology of diabetic neuropathy once it is established. Currently, there are only drugs that can mitigate or treat the symptoms associated with diabetic neuropathy such as pain. Moreover, a 2011 comprehensive review of the literature by American Association of Neuromuscular and Electrodiagnostic Medicine, the American Academy of Neurology, and the American Academy of Physical Medicine & Rehabilitation found no evidence of efficacy for any natural products in the treatment of diabetic neuropathy<sup>8</sup>.

#### **IV. Definition of Competent and Reliable Scientific Evidence in Section II of the Final Order**

Counsel for the FTC has advised me that Section II of the Final Order establishes certain requirements Defendants must meet before they claim a dietary supplement cures, mitigates, or treats any disease. Specifically, Section II states that Defendants must have competent and reliable scientific evidence in the form of human clinical testing of the dietary supplement or an Essentially Equivalent Product substantiating that the claim is true. The Final Order defines Essentially Equivalent Product as “a product 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; *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 is unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product.” Final Order, p. 5.

Section II also states that the human clinical testing must be “sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of

relevant and scientific evidence, to substantiate that the representation is true.” Section II further requires that the human clinical testing must be “(1) randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing.” In this report, I evaluate the substantiation submitted by Defendants according to the specific requirements for competent and reliable scientific evidence established in Section II. Below, I explain why these requirements are critically important in evaluating the efficacy of a dietary supplement.

**V. Importance of Using Randomized, Double-Blinded, Placebo-Controlled Trials to Test Efficacy**

Clinical trials involving human subjects are essential in evaluating the efficacy of a dietary supplement or drug in curing, mitigating, or treating diseases in humans. Although *in vitro* studies (using cells in culture) and animal studies may be useful preliminary tools to help formulate hypotheses, results from *in vitro* and animal studies cannot always be extrapolated to humans because of differences in physiology and metabolism between cells in culture, animal subjects, and humans.

Randomization in trials, which means that individual subjects are randomly assigned to either a treatment or control group, is also necessary to ensure that any observed effects in a trial can be isolated to the tested product or treatment alone rather than attributed to other known or unknown factors that might make an individual more or less responsive to treatment.

Clinical trials generally should be double-blinded, meaning that neither the subject nor the investigator knows whether the subject receives the placebo or active product or treatment. Double-blinding is critical in avoiding inadvertent or unconscious bias by either the subject or the investigator.

Clinical trials also generally should use a placebo control group, meaning that while one group of subjects receives the product or treatment that is being studied, another separate control group receives a “placebo,” which is a fake treatment or inert pill that has no therapeutic effect. This is important to account for a “placebo effect,” whereby a subject shows improvement even when given an ineffective treatment. Placebo effect is a well-recognized phenomenon in scientific research that can be caused by various factors.

Finally, the studies used to substantiate a product’s efficacy must test the product itself or an equivalent product with the same active ingredients at the same dosage that is claimed to produce effective outcomes. Testing the product itself or the same combination of active ingredients is necessary 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.

## **VI. Evaluation of Purported Substantiation Related to Neupathic**

Neupathic contains a mixture of active ingredients, taken once per day: Vitamins E (30 IU), B1 (33.3 mg), B6 (33.3 mg), B12 (16.7 mcg), and folate (266.7 mcg), and Evening Primrose Oil (EPO) (666.7 mg). *See* HRL004913 (Neupathic label). The extract from EPO in Neupathic contains 9% gamma linolenic acid (GLA). *See* HRL004913. The 666.7 mg of EPO in Neupathic therefore contains 60 mg of GLA.

After reviewing the materials supplied by Defendants and conducting my own review of relevant scientific literature, it is my expert opinion that there is no competent and reliable scientific evidence that Neupathic or its individual ingredients, can cure, mitigate, or treat

diabetes or diabetic neuropathy. Defendants do not have a randomized, double-blind, placebo-controlled clinical trial testing the same combination, form, and dose of active ingredients found in Neupathic. My opinion is based on the following primary observations, which are explained in greater detail later in this report:

(1) Neupathic has multiple active ingredients that have not been tested together in a randomized, double-blinded, placebo-controlled trial to evaluate the product's efficacy in curing, mitigating, or treating diabetic neuropathy or diabetes.

(2) The trials proffered by Defendants to substantiate their claims have instead tested some of the individual active ingredients found in Neupathic. These trials have serious flaws in either design (*i.e.*, not a randomized, double-blind, placebo-controlled trial) or data analysis (*i.e.*, serious and disqualifying problems with statistical analysis).

(3) In all but one of the studies Defendants supplied as substantiation, the dosage of individual ingredients tested was significantly higher than the dosage of the individual ingredients contained in Neupathic.

(4) The single study that tested the individual ingredient of EPO at a similar dose to that found in Neupathic was not a randomized, double-blind, placebo-controlled study<sup>9</sup>.

**A. Purported Substantiation Relating to Vitamins B1, B6, B12, Folic acid (B9), and E**

Defendants submitted a number of studies involving the individual ingredients of Vitamins B1, B6, B12, folic acid, and Vitamin E in support of claims for Neupathic. However, none of these studies tested a product with the same doses of these ingredients found in Neupathic. In addition, each study suffers from one or more design flaws, such as the absence of placebo controls, double-blinding, or randomization. Some also have serious statistical flaws.

For these reasons, none of the studies submitted by Defendants to the FTC provides competent and reliable scientific evidence to support claims that Neupathic, or its individual ingredients of Vitamins B1, B6, B12, folic acid, or Vitamin E, cure, mitigate, or treat diabetes or diabetic neuropathy. I briefly evaluate each of these studies in more detail below.

**Rizvi, et al. Pakistan Journal of Medical and Health Sciences Jul - Sep 2013; 7(3):801-803 (HRL005665-5668).** This was not a randomized or double-blinded study, and it did not test Neupathic or a product with the same combination of active ingredients. Furthermore, there are significant statistical problems in the way the authors analyzed the results. Most importantly, however, the study tested doses of Vitamin B1, B6 and B12 that were 6 to 10 times higher than the doses of those vitamins contained in Neupathic. This study therefore does not provide competent or reliable scientific evidence supporting the use of Neupathic or its ingredients Vitamins B1, B6 and B12 in curing, mitigating, or treating diabetic neuropathy or diabetes.

**Alvarado and Navarro. Journal of Diabetes Research 2016; 2016:4078695 (HRL005657-5664).** This is a multi-site, open-label, randomized study. In multi-site trials, the statistical analysis of the data must account for the fact that individuals from different sites may not be the same. For example, smoking rates may be different in one community than in another. However, the study report does not mention this issue, which suggests that the authors did not make the appropriate statistical adjustments to account for multiple locations. An open-label study is one where there is no blinding. In other words, both the subjects and investigators know who is receiving the active and control treatments.

This study did not test Neupathic or a product with the same combination of active ingredients. Instead, subjects in this study's treatment groups received either Pregabalin (75



mg/d ascending to 600 mg/d), a drug approved for the treatment of neuropathy symptoms, while the other group received the drug Gabapentin (300 mg/d ascending to 3600 mg/d) plus vitamin B1 and B12 (100 mg and 20 mg, respectively). Because this study included the administration of drugs known to have an effect on neuropathy-related pain (Pregabalin and Gabapentin), the effects of Vitamin B1 and B12 themselves cannot be established by this study. The dose of Vitamin B1 tested in this study was also 3 times greater, and the amount of Vitamin B12 was 1.3 times greater, than the doses of those ingredients found in Neupathic.

Although 346 subjects enrolled in the study, a substantial number of subjects (76) dropped out with only 270 subjects completing it. High dropout rates in a trial can skew results, especially in open label studies. This is because individuals who know they are in the control group may not feel like they are getting a benefit, and therefore may be more likely to leave the study than individuals who know they are in the treatment group. For the above reasons, this study does not provide competent or reliable scientific evidence supporting the use of Neupathic or Vitamins B1, B12 in curing, mitigating, or treating diabetic neuropathy or diabetes.

**Eckert and Schejbal. Fortschr Med. 1992 Oct 20;110(29):544-8 (HRL005669-5670 and HR007969-7970).** Defendants only submitted an abstract related to this study to the FTC. This was an unblinded (open label), non-randomized study involving 1149 subjects receiving a combination of B Vitamins (B1, B6, B12). This study did not involve the administration of a fixed dose of vitamins, and there was no placebo control. According to the provided abstract, “the form of administration...dosage and duration of treatment were left to the individual care-providing physician.” It was an observational study following patients with a variety of diseases who were treated by 234 physicians, not a clinical trial. The authors reported pain reduction in 69% of patients and some improvements in paresthesias (tingling or pricking sensation) and

muscular weakness in the legs. Given the many problems in this study's design, such as the decisions not to randomize, double-blind, or placebo control, this study does not provide competent or reliable scientific evidence supporting the use of Neupathic or Vitamins B1, B6 and B12 in curing, mitigating, or treating diabetic neuropathy or diabetes.

**Rajanandh, et al. Pharmacological Reports 66 (2014): 44-48 (HRL005671-5675 and HRL007941-7942).** This was a randomized, placebo-controlled trial. It is unclear from the description of the study whether it was double-blinded. The trial began with 112 subjects with diabetic neuropathy, and only 96 subjects completed the study. Half of the study subjects received a placebo, and the other half of study subjects in the treatment group received 400 mg/day of Vitamin E for 3 months. The dose of Vitamin E administered in this study was 20 times higher than the dose of Vitamin E found in Neupathic. It therefore does not provide competent and reliable scientific evidence to support claims that Neupathic or the individual ingredient of Vitamin E effectively cures, mitigates, or treats diabetic neuropathy or diabetes.

**Ogbera, et al. Indian Journal of Endocrinology and Metabolism. 2014;18(6):846-849 (HRL005640-5643 and HRL007902-7905).** This was an unblinded (open label), non-randomized study with 80 subjects receiving a combination of Vitamin E (400 mg/day) and EPO (500-1000 mg/day). The study assessed symptom relief at periods up to 3 months, and the study authors claim that 88% of subjects reported relief from burning pain. However, unblinded studies such as this one are inherently biased, especially when there is also no randomization. Additionally, the dose of Vitamin E used in this study was 20 times higher than the dose of Vitamin E in Neupathic. The EPO dose tested in this study was equivalent to the dose found in Neupathic. None of the other active ingredients present in Neupathic were tested in this study. Moreover, other studies testing Vitamin E that have been conducted as placebo-controlled trials

with more objective measures of nerve function have shown no effect on neuropathy.<sup>10</sup> For these reasons, this study does not provide competent and reliable scientific evidence that Neupathic or its ingredients Vitamin E or EPO are effective in curing, mitigating, or treating diabetes or diabetic neuropathy.

**Dabak, et al. Int. J. Vitam. Nutr. Res., 2012; 82(6):369-373 (HRL005648-5652 and HRL007965-7966).** This study examined blood samples to determine the amount of Thiamine (Vitamin B1) in patients' blood in a cross-sectional study of diabetic patients with and without amputations and compared them to controls. A cross-sectional study is one in which subjects are examined at a single point in time rather than followed over time. This study was not a clinical trial testing a particular treatment or any product, but instead simply measured the level of Thiamine in patients' blood. The study authors claim that their results showed that diabetics (both individuals with and without amputations) had higher levels of Thiamine in their blood than the non-diabetic control group. It is unclear what the researchers purported to show with this study, and it certainly does not provide competent or reliable scientific evidence that Neupathic or Vitamin B1 cures, mitigates, or treat diabetic neuropathy or diabetes.

**Luong and Nguyen. J. Clin. Med. Res. 2012;4(3):153-160 (HRL005653-005656).** This is a review article generally discussing the potential use of Thiamine (Vitamin B1) in the treatment of diabetes. Among the number of topics that are discussed in this review is a paragraph citing a few studies related to diabetic neuropathy, primarily in animal models. Because this is a review article rather than a published report of a study containing specific information about study design and resulting data, this article does not provide primary evidence

for the efficacy of Neupathic or Vitamin B1 in curing, mitigating, or treating diabetic neuropathy or diabetes.

**Mottaghi T, et al. Neurology Research. 2019 Apr; 41(4):364-368 (HRL007910-7911).** This was a double-blind, placebo-controlled study testing 1 mg/day of folic acid in subjects with diabetic neuropathy. This study tested the effect of folic acid on nerve function, and the authors claimed to have found a statistically significant change in the treated group in several measures of nerve function. Because there was no data provided showing statistical comparisons of the two groups at the beginning of the study, it is impossible to know whether the study was properly randomized. If the study was not properly randomized, then a different statistical approach would have been more appropriate to analyze the data. In addition, the dose of folic acid used in this study was 3.5 times higher than the dose of folic acid found in Neupathic. Given these deficiencies, this study does not provide competent and reliable scientific evidence to support claims that Neupathic or folic acid cure, treat, or mitigate diabetic neuropathy or diabetes.

**Roy, et al. Indian J. Endocrinology and Metabolism 2016 Sep-Oct; 20(5):631-637 (HRL007912- HRL007921).** This was a one-time, cross-sectional study that evaluated diabetic subjects to determine the amount of Vitamin B12 in subjects' blood and whether the amount of Vitamin B12 affected diabetic neuropathy. It was not a randomized, double blind, or placebo-controlled trial. The study examined three groups: (1) those who were not taking metformin (a drug known to lower vitamin B12); (2) those who were taking metformin alone; and (3) those taking metformin with another drug used to treat diabetes (which were not disclosed). This study did not test a specific intervention or product of any kind. In other words, subjects in this trial did not receive Vitamin B12 or any other ingredient in Neupathic. As a result, this study does

not provide competent and reliable scientific evidence that Neupathic or its individual ingredients can cure, treat or mitigate diabetic neuropathy or diabetes.

**Walker et al. Rev. Neurol. Disease 2010;7(4):132-9 (HRL007922-7923).** In this study, twenty individuals with diabetic neuropathy were treated for up to 1 year with a combination of 3 mg/day L-methylfolate (a form of folic acid), 2 mg/day of methylcobalamin (a form of Vitamin B12) and 35 mg/day of pyridoxal 5-phosphate (a form of Vitamin B6). This study was not double-blinded, nor was there any randomization. In addition, the formulation of the folic acid and B vitamins were not the same as those found in Neupathic. For these reasons, this study does not provide competent and reliable scientific evidence that Neupathic or its individual ingredients cure, treat, or mitigate diabetic neuropathy or diabetes.

**Yaqub, et al. Clin. Neur. and Neurosurg. 1992; 94:105-111 (HRL007932-007939).** In this double-blind study, 50 subjects with diabetic neuropathy received either 500 milligrams three times per day of methylcobalamin (a form of Vitamin B12) for 4 months or a placebo. This daily dose is thousands of times higher than the dose of Vitamin B12 in Neupathic (16 micrograms). After 4 months, the researchers performed a nerve conduction analysis. Although the study reported improvements in nerve function between the subjects who received the treatment and those who received the placebo, it did not evaluate the baseline characteristics between the placebo and treatment groups. The analysis instead only measured the change within each group, the so-called Difference in Nominal Significance (DINS), which is an invalid statistical test for analyzing data. This serious error of statistical analysis invalidates the study. For all of the above reasons, this study does not provide competent and reliable scientific evidence to support a claim that Neupathic or Vitamin B12 cures, treats or mitigates diabetic neuropathy or diabetes.

**Altun and Kurutas. Neural Regen Res. 2016 May; 11(5):842-845. (HRL007980-HRL007986).** This study evaluated tissue levels of various B vitamins, including Vitamin B12, in the crushed nerves of rats. This appears to have been done to see if damage to a nerve induces a change in Vitamin B12 levels. This rodent study does not test whether Vitamin B12 helps the animals with crush injury and does not replicate diabetic neuropathy in humans. It does not provide competent and reliable scientific evidence to support claims that Neupathic or its individual ingredients are effective in curing, mitigating, or treating diabetic neuropathy or diabetes in humans.

**Carmona-Cervantes J. Acta Ortopedica Mexicana. 2014 May-Jun; 28(3):168-172. (HRL007987- HRL007991).** This is a descriptive study of wound care for diabetic ulcers using thiamine pyrophosphate (a form of vitamin B1), along with antibiotics and surgery. It is not a double-blinded or placebo-controlled trial and does not provide competent and reliable scientific evidence for a claim that Neupathic or Vitamin B1 cure, treat, or mitigate diabetic neuropathy or diabetes.

**Song R, et al. Biomedical Research 2017; 28:6210-6215 (HRL007959-007964).** This is an animal study that suggests Vitamin B1 may influence neuropathy in rodents. Because it is not a randomized, double-blind, placebo-controlled clinical trial involving human subjects, it does not provide competent and reliable scientific evidence to support a claim that Neupathic or Vitamin B1 is effective in curing, mitigating, or treating diabetic neuropathy or diabetes in humans.

**Abbas and Swai. East Afr Med J. 1997 Dec;74(12):803-8 (HRL007967-7968).** Defendants only produced an abstract for this study to the FTC, and I was unable to find the full article elsewhere. The abstract suggests there was some randomization, but it is unclear whether

the study was blinded. There was no placebo group. The abstract claims that a combination of thiamine (Vitamin B1) and pyridoxine (Vitamin B6), administered at doses of 25 and 50 mg/day respectively, had a dramatic effect on subjective measures of neuropathy when compared to treatment with (Vitamin B1) and pyridoxine (Vitamin B6) at 1 mg/day and 1 mg/day, respectively. The doses of vitamins administered in this study were not the same as the doses of B1 and B6 found in Neupathic (33.3 mg). The study also does not appear to have been independently replicated in the 20 years since it was first published. For these reasons, the study does not provide competent and reliable scientific evidence for a claim that Neupathic or its ingredients Vitamins B1 or B6 cure, treat, or mitigate diabetic neuropathy or diabetes.

In addition to reviewing all of the studies and materials submitted by Defendants to the FTC, I also used PubMed, National Library of Medicine (“PubMed”) and the Google search engine to independently search for any published randomized, double-blind, placebo-controlled clinical trials that would provide substantiation for claims that Vitamins B1, B6, B12, folic acid, or Vitamin E cure, treat, or mitigate diabetes or diabetic neuropathy and did not find any.

#### **B. Purported Substantiation Relating to EPO and GLA**

Defendants also submitted studies to the FTC as purported substantiation that tested the individual ingredient EPO or GLA, a component of EPO. However, the GLA study conducted by Keen, et al. tested a much higher dose of GLA than Neupathic provides, and the study’s authors used faulty statistical analysis in evaluating results. The EPO study conducted by Ogbera et al. was not a randomized, double-blinded, or placebo-controlled trial. Importantly, neither of these studies tested the same combination of active ingredients found in Neupathic. As a result, neither of the studies represents competent and reliable scientific evidence to substantiate a claim that Neupathic or its individual ingredients EPO or GLA cure, mitigate, or

treat diabetes or diabetic neuropathy. I discuss each of these studies in more detail below as well as several abstracts related to EPO that Defendants submitted as purported substantiation.

**Keen, et al. Diabetes Care. 1993;16(1):8-15 (HRL005644-5645 and HRL007927-7928 and HRL007930-7931).** This was a randomized, double-blind, placebo-controlled study of 1-year duration involving 111 subjects who took 480 mg/day of GLA. This dose of GLA is 8 times higher than the dose of GLA in Neupathic. The authors state that the changes in 1 year in the GLA group were “more favorable” than the change in the placebo group when assessed by a series of objective measures (nerve conduction velocity evaluated using instruments) and subjective measures (sensation tests that the subject rated).

The statistical analysis was not performed correctly, as the study report discloses that “[t]he differences between the changes in the active and in the placebo groups were assessed by unpaired, two-tailed Student's t test.” The proper way to evaluate the data is to directly compare the relative values at the end of the study. In other words, the authors should have evaluated whether one group is different than the other group after treatment. Evaluating the “differences in changes” of the active treatment group and comparing them with changes in the placebo group does not provide an accurate measure of response to the tested product. Secondly, there were multiple measures of neuropathy evaluated in this study, and this means that the threshold for significance should have been adjusted for the multiple measures because of the increased risk for a “false positive” result. However, the report does not suggest that the authors made the appropriate adjustments. This is a fundamental statistical error.

For all of the above reasons, this study does not provide competent and reliable scientific evidence for a claim that Neupathic or its individual ingredients cure, treat, or mitigate diabetic neuropathy or diabetes.



**Jamal and Carmichael. Diabetes Med. 1990 May; 7(4):319-23 (HRL007925-7926).**

This was a preliminary study, with nearly identical design to that described in Keen, et al., addressed above. Dr. Jamal is a coauthor on the Keen, et al. paper. It used a similar design (double-blind and placebo-controlled), with a lower dose of GLA (360 mg vs. 480 mg for the Keen, et al. study). This study used a dose of GLA that is 6 times higher than that found in Neupathic. As a result, this study does not provide competent and reliable scientific evidence that Neupathic, or its ingredient GLA, is effective in curing, mitigating, or treating diabetic neuropathy or diabetes.

**Ogbera, et al. Indian Journal of Endocrinology and Metabolism. 2014;18(6):846-849 (HRL005640-5643).** This article describes an unblinded (open-label) study involving 80 subjects with diabetic neuropathy receiving a combination of Vitamin E (400 mg/day) and EPO (500-1000 mg/day). It was not randomized or placebo-controlled. Open label studies such as this one are inherently biased especially when there is no randomization. This study assessed symptom relief at periods up to 3 months. The authors claim 88% of subjects reported relief from burning pain, which is a symptom of diabetic neuropathy. However, the dose of Vitamin E tested in this study was 20 times higher than the dose of Vitamin E found in Neupathic. The EPO dose was equivalent to that found in the Neupathic formulation. As noted above, other studies involving tocopherols (which contain Vitamin E) have shown no effect on neuropathy when properly carried out as a placebo-controlled study with objective measures of nerve function<sup>10</sup>. For the above reasons, this study does not provide competent and reliable scientific evidence that Neupathic or its individual ingredients cure, mitigate, or treat diabetic neuropathy or diabetes.

**Horrobin, DF. Prostaglandins Leukot Essent Fatty Acids 1993; Jan;48(1):101-4 (HRL005647 and HRL007924) and Horrobin, DF, Agents Actions Suppl. 1992;37:120-44 (HRL005646 and HRL007929).** These are both review articles that do not provide primary data or competent and reliable scientific evidence to support claims that Neupathic, or its ingredient GLA, are effective in curing, mitigating, or treating diabetic neuropathy or diabetes.

**Mann RH. Natural Medicine Journal 2018;10 (HRL007943- HRL007958).** This is another review article, which does not provide primary data or competent and reliable scientific evidence to support claims that either Neupathic or its ingredient GLA is effective in curing, mitigating, or treating diabetic neuropathy or diabetes.

In addition to reviewing the studies submitted by Defendants to the FTC, I used PubMed and the Google search engine to independently search for any published randomized, double-blind, placebo-controlled clinical trials that would provide competent and reliable scientific evidence to support claims that EPO or GLA cure, treat, or mitigate diabetes or diabetic neuropathy and did not find any.

## **VII. CONCLUSIONS**

Based on my review of the materials that Defendants have submitted to the FTC as substantiation as well as my independent review of relevant scientific literature, I have reached the following conclusions. First, no randomized, double-blind, placebo-controlled clinical trials have tested Neupathic or a product with the same combination of active ingredients to prove efficacy of the product in curing, treating, or mitigating diabetic neuropathy or diabetes. Second, many of the studies submitted by Defendants have serious problems in either study design or in their statistical analysis. In many instances, the studies relied on by Defendants were not

randomized, double-blind, and placebo-controlled. Third, in addition to the significant flaws in design and statistical analysis, in each of the studies proffered by Defendants (with the exception of the EPO study conducted by Ogbera et al. <sup>9</sup> which was not a randomized, double-blind, placebo-controlled trial), the dosage of the individual ingredients tested in the trials were significantly higher than those found in Neupathic.

Defendants have provided to the FTC a series of publications as substantiation that do not provide competent and reliable scientific evidence to support claims that Neupathic or its individual ingredients can cure, treat, or mitigate diabetes or diabetic neuropathy. In my opinion, based on my professional experience, training, and review of the literature, it is highly unlikely that a properly conducted randomized, double-blind, placebo-controlled clinical trial would demonstrate efficacy of Neupathic or an Essentially Equivalent Product in curing, treating, or mitigating diabetes or diabetic neuropathy.

I declare under penalty of perjury under the laws of the United States of America that this report is a true and correct statement of my opinions and expert testimony. If called to testify, I could and would testify to this expert opinion.



---

Dr. Charles F. Burant

Executed on: December 8, 2019

Ann Arbor, Michigan

**References/footnotes:**

- 1 Donath, M. Y., Dinarello, C. A. & Mandrup-Poulsen, T. Targeting innate immune mediators in type 1 and type 2 diabetes. *Nat Rev Immunol*, doi:10.1038/s41577-019-0213-9 (2019).
- 2 Lee, H. S. & Hwang, J. S. Genetic aspects of type 1 diabetes. *Ann Pediatr Endocrinol Metab* **24**, 143-148, doi:10.6065/apem.2019.24.3.143 (2019).
- 3 Zheng, Y., Ley, S. H. & Hu, F. B. Global aetiology and epidemiology of type 2 diabetes mellitus and its complications. *Nat Rev Endocrinol* **14**, 88-98, doi:10.1038/nrendo.2017.151 (2018).
- 4 Wilmshurst, J. M., Ouvrier, R. A. & Ryan, M. M. Peripheral nerve disease secondary to systemic conditions in children. *Ther Adv Neurol Disord* **12**, 1756286419866367, doi:10.1177/1756286419866367 (2019).
- 5 Callaghan, B. C., Price, R. S., Chen, K. S. & Feldman, E. L. The Importance of Rare Subtypes in Diagnosis and Treatment of Peripheral Neuropathy: A Review. *JAMA Neurol* **72**, 1510-1518, doi:10.1001/jamaneurol.2015.2347 (2015).
- 6 Vinik, A. I., Nevoret, M. L., Casellini, C. & Parson, H. Diabetic neuropathy. *Endocrinol Metab Clin North Am* **42**, 747-787, doi:10.1016/j.ecl.2013.06.001 (2013).
- 7 Nathan, D. M. & Group, D. E. R. The diabetes control and complications trial/epidemiology of diabetes interventions and complications study at 30 years: overview. *Diabetes Care* **37**, 9-16, doi:10.2337/dc13-2112 (2014).
- 8 Bril, V. *et al.* Evidence-based guideline: Treatment of painful diabetic neuropathy: report of the American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation. *PM R* **3**, 345-352, 352 e341-321, doi:10.1016/j.pmrj.2011.03.008 (2011).
- 9 Ogbera, A. O., Ezeobi, E., Unachukwu, C. & Oshinaike, O. Treatment of diabetes mellitus-associated neuropathy with vitamin E and Eve primrose. *Indian J Endocrinol Metab* **18**, 846-849, doi:10.4103/2230-8210.140270 (2014).
- 10 Vitamin E in Neuroprotection Study (VENUS) Investigators *et al.* Efficacy of Oral Mixed Tocotrienols in Diabetic Peripheral Neuropathy: A Randomized Clinical Trial. *JAMA Neurol* **75**, 444-452, doi:10.1001/jamaneurol.2017.4609 (2018).

# **Expert Report of Charles F. Burant**

## **ATTACHMENT 1**

## CURRICULUM VITAE

### Charles Francis Burant, M.D., Ph.D.

Robert C. and Veronica Atkins Professor of Metabolism  
Professor, Internal Medicine, Division of Metabolism, Endocrinology, and Diabetes  
Professor, Molecular & Integrative Physiology  
Professor, Department of Nutritional Sciences, School of Public Health  
Adjunct Professor, Division of Movement Science, School of Kinesiology  
Director, A. Alfred Taubman Medical Research Institute

6903 Brehm Tower  
1000 Wall St.  
Ann Arbor, MI 48109-5678  
Phone: 734-615-3481  
E-Mail: burantc@umich.edu

### EDUCATION AND TRAINING

8/1975-5/1979 University of Wisconsin, Madison, Wisconsin; B.S. Biochemistry  
6/1979-7/1981 University of Wisconsin, Madison, Wisconsin; M.S. Environmental Toxicology  
7/1981-5/1987 Medical University of South Carolina, Charleston, S. Carolina; M.D. in Medicine  
7/1981-5/1987 Medical University of South Carolina, Charleston, S. Carolina; Ph.D. in Molecular and Cellular Biology

### POSTDOCTORAL TRAINING

6/1987-6/1988 University of California, San Francisco, California; Internship in Medicine  
6/1988-6/1989 University of California, San Francisco, California; Resident in Medicine  
7/1989-6/1991 University of Chicago; Fellow in Endocrinology, Department of Medicine

### ACADEMIC, ADMINISTRATIVE AND CLINICAL APPOINTMENTS

7/1991-6/1992 Instructor, Department of Medicine, University of Chicago  
7/1992-8/1998 Assistant Professor, Endocrinology Section, Department of Medicine, University of Chicago  
8/1998-8/2001 Research Fellow and Director, Cell Biology, Head, Metabolic Diseases, Parke-Davis Pharmaceuticals, Ann Arbor, MI  
4/1999-9/2001 Adjunct Assistant Professor of Medicine, University of Michigan  
10/2001-5/2008 Associate Professor of Medicine, University of Michigan  
10/2001-present Adjunct Professor of Kinesiology, University of Michigan  
1/2002-5/2006 Associate Professor of Molecular and Integrative Physiology, University of Michigan  
7/2002-present Member, Cell and Molecular Biology Training Program, University of Michigan

7/2004-present Program Director, Fellowship Program in Metabolic Diseases  
7/2005-present Member, Center for Computational Medicine and Biology  
5/2006-present Professor of Internal Medicine and Molecular and Integrative Physiology  
1/2006-present Director, Michigan Metabolomics and Obesity Center  
1/2006-present Director, Michigan Metabolomics and Obesity Center  
5/2006-present Robert C. and Veronica Atkins Professor of Metabolism  
12/2010-present Professor, Department of Nutritional Sciences, UM School of Public Health  
7/2017-present Director, A. Alfred Taubman Medical Research Institute

## CERTIFICATION AND LICENSURE

1988 National Board of Medical Examiners  
1992 American Board of Internal Medicine  
1993 American Board of Internal Medicine-Endocrinology, Diabetes and Metabolism  
2000 American Board of Internal Medicine-renewal  
2000 American Board of Internal Medicine-Endocrinology, Diabetes and Metabolism-renewal  
2013 American Board of Internal Medicine-Endocrinology, Diabetes and Metabolism-renewal

## ACTIVE RESEARCH SUPPORT

R24 DK097153 Burant (PI) 09/01/2012 – 07/31/2018  
National Institutes of Health \$2,121,742 (Year 1 Costs, total direct costs  
\$6,100,000)

### **Michigan Regional Comprehensive Metabolomics Research Core**

This is a project to expand the metabolomics capabilities at the University of Michigan to become a national metabolomics resource.

1R01DK099034 Burant (PI-MPI grant) 3/01/2013 – 02/28/2016  
National Institutes of Health Pending (Yearly Costs)

### **Genotype-Phenotype relationships underlying aerobic capacity and metabolic health**

This project will use phenotypic and transcriptomics profiling along with genotyping to understand the genetics of enhanced aerobic capacity.

5U01DK062370 Boehnke (PI) 01/01/2014 – 05/31/2019  
National Institutes of Health Pending (Yearly Costs)

### **Identifying Genes for Type 2 Diabetes: FUSION**

The present proposal builds on a longstanding and productive collaboration between researchers in the USA and Finland to understand the genetic basis of type 2 diabetes, and to use this information to reveal disease mechanisms. In this proposal, we will continue to identify genetic loci that influence risk to type 2 diabetes and variability in diabetes-related quantitative traits, and increasingly focus on identifying the causal variants, genes and other functional units, and the mechanisms by which they act.

Role: Co-investigator

1R01DK104339-01 Tishkoff (PI) 10/01/2014 – 09/30/2019  
National Institutes of Health.

### **Integrative Nutrigenomic and Metabolomics Analyses of Africans with Variable Diets**

This project will examine the relationship between metabolome, genome and diet in cardiovascular risk factors in diverse African populations.

Role: Co-investigator

U2CES026553

National Institutes of Health. Meeker (PI) 09/01/2015- 08/31/2019

**M-CHEAR: Michigan Children's Health Exposure Analysis Resource Laboratory Hub**

M-CHEAR will provide infrastructure and support to investigate the relationship between environmental exposures and health in the nation's children.

Role: Co-investigator, Director Untargeted Analysis Resource

U24 DK112342

Burant (PI-MPI grant with Jun Li)

12/01/2016 – 8/31/2022

National Institutes of Health.

**MiCAS-Michigan Chemical Analysis Element**

Role: Communicating Principal Investigator

The role of exercise in conferring health benefits will be examined by the Molecular Transducers of Physical Activity Consortium. The MiCAS will perform small molecule analysis and lead data integration across sites.

No Identifier

Burant (PI-MPI grant with Rothberg and J Lumeng) 1/01/2017 – 12/31/2018

Taubman Medical Research Institute.

**Modulation of the Intergenerational Risk of Obesity-Pilot Phase**

Role: Communicating Principal Investigator

This grant supports the planning phase of an application that will assess the effectiveness of preconception weight loss to modulate the risk of obesity in children born to mothers with obesity.

National Institutes of Health. Gao (PI-UT Houston)

06/01/2017 – 5/30/2022

**Diabetes Progression with Metabolomic and Genomic Profiling in Starr County Mexican Americans**

Role: Coinvestigator

This project will perform integrative analyses of this multi-omics datasets to understand dysregulation of metabolic pathways and their genomic underpinnings, leading to prediabetes, diabetes, and progression of the disease.

Role: Co-Investigator

R01HD074559

(J. Lee)

05/01/14 – 02/28/19

National Institutes of Health.

**Conventional and Metabolomic Predictors of Pediatric Prediabetes and Insulin Resistance**

The proposed study will evaluate the longitudinal test performance of an array of conventional biomarkers of glycemia, including Hemoglobin A1c (HbA1c), and novel metabolomic biomarkers for identifying progression of glucose tolerance (normal to prediabetes or prediabetes to diabetes) in an overweight and obese pediatric population.



U2CES030164 (Evans, Nevetskii) 7/1/18-6/30/22  
National Institutes of Health.

**Michigan Compound Identification Development Cores**

The main goal of this project is to use cutting-edge computational and experimental methods to systematically identify metabolites among the high proportion of features in untargeted metabolomics data which are presently considered unknown. In so doing, we will address a long-standing challenge in the field of metabolomics and enhance biological insights from extant and future metabolomics data.

Role: Co-Investigator

U01 CA2354387 (Karnovsky) 7/1/18-6/30/22  
NIH

**Methods and Tools for Integrative Functional Enrichment Analysis of Metabolomics Data**

This proposal is focused on building computational tools to enable the last stage of this workflow with the ultimate goal to help researchers generate testable hypotheses and derive biological knowledge from their data.

Role: Co-Investigator

**PENDING RESEARCH SUPPORT**

NONE

**COMPLETED RESEARCH SUPPORT (within last 5 years)**

UL1 RR024986 Shanley (PI) 06/01/2012 – 05/31/2017  
National Institutes of Health \$7,658,028 (Yearly Costs)

**Michigan Institute for Clinical and Health Research (MICHR)**

Role: Associate Director, Director Pilot and Feasibility Grant Program

R01 DK079084 Burant (PI) 08/01/2007 – 01/31/2012  
National Institutes of Health

**Using Systems Biology to Understanding Islet Adaptation and Failure**

R01 DK51563 MacDougald (PI) 07/01/2006 – 06/31/2011  
National Institutes of Health

**Regulation of adipocyte differentiation and metabolism**

R01 DK077200 Burant (PI) 04/01/2008 – 04/30/2014  
National Institutes of Health \$208,271 (Yearly Costs)

**Biology of Aerobic Capacity and Insulin Resistance**

The genomic and metabolomic profile in rats with different intrinsic running capacity will be assessed before and following exercise training and following caloric restriction.

Role: Principal Investigator

R01 DK088114 Oral (PI) 02/05/2011 – 12/31/2015  
National Institutes of Health

**Effects of Recombinant Human Leptin in Nonalcoholic Fatty Liver Disease (NAFLD)**

Role: Co-Investigator

DP3 DK094292 Burant (PI, MPI Grant) 09/30/2011 – 08/31/2016  
National Institutes of Health \$1,452,738 (Yearly Costs)  
**Tissue-Specific Metabolic Reprogramming in Diabetic Complications**  
Role: Principal Investigator

P30 DK089503-6 Burant (PI) 07/01/2015 – 06/30/2020  
National Institutes of Health  
**Michigan Nutrition Obesity Research Center (Grant transferred to R. Seeley)**  
Role: Principal Investigator

## HONORS AND AWARDS

1977 National Science Foundation - Undergraduate Research Award  
1981-1987 Medical Scientist Training Program Award  
1984 Alpha Omega Alpha National Medical Honor Society  
1985 Welcome Trust Young Investigator Award  
1985 Mead Johnson Award  
1985 American Medical Association Award for Outstanding Research  
1985 American Diabetes Association Award for Outstanding Research  
1990-1991 Juvenile Diabetes Federation Fellowship  
1991 Louis Block Award for Outstanding Young Faculty  
1992-1995 American Diabetes Association Career Development Award  
1994 Elected, Central Society for Clinical Research  
1999 Fellow, American College of Endocrinology  
2006 Endowed Chair, Robert C. and Veronica Atkins Professor of Metabolism  
2008 Cure, Care and Commitment Award, American Diabetes Association, Michigan Affiliate  
2011 A. Alfred Taubman Scholar  
2015 Ad hoc member, President's Council of Advisors on Science and Technology  
2016 American Association of Physicians

## MEMBERSHIPS IN PROFESSIONAL SOCIETIES

American Association for Advancement of Sciences  
American Diabetes Association  
Central Society for Clinical Investigation  
American College of Physicians, Elected Member  
American Association of Clinical Endocrinology  
American Physiological Society  
American Society for Nutrition  
American Association of Physicians

## EDITORIAL POSITIONS, BOARDS AND PEER-REVIEW SERVICE

### *Editorial Boards*

1994-1998 Editorial Board, Diabetes

1997-1999 Editorial Board, Peptide Therapy: Index and Reviews  
 1999-2007 Assistant Editor, Journal of Biological Chemistry  
 2000-2007 Associate Editor, American Journal of Physiology, Endocrinology and Metabolism  
 2011- Associate Editor, Journal of Lipid Research  
 2016- Associate Editor, Diabetes

*Study Sections*

1993 National Institutes of Health, Child Health Study Section (ad hoc)  
 1994-1995 Endocrinology Study Section (ad hoc)  
 1995 Metabolism Study Section (ad hoc)  
 1994-1996; 1998 NRSA Study Section  
 1997-2000 American Diabetes Association Research Grant Review  
 2001-2002 Chair, American Diabetes Association Grant Review Panel  
 2004 Center for Complementary and Alternative Medicine-NIH (ad hoc)  
 2004-2007 Integrative Physiology of Obesity and Diabetes Study Section-NIH  
 2010 Nutrition Obesity Research Center Review Panel-NIH  
 2011 Ad Hoc Special emphasis Review Panel-NIH  
 2011 Chair, Environmental Exposure and Metabolic Diseases Study Section-NIH  
 2011-2017 Chair, Nutrition Obesity Research Centers Grant Review Study Section-NIH  
 2013 DP2 “Pioneer” Grant Panel  
 2013 CIDO Study Section  
 2016 Intramural Program Reviewer, National Institutes of Aging

*Other*

1999-2001 American Diabetes Association- Research Policy and Marketing Committee  
 2001-2004 American Diabetes Association- Annual Meeting Organizing Committee  
 2003-present Advisory Panel, National Diabetes Education Initiative  
 2004-2007 American Diabetes Association Research Policy Committees  
 2004-2007 American Diabetes Association Research Foundation Board of Directors  
 2007-2009 American Diabetes Association Oversight Committees  
 2014-present Chair, Executive Committee, Regional Comprehensive Metabolomics Resource Cores-NIH  
 2017-present Executive Committee, Molecular Transducers of Physical Activity-NIH

**TEACHING**

2005-2014 Pre-clinical curriculum, 2d year Medical School. Endocrinology Sequence Lectures. Nutrition.  
 2005-2014 Pre-clinical curriculum, 2d year Medical School. Gastroenterology Sequence Lectures. Obesity.  
 2005-2014 Case discussions, Endocrinology for 2nd year Medical Students.  
 2007-2008 PIBS 507. Introduction to Translational Research. Sequence director.  
 2008-present PIBS 502. Endocrine Physiology  
 2010-present K-Award writing workshop director.  
 2011-present PIBS 555 Integrative Genomics

2013-present PIBS 610 Cellular Physiology

## MENTORING

Ph.D. Thesis Advisor for Janet Daniels (nee Chen), Human Nutrition. Degree conferred 5-97 (Assistant Professor, Rensselaer Polytech Institute).

Ph.D. Thesis Advisor for Dawn Belt (MSTP), Pathology Graduate Program Degree Conferred 7-2001, (Assistant Professor, University of Wisconsin).

Ph.D. Thesis Advisor for William Chutkow (MSTP), Department of Biology and Molecular Biology. Degree Conferred 7-97 (Assistant Professor, Harvard Medical School).

Ph.D. Thesis Advisor for Joseph Dosch (MCB) 5-04- 5-10 (Post-doctoral Fellow, University of Michigan)

Ph.D. Thesis Advisor for Andrew Miller (Physiology) 6-06- 6/08 (University of Michigan, SPH)

Ph.D. Thesis Advisor for Katherine Overmyer (Physiology) 2009-2014

Ph.D. Thesis Advisor for Erin Shellman (Bioinformatics) 2009-2012 (Data Scientis, Zymergen, Inc.)

Ph.D. Thesis Advisor for Chanisa Thonusin (Molecular and Integrative Physiology) (2012-2016)

M.S. Thesis Advisor for Tanu Soni (Biostatistics) 2010-2012 (Research Statistician, University of Michigan)

Ph.D. Thesis Advisor for Mahmoud El-Azzouny (Chemistry) 2010-2013 (Agilent Technologies).

Ph.D. Thesis Advisor for Teal Guidici (Statistics) 2014-2018

Ph.D. Thesis Advisor for James Casey (Human Nutrition) 2015-present

Ph.D. Thesis Advisor for Jennifer LaBarre (Human Nutrition) 2016-present

Ph.D. Thesis Advisor for Johanna Fleishman (Molecular and Integrative Physiology) 2019-present

Post-Doctoral Fellow Advisor for Janet Tobian, M.D., Ph.D. 1995-1998 (Vice President, Eli Lilly Co).

Post-Doctoral Fellow Advisor for Floris Bovelanders, Ph.D. 1995-1998 (Owner, Bovelanders Field Hockey Training Center (1996 Olympic Gold Medalist)).

Post-Doctoral Fellow Advisor for Christopher Corpe, Ph.D. 1994-1998 (Senior Director, Nestle Research Institute).

Post-Doctoral Fellow Advisor for Xiangquan Li, M.D., Ph.D. 1998-2002 (Assistant Professor, Syracuse University).

Post-Doctoral Fellow Advisor for Lanjing Zhang, M.D., M.S. 2002-2006 (Clinical Assistant Professor of Pathology Robert Wood Johnson Medical School-UMDNJ).

Post-Doctoral Fellow Advisor for Angele Subauste, M.D. 2002-2006 (Assistant Professor of Internal Medicine, University of Mississippi).

Post-Doctoral Fellow Advisor for Ann Chang, M.D. 2001-2005 (Senior Director, Lilly Pharmaceuticals)

Post-Doctoral Fellow Advisor for Mary-Ann Huang, M.D. 2003-2005. (Director, Amylin Pharmaceuticals)

Post-Doctoral Fellow Advisor for Emilie Collins, M.D. (Private Practice, Grand Rapids, MI). 2005-2007

Post-Doctoral Fellow Advisor for Amy Rothberg, M.D 2007-2009 (Associate Professor of Internal Medicine University of Michigan)

Post-Doctoral Fellow Advisor for Julian Munoz, MD, Ph.D. 2009-2011 (Assistant Professor, University of South Carolina)

Post-Doctoral Fellow Advisor for Cristina Lara-Castro, M.D. 2008-2010 (Medicine Resident, Palmetto Health Systems, Columbia South Carolina)  
Post-Doctoral Fellow Advisor for Charles Evans 2008-2010 (Assistant Professor, University of Michigan)  
Post-Doctoral Fellow Advisor for Mahmoud el-Azzouny 2013-2017 (Agilent Technologies)  
Post-Doctoral Fellow Advisor for Jacob Mahoney 2016-2017 (Post-Doctoral Fellow, Stanford University)

## COMMITTEE, ORGANIZATIONAL, AND VOLUNTEER SERVICE

1995-1998 Endocrine Fellowship Director, University of Chicago  
1996-1998 Member, Animal Care and Usage Committee, University of Chicago  
1997-1998 Chairman, Animal Care and Usage Committee, University of Chicago  
2002-2011 Associate Director, Molecular Biology Core, Michigan Diabetes Research and Training Center  
2003-present Advisory Panel, Michigan Diabetes Research and Training Center  
2004-present Working Group, Michigan Comprehensive Diabetes Center  
2004-2010 Director, Fellowship Program in Metabolic Diseases  
2005-present Founding Director, University of Michigan Metabolomics and Obesity Center  
2005-present Executive Committee, University of Michigan Translational Training Grant (K30) program  
2007-2008 Search Committee, Chair, School of Public Health Human Nutrition Program  
2006-present Associate Dean for Research (ORGS) Advisory Committee  
2007-2015 CTSA grant review panel  
2007-2014 Dean's Advisory Committee  
2008-2016 Unified Curriculum Committee, Translational Research Training Program, CTSA  
2009-2012 Founding Director University of Michigan Investigational Weight Management Clinic  
2009-2012 Basic Sciences Scholars Program Committee  
2009-2013 Director, Post-doctoral Translational Scholars Program  
2009-present Executive Committee, MICHR Educational Committee  
2010-present Director, Michigan Nutrition Obesity Research Center (NIH-P30)  
2011 ULAM Departmental Nomination Review Committee  
2012 Chair, Department of Computational Medicine and Bioinformatics Search Committee  
2012 Lead, Strategic Plan, 'Cure Obesity and Metabolic Diseases'  
2011-2015 Associate Director, MICHR, Lead P/F Grant Program  
2012-present Director, Michigan Regional Comprehensive Metabolomics Resource Core (NIH-R24)  
2012-present External Advisory Board, U. Washington Nutrition Obesity Research Center  
2012-2015 Associate Director (P/F program) Michigan Institute for Clinical and Human Research  
2012-2015 Executive Committee, MICHR (CTSA)  
2013-present Oversight Committee, School of Public Health *Momentum* Center  
2013-2014 Search Committee, Department of Human Nutrition, School of Public Health  
2013-2014 Search Committee, Department of Computational Medicine and Bioinformatics  
2014-2015 Search Committee, Exercise Science, School of Kinesiology  
2014-present External Advisory Board, IUPUI Bioengineering T32  
2014-present External Advisory Board, Boston Nutrition Obesity Research Center  
2014-present. Governance Committee, University of Michigan Central Biorepository

2016-present Oversight Committee, Michigan Genetics Initiative  
2016-present External Advisory Board, Colorado Obesity Research Center  
2017-present Co-lead, MoTrPAC Executive Committee (NIH Consortium)

## **CONSULTING POSITIONS**

1997-2000 Parke-Davis Pharmaceuticals  
1995-1997 Bristol-Meyers-Squibb  
1995-1998 'E.R.' television series, NBC Television  
2001-2015 Takeda Pharmaceuticals, North America, Scientific Advisory Board  
2001-2006 Allergan Pharmaceuticals  
2003-2007 Sankyo Pharmaceuticals  
2004-2007 Concurrent Pharmaceuticals  
2004-2007 Amylin, Scientific Advisory Board  
2006-present Zydus Pharmaceuticals, Scientific Advisory Board  
2006-present Metabolic Solutions Development Company, Scientific Advisory Board  
2011-2012 Daiichi-Sankyo, Scientific Advisory Board  
2011-present Diapan Therapeutics, Scientific Advisory Board  
2012-2014 GI-Dynamics, Scientific Advisory Board  
2014-2015 Morgridge Institute, University of Wisconsin-Madison  
2016-present Johnson & Johnson

## **PATENTS**

Apolipoprotein B mRNA editing protein compositions and methods  
Patent number: 5550034  
Method of treating fatty liver diseases and conditions in non-lipodystrophic subjects.  
Patent number: 8501686

## BIBLIOGRAPHY

### *Peer-Reviewed Publications*

1. Hsia, M.T.S. and Burant, C.F. 1979. Preparation and spectral analysis of 3,3',4,4' tetrachloroazobenzene and the corresponding azo and hydrazo analogs. *J. Assoc. Off. Anal. Chem.* 62:746.
2. Hsia, M.T.S., Kreamer, B.L., Burant, C.F. and Treutelaar, M.K. 1980. General health effects of prolonged exposure to 3,3',4,4'-tetrachloroazobenzene in rats. *Drug and Chem. Toxicol.* 3:47.
3. Hsia, M.T.S., Burant, C.F., Kreamer, B.L. and Schrankel, K.R. 1982. Thymic atrophy induced by acute exposure of TCAB and TCAOB in rats. *Toxicology* 24:243.
4. Burant, C.F. and Hsia, M.T.S. 1984. Excretion and distribution of two occupational toxicants, tetrachloroazobenzene and tetrachlorazoxybenzene in the rat. *Toxicology* 29:243.
5. Burant, C.F., Treutelaar, M.K., Landreth, G.E. and Buse, M.G. 1984. Phosphorylation of insulin receptors solubilized from rat skeletal muscle. *Diabetes* 33:704.
6. Burant, C.F., Lemmon, S.K., Treutelaar, M.K. and Buse, M.G. 1984. Insulin resistance of denervated rat skeletal muscle: A model for impaired receptor-function coupling. *Am. J. Physiol.* 247:E657.
7. Burant, C.F., Treutelaar, M.K. and Buse, M.G. 1986. Diabetes induced structural and functional changes in insulin receptors from rat skeletal muscle. *J. Clin. Invest.* 67:61.
8. Burant, C.F., Treutelaar, M.K., Buse, M.G. 1986. In vivo and in vitro activation of the insulin receptor kinase in control and denervated skeletal muscle. *J. Biol. Chem.* 261:8985.
9. Burant, C.F., Treutelaar, M.K., Block, N.E. and Buse, M.G. 1986. Structural differences between liver- and muscle- derived insulin receptors. *J. Biol. Chem.* 261:14301.
10. Burant, C.F., Treutelaar, M.K., Sens, D., Allen, K.D. and Buse, M.G. 1987. Comparison of insulin and insulin-like growth factor-I receptors from rat skeletal muscle and L-6 myocytes. *Biochem. Biophys. Res. Comm.* 147:100.
11. Burant, C.F., Treutelaar, M.K. and Buse, M.G. 1988. Tissue specific differences in the activation of the insulin receptor kinase in vivo and vitro. *Endocrinology* 122:427.
12. Sowell, M.O., Burant, C.F., Treutelaar, M.K. and Buse, M.G. 1988. Minimal effects of phorbol esters on glucose transport and insulin sensitivity of rat skeletal muscles. *Diabetes* 37:499.
13. Ganzler, T., Allen, K.D., Burant, C.F., Inabnett, T. Scott, A., Buse, M.G., Sens, D.A. and Garvin, A.J. 1988. Detection of Type I insulin-like growth factor receptors in Wilms' Tumors. *Am. J. Pathol.* 130:431.
14. Burant, C.F., Treutelaar, M.K., Peavy, D.E., Frank, B.H. and Buse, M.G. 1988. Differential binding of monoiodinated insulin to muscle and liver derived receptors and activation of the receptor kinase. *Biochem. Biophys. Res. Comm.* 152:1353.

15. Buse, M.G., Burant, C.F. and Block, N.E. 1989. Tissue specific differences in insulin receptor structure and function, in *NORDISK Insulin Symposium #3; Genes and Gene Products in Development of Diabetes Mellitus-Basic and Clinical Aspects*, Oslo, Norway. Elsevier, Amsterdam. pp. 205-224.
16. Bell, G.I., Kayano, T., Buse, J.B., Burant, C.F., Takeda, J., Lin, D., Fukumoto, H. and Seino, S. 1990. Molecular biology of mammalian glucose transporters. *Diabetes Care* 13:198-208.
17. Kayano, T., Burant, C.F., Fukumoto, H., Gould, G.W., Fan, Y-S., Eddy, R.L. Byers, M.G., Shows, T.B., Seino, S. and Bell, G.I. 1990. Human Facilitative glucose transporters: isolation, functional characterization and gene localization of cDNAs encoding an isoform (GLUT5) expressed in small intestine kidney muscle and adipose tissue and an unusual glucose transporter pseudogene-like sequence (GLUT6). *J. Biol. Chem.* 265:13276-13282.
18. Nagamatsu, S., Kornhauser, J.M., Burant C.F., Seino, S., Mayo, K.E and Bell, G.I. 1991. Glucose transporter expression in brain: cDNA sequence of mouse GLUT3, the brain facilitative glucose transporter isoform, and identification of sites of expression by in situ hybridization. *J. Biol. Chem.* 267:467-472.
19. Davidson, N.O., Hausman, A.M.L., Ifkovits, C., Buse, J.B., Gould, G.W., Burant, C.F. and Bell, G.I. 1992. Expression of glucose transporters in human fetal and adult small intestine: Localization of the facilitative glucose transporter isoform, GLUT5, to the luminal surface of absorptive epithelial cells. *Am. J. Physiol.* 262 (Cell Physiol. 31):C795- C800.
20. Burant, C.F. and Bell, G.I. 1992. Mammalian facilitative glucose transporters: Evidence for similar substrate recognition sites in functionally monomeric proteins. *Biochemistry* 31:10414-10420.
21. Burant, C.F., Takeda, J, Brot-Laroche, E., Bell G.I., and Davidson, N.O. 1992. Fructose transporter in human spermatozoa and small intestine is GLUT5. *J. Biol. Chem.* 267:14523-14526.
22. Rand, E., DePaoli, A.M., Davidson, N.O., Bell, G.I., and Burant, C.F. 1993. Sequence, tissue distribution and functional characterization of the rat fructose transporter, GLUT5. *Am. J. Physiol.* 262 (Gastrointest. Liver Physiol 27):G1169-G1176.
23. Teng, B., Burant, C.F. and Davidson, N.O. 1993. Molecular cloning of an apolipoprotein B mRNA editing protein. *Science* 260:1816-1819.
24. Bell, G.I., Burant, C.F., Takeda, J. Gould, and G.W. 1993. Structure and function of facilitative sugar transporters. *J. Biol. Chem.* 268:19161-19164.
25. Burant, C.F., DePaoli, A.M., Flink, S., Chen, J., Hediger, M., Buse, J.B. and Chang, E.B. 1994. Small intestinal hexose transport in experimental diabetes: Increased transporter mRNA and protein expression in enterocytes. *J. Clin. Invest.* 93:578-585.
26. Giannoni, F., Bonen, D.K., Funahashi, T., Hadjuafapiou, C., Burant, C.F. and Davidson, N.O. 1994. Induction of apolipoprotein B mRNA editing in human liver accompanied by secretion of apolipoprotein B48. *J. Biol. Chem.* 269:5932-5936.



27. Burant, C.F. and Saxena, M.D. 1994. Rapid, reversible substrate regulation of fructose transporter (GLUT5) expression in rat small intestine and kidney. *Am. J. Physiol.* 267 (Gastrointes. Liver Physiol. 30):G71-G79.
28. Andersen, D.K., Ruiz, C.L. and Burant, C.F. 1994. Insulin regulation of hepatic glucose transporter protien is impaired in chronic pancreatitis. *Ann. Surg.* 219:679-687.
29. Hayashi, Y., DePaoli, A.M., Burant, C.F., and Refetoff, S. 1994. Expression of a thyroid hormone-responsive recombinant gene introduced into adult mice livers by replication-defective adenovirus can be regulated by endogenous thyroid hormone receptors. *J. Biol. Chem.* 269:23872-23875.
30. Cho, J.H., Musch, M.W., DePaoli, A.M. Bookstein, C., Xie, Y., Burant, C.F., Rao, M., Chang, E.B. 1994. Glucocorticoids regulate NHE3, an apical sodium/hydrogen exchanger, in a regional and tissue specific manner. *Am. J. Physiol.* 267 (Cell Physiol.):C796-803.
31. Burant, C.F. and Davidson, N. O. 1994. Expression of GLUT3 glucose transporter isoform in rat testis: Site of expression, effect of diabetes and comparison to human testis. *Am. J. Physiol.* 267 (Regul. Integr. Comp. Physiol. 6). R1488-R1495.
32. Corpe, C. P. and Burant, C.F. 1996. Hexose transporter expression in rat small intestine: Effect of diet on diurnal variations. *Am. J. Physiol.* 271(Gastrointest. Liver Physiol. 34):G211-G216.
33. Sreenan, S., Sturis, J., Pugh, W., Burant, C.F. and Polonsky, K.S. 1996. Prevention of hyperglycemia in the Zucker Diabetic Fatty rat by treatment with metformin and troglitazone. *Am. J. Physiol.* 271(Endocrinol. Metab. 34):E742-E747
34. Chutkow, W.C., Simon, M.C., Le Beau, M.M. and Burant, C.F. 1996. Cloning, tissue expression and chromosomal localization of SUR2, the putative drug binding subunit of cardiac, skeletal muscle and vascular KATP channels. *Diabetes* 45:1439-1445.
35. Ghazzi, M., Antonucci, T., Driscoll, J., Huang, S., Gaja, B., Perez, J., Dandona, P., Wilson, M., McGill, J.B., Burant, C., Lang, R., Rao, R.H., Gorscan, J., Rendell, M., Mohiuddin, S., and Witcomb, R. 1997. Cardiac and glycemic benefits of troglitazone treatment in NIDDM. *Diabetes* 46:433-439.
36. Rumsey, S.C., Kwon, O., Xu, G., Burant, C. F., Simpson, I., and Levine, M. 1997. Glucose transporter isoforms GLUT1 and GLUT3 transport dehydroascorbic acid. *J. Biol. Chem.* 272:18982-18989.
37. Burant, C.F., Sreenan, S., Hirano, K., Chang, T., Lohmiller, J., Lukens, J. Davidson, N. Ross, S. and Graves, R. 1997. Troglitazone action is independent of adipose tissue. *J. Clin. Invest.* 100:2900-2909.
38. Buse, J.B., Gumbiner, B., Mathias, N., Nelson, D., Whitcomb, R., and the Troglitazone Study Group (C.F. Burant). Troglitazone reduces exogenous insulin dose in insulin treated type II diabetes patients. *Diabetes Care.* 21. 1455-1461.
39. Maggs, D.G., Buchanan, T.A., Burant, C.F., Cline, G., Gumbiner, B., Hsueh, W.A., Inzucchi, S., Kelly, D., Nolan, D., Olefsky, J.M., Polonsky, K.D., Silver, D., Valiquett, T.R. and Shulman, G.I. 1998. The metabolic effects of troglitazone in non-insulin dependent diabetes: a randomized, double-blind, placebo-controlled trial. *Ann. Int. Med.* 128: 176-185.

40. Corpe CP, Bovelander FJ, Hoekstra J, and Burant CF. The control of GLUT5 expression by fructose occurs in mature enterocytes by diurnally influenced transcriptional and post-transcriptional events. *Biochem. Biophys. Acta.* 1402:229-238.
41. Pohlenz J, Rosenthal I.M, Weiss RE, Jhiang SM, Burant CF. and Refetoff, S. 1998. Congenital hypothyroidism due to iodide transport defect caused by compound heterozygous mutations in the sodium/iodide symporter (NIS) gene. *J. Clin. Invest.* 101:1028-1035.
42. Chutkow WA, Michealski J, Nelson DA., Fan Z. and Burant, CF. 1999. Alternative Splicing of SUR2 regulates nucleotide sensitivity of K<sub>ATP</sub>. *J. Biol. Chem.* 274(19):13656-13665.
43. Corpe CP, Hoekstra H, and Burant CF. 1999. Intestinal Fructose Adsorption, Clinical and molecular aspects. *J. Pediatr. Gastroenterol. Nutr.* 28:364-374.
44. Sreenan S, Keck, SA, Fuller, TP, and Burant CF. 1999. Troglitazone induced changes in substrate storage and metabolism in insulin resistant skeletal muscle. *Am. J. Physiol.* 276:E1119-1129.
45. Corpe CP, Sreenan S and Burant, CF. 2000. Effects of type-2 diabetes and troglitazone on the expression patterns of small intestinal sugar transporters and PPAR-gamma in the Zucker diabetic fatty rat. *Digestion* 63:116-123.
46. Chutkow WA, Samuel, V, Hansen, PA, Pu, J, Valdivia CR, Makielski, JC, and Burant, CF. 2001. Disruption of SUR2-Containing K<sub>ATP</sub> Channels Enhances Insulin Stimulated Glucose Uptake in Skeletal Muscle. *Proc. Natl. Acad. Sci. (USA)* 98:11760-11764.
47. Sreenan SK, Zhou YP, Otani K, Hansen PA, Currie KP, Pan CY, Lee JP, Ostrega DM, Pugh W, Horikawa Y, Cox NJ, Hanis CL, Burant CF, Fox AP, Bell GI, Polonsky KS. 2001. Calpains play a role in insulin secretion and action. *Diabetes* 50:2013-2020.
48. Corpe C, Sreenan SK and Burant CF. 2001. Effects of type-2 diabetes and troglitazone on the expression patterns of small intestinal sugar transporters and PPAR-gamma in the Zucker diabetic fatty rat. *Digestion* 63:116-123.
49. Watson PA, Nesterova A., Burant, CF, Klemm DJ and Reusch, JE. 2001. Diabetes-related changes in CREB content enhance smooth muscle cell proliferation and migration. *J. Biol. Chem.* 276:46142-45150.
50. Macchia, P.E., Jiang, P., Yuan, Y-D., Chandararadna, R.A.S., Weiss, R.E., Chassande, O., Samarut, J., Refetoff, S. and Burant, C.F. 2002. RXR Receptor Agonist Suppression of Thyroid Function: Central Effects in the Absence of Thyroid Hormone Receptor. *Am. J. Physiol. (Endocrinol. Metab.)* Am. J. Physiol. (Endocrinol Metab). 283:E326-31.
51. Corpe CP, Bovelander, FP, Munoz CM, Hoekstra JH, Simpson IA, Kwon O, Levine M and Burant CF 2002. Cloning and functional characterization of the mouse fructose transporter, GLUT5. *Biochem. Biophys. Acta.* 1576:191-7
52. Chutkow WA, Pu J, Wheeler, MT, Wada T, Makielski JC, Burant CF\* and McNally EM\* 2002. Prinzmetal-like vasospasm, hypertension, and early death result from the absence of *Sur2* K<sub>ATP</sub> channels in mice. *J. Clin. Invest.* 110:203-208 \*communicating authors.

53. Treutelaar MK, Skidmore JM., Dias-Leme CL, Har, M, Zhang L, Simeone D, Martin DM, and Burant CF. 2003. Nestin-lineage cells contribute to microvasculature but not endocrine cells of the pancreatic islet. *Diabetes* 52:2503-2512.
54. Zhang L, Zheng F, Binkley C., Giordano T, Burant CF, Logsdon CD, and Simeone DM. 2004. Raf kinase inhibitory protein (RKIP) inhibits  $\beta$  Cell proliferation. *Surgery* 136:708-15.
55. Borer K, Wuorinen E, Chao C and Burant CF. Exercise energy expenditure is not consciously detected due to oro-gastric, not metabolic, basis of hunger sensation. 2005. *Appetite* 45:177-181.
56. Gerin I, Dolinsky VW, Chiang S-H, Burant CF, Steffensen KR, Gustafsson J-A. and MacDougald, OA. 2005. LXR $\beta$  is required for adipocyte hypertrophy, glucose homeostasis and  $\beta$ -cell function in aged mice. *J. Biol. Chem.* 280:23024-23031.
57. Li X., Hansen, P, Chandraratna RAS, and Burant, CF 2005. High affinity Retinoid X Receptor ligands decrease hepatic glucose production without peripheral insulin sensitization: antihyperglycemic effects in the absence of activation of the peroxisome proliferator-activated receptor  $\gamma$ -RXR heterodimer. *J. Biol. Chem.* 280:38317-38327.
58. Zhou Y-P, Madjidi A, Johnson, JH, Palma, JF, Schweitzer A, Burant CF, Blume, JE, Johnson JD 2005. MMP-Mediated Tissue Remodeling Underlies  $\beta$ -Cell Failure in the Pancreatic Islets of Zucker Diabetic Fatty Rats. *Diabetes* 54:2612-2619.
59. Zhang L, Chenwei L, Li X, Mahmood R., van Golen R., Greenson J, Li G, D'Silva NJ, Burant CF, Logsdon CD, and Simeone DS. 2006. Identification of a candidate tumor suppressor gene rap1GAP in pancreatic cancer. *Cancer Res.* 66:898-906.
60. Simeone, D.M., Zhang, L., Treutelaar, M.K., Binkley, C., Logsdon, C.D., Zhang L., and Burant C.F. 2006. Regulation of adult islet size by TGF $\beta$  family-mediated regulation of an islet precursor cell population. *Am. J. Physiol.* 291(6):E1305-1316.
61. Li, X., Zhang, J., Meshinchi, S., Raffin, D., Dias-Leme, C., Johnson, J.D., Treutelaar, M.K., and Burant, C.F. 2006. Islet microvasculature in islet hyperplasia and islet failure in Type 2 diabetes. *Diabetes* 55:2965-2973.
62. Chenwei, L., Heidt, D.G., Dalerba, P., Burant, C.F., Zhang, L. Adsay, V., Wicha, M., Clarke, M.F., and Simeone, D.S. 2007. Identification of pancreatic cancer stem cells. *Cancer Res.* 67:1030-1037.
63. Wright, W.S., Longo, K.A., Dolinsky, V.W., Gerin, I., Kang, S., Bennett, C.N., Chiang, S.H., Prestwich, T.C., Gress, C., Burant, C.F., Susulic, V.S., Macdougald, O.A. 2007. Wnt10b Inhibits Obesity in ob/ob and Agouti Mice. *Diabetes* 56:295-303.
64. Li C., Heidt D.G., Dalerba P, Burant C.F., Zhang L., Adsay V., Wicha M., Clarke M.F., Simeone D.M. 2007. Identification of pancreatic cancer stem cells. *Cancer Res.* 67:1030-1037.
65. Heidt D.G., Burant C.F., Simeone D.M. 2007. Total pancreatectomy: indications, operative technique, and postoperative sequelae. *J Gastrointest Surg.* 11:209-16.
66. Subauste A.R., Burant C.F. 2007. Role of FoxO1 in FFA-induced oxidative stress in adipocytes. *Am. J. Physiol. Endocrinol. Metab.* 293:E159-164.

67. Borer, K.T., Wuorinen, E, Lukos, J, Denver, J, Porges, S.W. and Burant, C.F. 2009. Two bouts of exercise before meals, but not after meals, lower daily blood glucose in nondiabetic women. *J. Sports Medicine* 41:1606-1614.
68. Singer, B, Jutkiewicz, E, Fuller, C, Lichtenwalner, R, Zhang, H, Velandar, A, Li, X., Gnegy, M, Burant, C.F. and Parent, J. 2009. Conditional Ablation and Recovery of Forebrain Neurogenesis in the Mouse. *J Comp Neurol.* 514:567-582.
69. Thyfault, J.P., Rector, R.S., Uptergrove, G. M. Borengasser, S. J., Morris, E. M., Wei, Y., Laye, M. J., Burant, C.F., Qi, N. Ridenhour, S.E.C., Koch, L.G., Britton, S. L., and Ibdah J. A. 2009. Rats selectively bred for low aerobic capacity have reduced hepatic mitochondrial oxidative capacity and susceptibility to hepatic steatosis and injury. *J. Physiol.* 587, 1805-1816.
70. Borer, KT, Wuorinen E, Ku K, Burant CF. 2009. Appetite responds to changes in meal content while ghrelin, leptin and insulin track changes in energy availability. *J. Clin. Endo. Metabol.* 94:2290-2298.
71. Schenk S, Harber MP, Shrivastava CR, Burant CF, Horowitz JF. 2009. Improved insulin sensitivity after weight loss and exercise training is mediated by a reduction in plasma fatty acid mobilization, not enhanced oxidative capacity. *J Physiol.* 587:4949-4961.
72. Singer BH, Jutkiewicz EM, Fuller CL, Lichtenwalner RJ, Zhang H, Velandar AJ, Li X, Gnegy ME, Burant CF, Parent JM. 2009. Conditional ablation and recovery of forebrain neurogenesis in the mouse. *J Comp Neurol.* 514:567-82.
73. Bogan, K.L., Evans, C., Song, P., Burant, C.F., Kennedy, R.T., Brenner, C. 2009. Identification of Isn1 and Sdt1 as glucose and vitamin-regulated NMN and NaMN 5'-nucleotidases responsible for production of nicotinamide riboside and nicotinic acid riboside. *J. Biol. Chem* 284:34861-9.
74. Liu D, Sartor MA, Nader GA, Gutmann L, Treutelaar MK, Pistilli EE, Iglayreger HB, Burant CF, Hoffman EP. 2010. Gordon PM. Skeletal muscle gene expression in response to resistance exercise: sex specific regulation. *BMC Genomics.* Nov 24;11:659
75. Gerin I, Clerbaux LA, Haumont O, Lanthier N, Das AK, Burant CF, Leclercq IA, MacDougald OA, Bommer GT. 2010. Expression of miR-33 from an SREBP2 intron inhibits cholesterol export and fatty acid oxidation. *J Biol Chem.* 285(44):33652-61.
76. Subauste AR, Elliott B, Das AK, Burant CF. 2010. A role for 1-acylglycerol-3-phosphate-O-acyltransferase-1 in myoblast differentiation. *Differentiation.* 80:140-6.
77. Evans C, Bogan KL, Song P, Burant CF, Kennedy RT, Brenner C. 2010. NAD+ metabolite levels as a function of vitamins and calorie restriction: evidence for different mechanisms of longevity. *BMC Chem Biol.* 10:2.
78. Liu D, Sartor MA, Nader GA, Gutmann L, Treutelaar MK, Pistilli EE, Iglayreger HB, Burant CF, Hoffman EP. Gordon PM. 2010. Skeletal muscle gene expression in response to resistance exercise: sex specific regulation. *BMC Genomics.* Nov 24;11:659. PMC3091777
79. Gao J, Tarcea VG, Karnovsky A, Mirel BR, Weymouth TE, Beecher CW, Cavalcoli JD, Athey BD, Omenn GS, Burant CF, Jagadish HV. 2010. Metscape: a Cytoscape plug-in for visualizing and interpreting metabolomic data in the context of human metabolic networks. *Bioinformatics.* 26(7):971-3. PMC3044292

80. Su G, Burant CF, Beecher CW, Athey BD, Meng F. 2011. Integrated metabolome and transcriptome analysis of the NCI60 dataset. *BMC Bioinformatics*. 12:S36 1-7. PMC3044292
81. Lorenz, MA, Burant, CF, Kennedy, RT. Reducing Time and Increasing Sensitivity in Sample Preparation for Adherent Mammalian Cell Metabolomics. 2011. *Analytical Chemistry*. 83:3406-14. PMC3094105
82. Burniston JG, Kenyani J, Wastling JM, Burant CF, Qi NR, Koch LG, Britton SL. 2011. Proteomic analysis reveals perturbed energy metabolism and elevated oxidative stress in hearts of rats with inborn low aerobic capacity. *Proteomics*. 11(16):3369-79. PMID: 21751351.
83. Koch LG, Kemi OJ, Qi N, Leng SX, Bijma P, Gilligan LJ, Wilkinson JE, Wisløff H, Høydal MA, Rolim N, Abadir PM, van Grevenhof EM, Smith GL, Burant CF, Ellingsen O, Britton SL, Wisløff U. Intrinsic aerobic capacity sets a divide for aging and longevity. *Circ Res*. 2011 Oct 28;109(10):1162-72. PMC3236084.
84. Evans SJ, Prossin AR, Harrington GJ, Kamali M, Ellingrod VL, Burant, CF, McInnis, MG. 2012. Fats and Factors: Lipid Profiles Associate with Personality Factors and Suicidal History in Bipolar Subjects. *PLoS ONE* 7(1): e29297
85. Karnovsky A, Weymouth T, Hull T, Tarcea VG, Scardoni G, Laudanna C, Sartor MA, Stringer KA, Jagadish HV, Burant C, Athey B, Omenn GS. 2012. Metscape 2 bioinformatics tool for the analysis and visualization of metabolomics and gene expression data. *Bioinformatics*. 28:373-380. PMC3268237
86. Burant, CF, Viswanathan, P, Marcinak, J, Cao C, Vakilynejad M, Xie B and Leifke, E. 2012. TAK-875, a G Protein–Coupled Receptor 40 Agonist, for the Treatment of Type 2 Diabetes Mellitus: A Phase II, Randomized, Double-Blind, Placebo- and Active-Controlled Study. *Lancet* 379(9824):1403-11.
87. Pratley, R.E., Burant, C.F. Wilson, C. Mekki, Q., Fleck, P. and Defronzo, R.A. 2012. Efficacy and Tolerability of the DPP-4 Inhibitor Alogliptin Combined With Pioglitazone, in Metformin-Treated Patients With Type 2 Diabetes. *J. Clin. Endo. Metab.* 97:1615-22.
88. Kiefer, F.W., Orasanu, G., Qi, N.R., Burant, C.F., Nallamshetty, S., Brown, J.D., Duester, G. and Plutzky, J. 2012. Retinaldehyde dehydrogenase 1 coordinates hepatic gluconeogenesis and fatty acid metabolism independent of body weight. *Endocrinology* 153:3089-99. PMID 22555438
89. Haschemi, A, Kosma, P, gille, L, Evans, C, Burant, CF, Starkl, Ph, Knapp, B, Haas, R, Schmid, JA, Jandl, C, Amir, S, Lubec, G, Park, J, Esterbauer, H, Bilban, M, Brizuela, L, Pospisilik, AJ, Wotterbein, LE, and Wagner, O. 2012. The Sedoheptulose Kinase CARKL Directs Macrophage Polarization Through Control of Glucose Metabolism. *Cell Metabolism* 15: 813-826. PMID 22682222
90. Izadpanah A, Barnard RJ, Eliseo AJ, Baldwin GC, Bridges S, Burant CF and Roberts CK. 2012. A Short-term diet and exercise intervention ameliorates inflammation and markers of metabolic health in overweight/obese children in the absence of obesity reversal. *Am. J. Physiol. Endo Metab.* 303:E542-50 PMID 22713506

91. Evans SJ, Kamali M, Prossi, AR, Harrington, GJ, Ellingro, VL, McInni, MG and Burant, CF. 2012. Association of Plasma Omega-3 and Omega-6 Lipids with Burden of Disease Measures in Bipolar Subjects *J. Psychiatric Res.* 46(11):1435-41 PMID 22884424
92. Subauste, AR, Das, AK, Li, X, Elliot, B, Evans, C, El Azzouny, M, Treutelaar, M, Oral, E, Leff, T and Burant, CF. 2012. Alterations in lipid signaling underlie lipodystrophy secondary to AGPAT2 mutations. *Diabetes* 61(11):2922-31. PMID 22872237
93. Jasinska A, Yasud M, Burant CF and Falk E. 2012. Impulsivity and inhibitory control deficits are associated with unhealthy eating in young adults. *Appetite.* 59(3):738-747. PMID 22885454
94. Peterson MD, Hurvitz, EA and Burant CF. 2012. Secondary Muscle Pathology and Metabolic Dysregulation in Adults with Cerebral Palsy. *Am. J. Physiol. Endo Metab* 303:E1085-93. PMID 22912367
95. Shellman, ER, Burant, CF and Schnell, S. 2012. Elucidating Properties of Metabolic Pathways with Motifs. *Molecular BioSystems* 9:352-60. PMID 23287894
96. Lorenz MA, El Azzouny, MA, Kennedy RT, Burant CF. 2013.  $\beta$ -cell metabolome response to glucose-stimulated insulin secretion. *J. Biol. Chem.* 288: 10923-10935. PMID: 23426361, PMC4036363
97. McDonnell SRP, Hwant SR, Rolland D, Murga-Zamalloa C, Basruru V, Conlon KP, Fermin D, Wolfe T, Raskind, A. Ruan C. Thomas C., Hogaboam CM, Burant CF, Dlenitoba-Johnson KSJ, Lim, MS. 2013. Integrated Phosphoproteomic and Metabolomic Profiling Reveals NPM-ALK-Mediated Phosphorylation of PKM2 and Metabolic Reprogramming in Anaplastic Large Cell Lymphoma. *Blood* 122:958-68. PMID 23814019
98. Snider NT, Griggs NW, Singla A, Moons DS, Weerasinghe SVW, Lok AS, Ruan C, Burant CF, Thompson LF, Omary MB. 2013. CD73 (5'-ectonucleotidase) hepatocyte levels differ across mouse strains and contribute to Mallory-Denk body formation. *Hepatology* 58(5):1790-800. PMID 23729294. PMC3796030
99. Ren Y-y, Overmyer KA., Qi NR, Treutelaar MK, Heckenkam L, Kalahar M, Koch LG, Britton SL, Burant CF and Li JZ. Genetic Analysis of a Rat Model of Aerobic Capacity and Metabolic Fitness. *PLoS One* 8(10): e77588. PMID:24147032 PMC3795692
100. Rothberg AE, McEwen LN, Fraser T, Burant CF and Herman WH. 2013. The impact of a managed care obesity intervention program on clinical outcomes and costs: A prospective observational study. *Obesity* 21(11):2157-62. PMC3947418.
101. Rothberg AE, McEwen Neshewat GM, Fowler CE, Kraftson AT, Burant CF and Herman WH. 2014. The Impact of Weight Loss on Health-Related Quality of Life: Implications for Cost-Effectiveness Analyses. *Qual. Life Res* 23(4):1371-6. PMID: 24129672.
102. Evans CR, Karnovsky A, Kovach M, Standiford T, Burant CF and Stringer K. 2014. Untargeted LC-MS Metabolomics of Bronchoalveolar Lavage Fluid Differentiates Acute Lung Injury from Health. *J. Proteome Res.* 13:640-9. PMID: 24289193
103. Wardlaw SL, Meece K, Klein S, White A, Kasten T, Lucey B, Bateman RJ and Burant CF. Continuous 24-Hour Leptin, Proopiomelanocortin and Amino Acid Measurements in Human

- Cerebrospinal Fluid: Correlations with Plasma Leptin, Soluble Leptin Receptor and Amino Acid Levels. 2014. *J. Clin. Endo. Metab.* 99:2540-8. PMID 24670082
104. El-Azzouny M.A., Evans CR, Kennedy RT, and Burant CF. 2014. Increased Glucose Metabolism and Glycerolipid Formation by Fatty Acids and GPR40 Underlies the Fatty Acid Potentiation of Insulin Secretion. *J. Biol. Chem.* 289:13575-88. PMID:24675078 PMC4036363
105. Duren, W, Weymouth T, Hull T, Omenn GS, Burant CF, Karnovsky A. 2014. MetDisease – connecting metabolites to diseases via literature. *Bioinformatics* 30(15):2239-41. PMC4103594
106. Evans SJ, Ringrose RN, Harrington GJ, Mancuso P, Burant CF, McInnis MG. 2014. Dietary intake and plasma metabolomic analysis of polyunsaturated fatty acids in bipolar subjects reveal dysregulation of linoleic acid metabolism. *J. Psych. Res.* 57:58-64.
107. Shellman ER, Chen Y, Lin X, Burant CF, Schnell S. 2014. Metabolic network motifs can provide novel insights into evolution: The evolutionary origin of Eukaryotic organelles as a case study. *Comp. Biol. Chem.* 53PB:242-250. PMID: 23292343 (PMCID pending)
108. Gallagher KA, Joshi, A, Carson, WF, Mukerjee S, Kittan N, Schaller M, Feldman EL Henke PK, Hogaboam Burant CF and Kunkel SL. 2015. Epigenetic Changes in Bone-Marrow Alter Macrophage Phenotypes in Diabetic Wounds. *Diabetes* 64:1420-30. PMC4375075
109. Peterson MD, Al Snih, S, Serra-Rexach JA and Burant CF. 2015. Android Adiposity and Lack of Moderate and Vigorous Physical Activity Are Associated With Insulin Resistance and Diabetes in Aging Adults. *J. Gerontology: Med. Sci.* 70(8):1009-17. PMC4506315
110. Evans CR, Overmyer KA, Qi N, and Burant, CF. 2015. Reducing variability and improving biological fidelity for targeted and unbiased untargeted metabolomics of polar molecules in mammalian tissues. *PLoS One* 10(2):e0117232. PMC4319778
111. Ren YY, Qi NR, Treutelaar MK, Koch LG, Britton SL, Burant CF, Li JZ. 2015. Selection-, age-, and exercise-dependence of skeletal muscle gene expression patterns in a rat model of metabolic fitness. *bioRxiv* doi: <http://dx.doi.org/10.1101/013706>.
112. El-Azzouny M, Evans CR, Burant CF and Kennedy RT. 2015. Metabolomics analysis reveals that AICAR affects glycerolipid, ceramide and nucleotide synthesis pathways in INS-1 cells. *PLoS One.* 10(6):e0129029. PMC4480354
113. Overmyer KA, Evans CR, Qi N, Minogue CE, Carson JJ, Chemside-Scabbo CJ, Koch LG, Britton SL, Pagliarini DJ, Coon JJ, Burant CF. 2015. Maximal oxidative capacity during exercise is associated with skeletal muscle fuel selection and dynamic changes in mitochondrial protein acetylation. *Cell Metabolism* 21, 468-478. PMC4350023.
114. Abi Salloum B, Veiga-Lopez A, Abbott DH, Burant CF, Padmanabhan V. 2015. Developmental programming: exposure to testosterone excess disrupts steroidal and metabolic environment in pregnant sheep. *Endocrinology* 156:2323-37. PMC4430607.
115. Burghardt PR, Rothberg AE, Dykhuis KE, Burant CF, and Zubieta, J-K. 2015 Endogenous opioid mechanisms are implicated in obesity and weight loss in humans. *J. Clin. Endo. Metab.* 100(8):3193-201. PMID:26108093.

116. Evans SJ, Prossin AR, Mcinnis MD, Burant CF and Ellingrod VE. 2015. Plasma Linoleic Acid Partially Mediates the Association of Bipolar Disorder on Self-Reported Mental Health Scales Journal of Psychiatric Research. J. Psych. Res. 68:61-7. PMID: 26228402
117. Byrd JB, Rothberg AE, Chomic R, Burant CF, Brook RD and Auchus RJ. 2015. Serum cortisol-to-cortisone ratio and blood pressure in severe obesity before and after weight loss. CardioRenal Medicine 6:1-7.
118. Wynn ML, Yates JA, Evans CR, Van Wassenhove L, Wu ZF, Bridges S, Bao L, Fournier C, Ashrafzadeh S, Merrins MJ, Satin LS, Schnell S, Burant CF and Merajver SD. RhoC is a potent regulator of glutamine metabolism and N-acetylaspartate production in inflammatory breast cancer cells. J. Biol. Chem. 291(26):13715-29. PMC4919454
119. Visovatti S, Hyman M, Goonewardna S, Anyanwu A, Kanthi Y, Robichaud P, Wang W, Petrovic-Djergovic D, Rattan R, Burant C and Pinsky D. Purinergic dysregulation in pulmonary hypertension. Am J Physiol Heart Circ Physiol. 2016 Jul 1;311:H286-98. PMID 27208163
120. Sud M, Fahy E, Cotter D, Azam K, Vadivelu I, Burant CF, Edison A, Fiehn O, Higashi R, Nair S, Sumner S, Subramaniam S. Metabolomics Workbench: An international data repository for metabolomics data and metadata, metabolite standards, protocols, tutorials and training, and analysis tools. Nucleic Acid Res. 4:D463-70. PMC4702780.
121. Min JS, DeAngelis RA, Gupta S, Maurva MR, Evans C, Das A, Burant, CF, Lambris, JD and Subramaniam S. 2016. Systems analysis of the complement-induced priming phase of liver regeneration reveals an integrated pathway with acute phase proteins and cholesterol metabolism. J. Immun. 197:2500-8.
122. Phatchariya P, Ansari IH, El Azzouny M, Longacre MJ, Burant CF, Jitrapakdee S and Michael J MacDonald MJ. 2016. Suppression of Pyruvate Carboxylase in Invasive Breast Cancer Cells Inhibits Cell Growth in Association with Impaired Pyruvate Cycling and Anaplerotic Flux. Mol. Metabol. (in press). PMID: 27689010
123. Callaghan BC, Xia R, Reynolds E, Banerjee M, Burant CF, Rothberg AR, Busui R, Villegas-Umana E, Feldman EL. 2016. Diabetes, pre-diabetes, and obesity are associated with polyneuropathy. J. Am. Med. Assn. Neurology 73:1468-1476.
124. Marchlewicz E, Dolinoy D, Tang L, Milewski S, Jones T, Goodrich J, Tanu Son Ti, Domino S, Song P, Burant CF, and Vasantha Padmanabhan V. 2016. Lipid metabolism is associated with developmental epigenetic programming. Nature Sci. Reports. 6:34857.
125. Sas KM, Kyampill P, Byun J, Nair N, Hinders LM, Hur J, Zhang H, Lin C, Qi NR, Michailidis G, Groop P, Darshi M, Sharma K, Schelling JR, Sedor JR Pop-Busui R, Weinberg SM, Soleimanpour SA, Abcowers SF, Gardner TW, Burant CF, Feldman EL, Kretzler M, Brosius FC and Pennathur S. 2016. Tissue-specific metabolic reprogramming drives nutrient flux in diabetic complications. J. Clin. Invest. Insights. 22;1:e86976. PMID: 27699244.
126. Ren YY, Koch LG, Britton SL, Qi NR, Treutelaar MK, Burant CF, Li JZ. 2016. Selection-, age-, and exercise-dependence of skeletal muscle gene expression patterns in a rat model of metabolic fitness. Physiol. Genomics. 48:816-825. PMID: 27637250.



127. Ma S, Upneja A, Galecki A, Tsai Y, Burant CF, Raskind S, Seluanov A, Gorbunova V, Clish CB, Miller RA and Gladyshev, VN. 2017. Cell culture-based profiling across mammals reveals DNA repair and metabolism as determinants of species longevity. *ELife* pii: e19130 PMC5148604
128. Phannasil P, Ansari IH, El Azzouny M, Longacre MJ, Rattanapornsompong K, Burant CF, Jitrapakdee S, MacDonald MJ. 2016. Mass spectrometry analysis shows the biosynthetic pathways supported by pyruvate carboxylase in highly invasive breast cancer cells. *Biochim Biophys Acta*. S0925-4439, 30313-1.
129. Wahl DR, Dresser J, Wilder-Romans K, Zhao SG, Davis M, Zhao L, Kachman M, Wernisch S, Burant CF, Morgan, MA, Feng FY, Speers C, Lyssiotis CA, Lawrence TS. 2017. Inhibiting Isocitrate Dehydrogenase 1-mediated Reductive Biosynthesis to Augment Glioblastoma Therapy *Cancer Research* 77; 960-70. PMID:27923831 PMC5726266.
130. Basu S, Duren W, Evans CR, Burant CF, Michailidis G, Karnovsky A. 2017. Sparse network modeling and Metscape-based visualization methods for the analysis of large-scale metabolomics data. *Bioinformatics* 33(10):1545-1553. PMID: 28137712
131. ElAzzouny M, Tom CTBM, Evans CR, Olson LL, Tanga, MJ, Gallagher KA, Martin BR, Burant CF. 2017. Dimethyl itaconate is not metabolized into itaconate intracellularly. *J. Biol. Chem* 292:4766-4769. PMID: 28188288.
132. Rothberg AE, McEwen LN, Kraftson AT, Ajluni N, Fowler CE, Nay CK, Miller NM, Burant CF, Herman WH. 2017. Impact of weight loss on waist circumference and the components of the metabolic syndrome. *BMJ Open Diabetes Res Care*. Feb 20:5(1):e000341. PMC5337678
133. Biwer C, Rothberg AR, IglayRager H, Derksen H, Burant CF and Najarian K. 2017. Windowed Persistent Homology: A Novel Signal Processing Algorithm Applied to Analyze Clinical Obesity Data. *PLOS One* 12(5):e0177696. PMID pending
134. Kim DS, Jackson AU, Li YK, Stringham HM, Kuusisto J, Kangas AJ, Soinen P, Ala-Korpela M, Burant CF, Boehnke M, Laakso M, Speliotes EK. 2017. Novel association of TM6SF2 rs58542926 genotype with increased serum tyrosine levels and decreased apolipoprotein B-100 particles: the METSIM study. *J. Lipid Res*. 58:1471-1481. PMID pending
135. Calvert AE, Chalastanis A, Wu Y, Hurley LA, Kouri FM, Bi Y, Kachman M, May JL, Bartom E, Hua Y, Mishra RK, Schiltz GE, Dubrovskiy O, Mazar AP, Peter ME, Zheng H, James CD, Burant CF, Chandel NS, Davuluri RV, Horbinski C, Stegh AH. 2017. Cancer-Associated IDH1 Promotes Growth and Resistance to Targeted Therapies in the Absence of Mutation. *Cell Rep*. 19:1858-1873.
136. Kimball A, Joshi A, Carson WF, Boniakowski A, Davis F, Schaller M, Allen R, Bermick J, Henke PK, Burant CF, Kunkel SL, Gallagher KA. 2017. The Histone Methyltransferase, MLL1, Directs Macrophage-Mediated Inflammation in Wound Healing and is Altered in a Murine Model of Obesity and Type 2 Diabetes. *Diabetes* 66:2459-2471. PMC5566299.
137. Perng W, Hector EC, Song P, Tellez Rojo MM, Raskind S, Kachman M, Cantoral A, Burant CF, Peterson KE. 2017. Metabolomic Determinants of Metabolic Risk in Mexican Adolescents. *Obesity (Silver Spring)*. 25:1594-1602. PMC5573626.

138. Thonusin C, IglayReger HB, Rothberg AE, Burant CF and Evans CR. 2017. A drift-correction and batch combination tool for MS-based metabolomics data. *J. Chromatography A* 1523:265-274. PMID:28927937
139. Liu D, Morales FE, IglayReger HB, Treutelaar MK, Rothberg AE, Hubal MJ, Nadler EP, Robidoux J, Barakat H, Horowitz JF, Hoffman EP, Burant CF, Gordon, PM. 2018. Expression of macrophage genes within skeletal muscle correlates inversely with adiposity and insulin resistance in humans. *Applied Physiol. Nutr. Metab.* 43:187-193.
140. Maile MD, Standiford TJ, Engoren MC, Stringer KA, Jewell ES, Rajendiran TM, Soni T and Burant CF. 2018. Associations of the plasma lipidome with mortality in the acute respiratory distress syndrome: a longitudinal cohort study *Resp. Res.* 19:60-67.
141. den Hartigh LJ, Gao Z, Goodspeed L, Wang S, Das AK, Burant CF, Chait A, Blaser MJ. 2018. Obese Mice Losing Weight Due to trans-10,cis-12 Conjugated Linoleic Acid Supplementation or Food Restriction Harbor Distinct Gut Microbiota. *J Nutr.* Apr 1;148:562-572. PMID: 29659960.
142. Callaghan BC, Xia R, Reynolds E, Banerjee M, Burant C, Rothberg A, Pop-Busui R, Villegas-Umana E, Feldman EL. 2018. Better diagnostic accuracy of neuropathy in obesity: A new challenge for neurologists. *Clin Neurophysiol.* 129:654-662 PMID: 29414409.
143. Choksi P, Rothberg A, Kraftson A, Miller N, Zurales K, Burant C, Van Poznak C, Peterson M. 2018. Weight loss and bone mineral density in obese adults: a longitudinal analysis of the influence of very low energy diets. *Clin Diabetes Endocrinol.* 19:4:14. PMID:29946482
144. Stojanovska J, Lumeng CN, Griffin C, Hernando D, Hoffmann U, Haft JW, Kim KM, Burant CF, Singer K, Tsodikov A, Long BD, Romano MA, Tang PC, Yang B, Chenevert TL. 2018. Water-fat magnetic resonance imaging quantifies relative proportions of brown and white adipose tissues: ex-vivo experiments. *J Med Imaging.* 5:024007.
145. Shervin Assari S, Rothberg AE, Evans SJ, Iglay Reger IglayReger, HB and Burant CF. 2018. Depressive Symptoms and Well-being of Individuals with Obesity; Race and Gender Differences. *Int. J. Endo. Metab.* (in press).
146. Stojanovska J, Lumeng CN, Griffin C, Hernando D, Hoffmann U, Haft JW, Kim KM, Burant CF, Singer K, Tsodikov A, Long BD, Romano MA, Tang PC, Yang B, Chenevert 2018. TL. Water-fat magnetic resonance imaging quantifies relative proportions of brown and white adipose tissues: ex-vivo experiments. *J Med Imaging (Bellingham).* 5:024007. PMID: 30137870.
147. Kelley AS, Banker M, Goodrich JM, Dolinoy DC, Burant CF, Domino S, Smith YR, Song PXX, Padmanabhan V. 2019. Early pregnancy exposure to endocrine disrupting chemical mixtures are associated with inflammatory changes in maternal and neonatal circulation. *Scientific Reports* (in press).
148. Goodrich JM, Ingle ME, Domino SE, Treadwell MC, Dolinoy DC, Burant CF, Meeker JD, Padmanabhan V. 2019. First Trimester Maternal Exposures to Endocrine Disrupting Chemicals and Metals and Fetal Size in the Michigan Mother Infant Pairs Study. *J. Develop. Origins of Health and Disease.* 30:1-12. PMID:30696509
149. Kelley AS, Banker M, Goodrich JM, Dolinoy DC, Burant C, Domino SE, Smith YR, Song PXX, Padmanabhan V. Early pregnancy exposure to endocrine disrupting chemical mixtures are associated with inflammatory changes in maternal and neonatal circulation. *Scientific Reports Sci Rep.* 2019 9(1):5422 PMID:30931951

150. Kimball AS, Davis FM, denDekker A, Joshi AD, Schaller MA, Bermick J, Xing X, Burant CF, Obi AT, Nysz D, Robinson S, Allen R, Lukacs NW, Henke PK, Gudjonsson JE, Moore BB, Kunkel SL, Gallagher KA. 2019. The Histone Methyltransferase Setdb2 Modulates Macrophage Phenotype and Uric Acid Production in Diabetic Wound Repair. *Immunity*. S1074-7613(19)30285-7 [Epub ahead of print] PMID:1350176.
151. Heden TD, Johnson JM, Ferrara PJ, Eshima H, Verkerke ARP, Wentzler EJ, Siripoksup P, Narowski TM, Coleman CB, Lin CT, Ryan TE, Reidy PT, de Castro Brás LE, Karner CM, Burant CF, Maschek JA, Cox JE, Mashek DG, Kardon G, Boudina S, Zeczycki TN, Rutter J, Shaikh SR, Vance JE, Drummond MJ, Neuffer PD, Funai K. 2019. Mitochondrial PE potentiates respiratory enzymes to amplify skeletal muscle aerobic capacity. *Sci Adv*. 2019 Sep 11;5(9):eaax8352. PMID: 31535029
152. Kachman M, Habra H, Duren W, Wigginton J, Sajjakulnukit P, Michailidis G, Burant CF, and Karnovski, A. 2019. Deep annotation of untargeted LC-MS metabolomics data with Binner. *Bioinformatics* (in Press).
153. Goo J, Aguilar D, Evans CR, Burant CF Hanis CL. (2019). Metabolomic Profiles Associated with Subtypes of Prediabetes Among Mexican Americans in Starr County, Texas. *Diabetologia* (in press). PMID: 31802145
154. Rothberg AE, Herman WH, Wu C, IglayReger HB, Horowitz JF, Burant CF, Galecki AT, Halter JB. 2019. Weight Loss Improves  $\beta$ -Cell Function in People with Severe Obesity and Impaired Fasting Glucose: A Window of Opportunity. *J Clin Endocrinol Metab*. (in press) PMID: 31720686
155. Marlatt KL, Lovre D, Beyl RA, Tate CR, Hayes EK, Burant CF, Ravussin E, Maubai-Jarvis F. No effect of conjugated estrogens and bazedoxifene on insulin sensitivity and ectopic fat despite stimulation of hepatic de novo lipogenesis and triglyceride production in obese postmenopausal women (in Press).

### ***Articles Submitted for Publication***

1. Guidici T, Rajendiran, T, Rothberg, A, Soni, T, Burant CF, Michailidis, G. Integrative data-driven module discovery of metabolic perturbations induced by diet. (in revision).
2. LaBarre JL, Puttabyatappa M, Song PXX, Goodrich JM, Zhou L, Rajendiran TM, Soni T, Domino SE, Treadwell M, Dolinoy DC, Padmanabhan V, Burant CF. Maternal lipid levels across pregnancy impact the umbilical cord blood lipidome and infant birth weight (Submitted).

### ***Invited Reviews***

1. Burant, C.F. 1994. Molecular biology of glucose transport. In *Advances in Molecular and Cell Biology*. E. Bittar and N. Bittar eds. Jai Press Inc. Greenwich, CT.
2. Burant, C.F., Sivitz, W.I., Fukumoto, H., Kayano, T., Nagamatsu, S., Seino, S., Pessin, J.E. and Bell, G.I. 1991. Mammalian glucose transporters: structure and molecular regulation. In *Rec. Prog. Hormone Res.* 47:349-388.

3. Bell, G.I., Fukumoto, H., Burant, C.F., Seino, S., Sivitz, W.I. and Pessin, J.E. 1990. Facilitative glucose transporter proteins: structure and regulation of expression in adipose tissue. In *Progress In Obesity Research 1990: Proceedings of the Sixth International Congress on Obesity*. Osaka, Japan. Y. Oomura et al. eds., J. Libbey & Co., Ltd., London, England. pp. 269-275.
4. Burant, C.F. Insulin Sensitization. 2000. In *Obesity: Pathology and Therapy*. D.H. Lockwood and T.G. Heffner, Eds. Springer, New York. pp. 369-402.
5. Burant, C. and Simeone, D. 2002. Connecting islet development to developing useful islets. *Trends Endo. Metab.* 13:48-49.
6. Subauste, A. and Burant, C.F. 2003. DGAT: Novel therapeutic target for obesity and type diabetes mellitus. *Curr. Drug Targets Immune Endo. Metabol. Disord.* 3: 263-270.
7. MacDougald, O.A. and Burant, C.F. 2005. Fickle factor foils fat fate. *Nat Cell Biol.* 7:543-545.
8. MacDougald, O.A. and Burant, C.F. 2007. Obesity and metabolic perturbations following loss of aquaporin 7, the adipose glycerol transporter. *Proc. Nat. Acad. Sci.* 102:10759-10760.
9. Heidt D.G., Burant C.F., and Simeone D.M. 2007. Total Pancreatectomy: Indications, Operative Technique, and Post-Operative Sequelae. *J. Gastrointest. Surg.* 11:209-16.
10. Macdougald, O.A. and Burant, C.F. 2007. The Rapidly Expanding Family of Adipokines. *Cell Metab.* 6:159-161.
11. Oral EA, Burant C. 2009. Leptin and insulin resistance: good, bad, or still unclear? *Am J Physiol Endocrinol Metab.* 296:E394-395.
12. Myers MG Jr, Burant CF. PPAR- $\gamma$  action: it's all in your head. *Nat Med.* 2011 May;17:544-5. PMID 21546969.
13. Athey BD, Cavalcoli JD, Jagadish HV, Omenn GS, Mirel B, Kretzler M, Burant C, Isopheki RD, Delisi C; the NCIBI faculty, trainees, and staff. 2011. The NIH National Center for Integrative Biomedical Informatics (NCIBI). *J Am Med Inform Assoc.*
14. Hinder, L. M., Vincent, A. M., Burant, C. F., Pennathur, S., and Feldman, E. L., 2012. Bioenergetics in diabetic neuropathy: what we need to know. *Journal of the Peripheral Nervous System* 17, 10-14.
15. Burant, CF. Activation of GPR40 as a therapeutic target for the treatment of type 2 diabetes. 2013. *Diabetes Care* 36 Suppl 2:S175-9.
16. Kurland, IJ, Accili D, Burant, CF., Fischer, SM, Kahn, BB, Newgard, CB, Ramagiri, S, Ronnett, GV, Ryals, JA, Sanders, M, Shambaugh, J, Shockcor, J and Gross, S. 2013. Metabolomics in biological processes. *Annals New York Acad. Sci.* 1287:1-16. PMID: 23659636
17. Burant CF, Robinson KR, Buse CA and Buse JB. 2016. Maria Buse: All in the family, her 6 decades of diabetes discovery. *Diabetes Care* 39(6):852-6.

### ***Books and Book Chapters***

1. Bell, G.I., Fukumoto, H., Burant, C.F. and Seino, S. 1990. Genetics of glucose transporters. In *Genetics and Human Nutrition*, edited by Randle, P.J., Bell, J.I. & Scott, J., J. Libbey & Co., Ltd., London pp. 121-131.

2. Burant, C.F., Buse, J.B., and Polonsky, K.S. 2003. *Type 2 Diabetes*. Williams Textbook of Endocrinology. Larsen, R.P., Kronenberg, H.M, Melmed, S and Polonsky, K.S. eds. Saunders W B Co, N.Y., N.Y.
3. Burant, C.F. 2004. Medical Management of Type 2 Diabetes, Fifth Edition. American Diabetes Association, Alexandria, VA.
4. Burant, C.F., Polonsky, K.S. and Buse, J.B. 2007. *Type 2 Diabetes*. Williams Textbook of Endocrinology. Larsen, R.P., Kronenberg, H.M, Melmed, S and Polonsky, K.S. eds. Saunders W B Co, N.Y., N.Y.
5. Burant, C.F. 2008. Medical Management of Type 2 Diabetes, Sixth Edition. American Diabetes Association, Alexandria, VA.
6. Burant, C.F., Polonsky, K.S. and Buse, J.B. 2011. *Type 2 Diabetes*. Williams Textbook of Endocrinology. Larsen, R.P., Kronenberg, H.M, Melmed, S and Polonsky, K.S. eds. Saunders W B Co, N.Y., N.Y.
7. Burant, C.F. 2012. Medical Management of Type 2 Diabetes, Sixth Edition. American Diabetes Association, Alexandria, VA.
8. Polonsky, K.S. and Burant, C.F. 2016. *Type 2 Diabetes*. Williams Textbook of Endocrinology. Larsen, R.P., Kronenberg, H.M, Melmed, S and Polonsky, K.S. eds. Saunders W B Co, N.Y., N.Y.

**PX 5**

**DECLARATION OF ADAM ROTTNER**

I, Adam Rottner, hereby state that I have personal knowledge of the facts set forth below.

If called as a witness, I could and would testify as follows:

1. I am a United States citizen and am over eighteen years of age. I am employed by the Federal Trade Commission (“FTC” or “the Commission”) as an Investigator in the Division of Enforcement, Bureau of Consumer Protection. My office address is 600 Pennsylvania Ave., NW, CC-9528, Washington, D.C. 20580.

2. As an Investigator with the FTC, my duties include investigating possible violations of the laws and regulations that the FTC enforces and possible violations of Orders obtained by the Commission. I was assigned to work on the Commission’s compliance investigation in *FTC and Maine v. Health Research Laboratories, LLC, et al.*, 2:17-CV-00467-JDL (D. Maine).

**DESCRIPTION OF INVESTIGATIVE  
TOOL AND SOURCES OF EVIDENCE**

3. As an FTC Investigator, my duties include the collection, analysis, and preservation of evidence relevant to the investigations I conduct into potential violations of the laws, regulations, and Orders that the FTC enforces. As part of this investigation, I utilized the investigative tool described in detail below.

4. *Snagit*. Website and image captures were made using the program Snagit, which takes an image of single webpages, or a smaller selected area as they existed on

the day of the capture. These files are typically .jpeg files, but I convert them to .pdf files for compatibility reasons.

### **WEBSITE CAPTURES**

5. On September 18, 2019, Counsel for the FTC asked me to visit and capture product information from the website <https://www.hrlsupplements.com/>.
  - a. At 2:52 PM, I used an FTC computer to visit the website <https://www.hrlsupplements.com/shop/neupathic/>. I used the Snagit tool to capture a copy of the webpage as it existed on September 18, 2019. A true and correct copy of the website <https://www.hrlsupplements.com/shop/neupathic/> is attached hereto as Attachment A.
  - b. At 2:53 PM, I used an FTC computer to visit the website <https://www.hrlsupplements.com/shop/black-garlic-botanicals/>. I used the Snagit tool to capture a copy of the webpage as it existed on September 18, 2019. A true and correct copy of the website <https://www.hrlsupplements.com/shop/black-garlic-botanicals/> is attached hereto as Attachment B.
  - c. At 2:56 PM, I used an FTC computer to visit the website <https://www.hrlsupplements.com/shop/the-ultimate-heart-formula/>. I used the Snagit tool to capture a copy of the webpage as it existed on September 18, 2019. A true and correct copy of the website



<https://www.hr1supplements.com/shop/the-ultimate-heart-formula/> is attached hereto as Attachment C.

6. On September 18, 2019, Counsel for the FTC asked me to visit and capture product information from the website <https://www.wholebodysupplement.com>.

a. At 3:00 PM, I used an FTC computer to visit the website

<https://www.wholebodysupplement.com/shop/black-garlic-bg18/>. I used the Snagit tool to capture a copy of the webpage as it existed on September 18, 2019. A true and correct copy of the website <https://www.wholebodysupplement.com/shop/black-garlic-bg18/> is attached hereto as Attachment D.

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

Executed on: December 4, 2019  
Washington, D.C.



Adam Rottner

# ATTACHMENT A

MEN'S HEALTH  
 NUTRITION  
 WOMEN'S HEALTH

Home / Shop / Women's Health / Neupathic with GLA

**NEWSLETTER**  
 SIGN-UP TO RECEIVE THESE GREAT BENEFITS:  
 \$10 OFF YOUR NEXT PURCHASE  
 HEALTH TIPS & FACTS  
 SALES & CLEARANCE NOTICES  
 PERSONALIZED OFFERS

YOUR EMAIL ADDRESS  **SIGNUP**

**NEUPATHIC**



Order Information:

- BUY 1 BOTTLE** \$49.95 BOTTLE
  - BUY 3 BOTTLES** \$29.98 BOTTLE
  - BUY 6 BOTTLES** \$21.66 BOTTLE
  - BUY 12 BOTTLES** \$16.66 BOTTLE
- In Stock |  Categories: Men's Health, Nutrition, Women's Health
- 

Description | Supplement Facts

View 51K+ Likes 0 Tweets

Neupathic delivers a pure, high concentration of Evening Primrose Oil, which is rich with Gamma Linoleic Acid, or GLA... the "lifeline" nutrient hailed by doctors and patients alike. Each and every capsule of Neupathic also provides an effective dosage of antioxidants Vitamin B1 (Benfotiamine), Vitamin B6 (Pyridoxal-5-Phosphate), Vitamin B12 (Methylcobalamin), and Folic Acid to restore balance to your system and defeat the harmful damage caused by free radicals to your 80 trillion body cells and 75,000 miles of blood vessels.

Neupathic was formulated to support healthy nerve endings and help ease some of the following issues associated with nerve endings:

- Burning
- Tingling
- Itching
- Numbness
- Constant coldness
- Swelling and heaviness
- Cramps and restlessness

Related Products



- RejuvaLifeQx Health Supplement
- Betarol Prostate Supplement
- The Ultimate Heart Formula Health Supplement



The Ultimate Cardio-Cleanse

All content is copyright © 2019 Health Research Labs Supplements. The products and the claims made about specific products on or through this site have not been evaluated by the United States Food and Drug Administration (FDA) and are not approved to diagnose, treat, cure or prevent disease. Consult your doctor.

## **ATTACHMENT B**

FREE SHIPPING FOR ALL PREMIUM MEMBERS!

LOGIN ITEMS: \$0.00



PRODUCTS DR. COHEN'S HEALTHY NEWS FAQS MEET DR. COHEN CONTACT

MEN'S HEALTH  
 NUTRITION  
 WOMEN'S HEALTH

Home / Shop / Botanicals / Black Garlic Botanicals

## Black Garlic Botanicals

- BUY 1 BOTTLE **\$39.95** /bottle
- BUY 3 BOTTLES **\$26.65** /bottle
- BUY 6 BOTTLES **\$19.99** /bottle
- BUY 12 BOTTLES **\$15.83** /bottle

**NEWSLETTER**  
 SIGN UP TO RECEIVE THESE GREAT BENEFITS!  
 • 10% OFF YOUR NEXT PURCHASE  
 • HEALTH TIPS & FACTS  
 • SALES & CLEARANCE NOTICES  
 • PERSONALIZED OFFERS  
 YOUR EMAIL ADDRESS  **SIGNUP!**



10,343 Reviews | Category: Botanicals  
 Like 0 | Tweet 5 | Pin 2

Description Supplement Facts

Price: \$14.4 [Like 0](#) [Tweet](#)

Black Garlic Botanicals contains aged and fermented Black Garlic, which starts out just like regular garlic, but then it is fermented in precise, highly controlled conditions for over 60 days, which is what gives it its black color. And the longer it ferments, the more it increases in potency. Eventually, it will transform to contain 18 different amino acids and other nutrients that are desperately needed by the human body. While some are hesitant to try it because of its black color, in capsule form, it is very easy to digest and 100% tasteless and odorless.

Black Garlic Botanicals promotes a healthy heart in many ways:

- Help maintain healthy blood sugar levels
- Promote healthy blood flow and vital circulation
- Support healthy cholesterol levels
- Encourage healthy heart muscle function
- Help maintain healthy blood pressure levels
- Help keep your blood vessels healthy
- Help protect your digestive system
- Support a healthy circulatory system to encourage a vibrant, active life

### Related Products



BloStem Blue Green Algae Supplement

Select options



Regimen Cell Rejuvenation

Select options



Glucophene Topical Gel

Select options



Maximum T Testosterone Therapy

Select options

#### PRODUCTS

New Arrivals  
 Men's Health  
 Women's Health  
 Skin Care  
 Nutrition

Affiliates  
 Contact Us  
 Disclaimer  
 Return Policy

#### SHOPPING & HELP

My Cart  
 My Account  
 Return Policy  
 Privacy Policy

Login  
 Shop  
 Clearance  
 Disclaimer

ALL INFORMATION PASSED TO OR FROM THIS WEBSITE IS SECURED WITH FULL 256-BIT SSL ENCRYPTION

#### ABOUT HRL

Contact Us  
 Dr. Cohen's Healthy News  
 Meet Dr. Cohen

800.417.4432

CONTACT US ONLINE



All content is copyright 2019 Health Research Laboratories. The products and the claims made about specific products on or through this site have not been evaluated by the United States Food and Drug Administration (FDA) and are not approved to diagnose, treat, cure or prevent disease. Consult your doctor.

## **ATTACHMENT C**

FREE SHIPPING FOR ALL PREMIUM MEMBERS!

LOGIN ITEMS: \$0.00



PRODUCTS DR. COHEN'S HEALTHY NEWS FAQS MEET DR. COHEN CONTACT

MEN'S HEALTH  
 NUTRITION  
 WOMEN'S HEALTH

Home / Shop / Women's Health / The Ultimate Heart Formula Health Supplement

The Ultimate Heart Formula



**NEWSLETTER**  
 SIGNUP TO RECEIVE THESE GREAT BENEFITS:  
 \$10 OFF YOUR NEXT PURCHASE  
 HEALTH TIPS & FACTS  
 SALES & CLEARANCE NOTICES  
 PERSONALIZED OFFERS

YOUR EMAIL ADDRESS  SIGNUP



Order Information:

- BUY 1 BOTTLE \$49.95 /BOTTLE
- BUY 3 BOTTLES \$26.65 /BOTTLE
- BUY 6 BOTTLES \$19.99 /BOTTLE

My Store | Categories: [Women's Health](#) | [Men's Health](#) | [Nutrition](#) | [Dr. Cohen's Healthy News](#)

Facebook 52 | Twitter 22 | YouTube 24

Description Supplement Facts

View Buy Like 17 Tweet

Scared About Your Heart?

Millions are in danger of suffering from poor cardiovascular health because they are overweight, have high cholesterol, high blood pressure, or suffer from congenital heart defects. But healthy individuals also could be suffering from a little-known threat. Fortunately, the formulators of The Ultimate Heart Formula have created a starring role of Nattokinase – a nutrient derived from soy that can have profound effects for the heart. Combined with other known heart-promoting compounds... including Ubiquinol, Bromelain, Allium sativum, Zingiber officinale, EDTA and more, The Ultimate Heart Formula helps to:

- Help maintain clear and flexible arteries
- Promote healthy blood flow and circulation
- Support healthy cholesterol levels
- Encourage healthy heart muscle function
- Helps maintain healthy blood pressure levels
- Help protect against harmful free radicals
- Help resist the harmful effects of stress
- Support healthy energy levels in the body

Use The Ultimate Heart Formula to give your body 6 heart-promoting nutrients every day for optimum cardiovascular health.

Related Products



Black Garlic Botanicals

Select options



The Ultimate Cardio-Cleanse

Select options



Betarol Prostate Supplement

Select options



Regimen Cell Rejuvenation

Select options

PRODUCTS

New Arrivals  
 Men's Health  
 Women's Health  
 Skin Care  
 Nutrition

Affiliates  
 Contact Us  
 Disclaimer  
 Return Policy

SHOPPING & HELP

My Cart  
 My Account  
 Return Policy  
 Privacy Policy

Login  
 Shop  
 Clearance  
 Disclaimer

ALL INFORMATION PASSED TO OR FROM THIS WEBSITE IS SECURED WITH 128-BIT SSL ENCRYPTION

ABOUT HRL

Contact Us  
 Dr. Cohen's Healthy News  
 Meet Dr. Cohen

800.417.4432  
 CONTACT US ONLINE



All content is copyright ©2019 Health Research Labs Supplements. The products and the claims made about specific products on or through this site have not been evaluated by the United States Food and Drug Administration (FDA) and are not approved to diagnose, treat, cure or prevent disease. Consult your doctor.

## **ATTACHMENT D**





LOGIN 0 ITEMS - \$0.00

HOME PRODUCTS BLOG FAQS MEET DR. COHEN CONTACT US

MEN'S HEALTH  
 NUTRITION  
 WOMEN'S HEALTH

Home / Shop / Nutrition / Black Garlic BG18

## BG18

- BUY 1 BOTTLE **\$39.95** /bottle
- BUY 3 BOTTLES **\$26.65** /bottle SAVE 33%
- BUY 6 BOTTLES **\$19.99** /bottle SAVE 50%
- BUY 12 BOTTLES **\$15.83** /bottle SAVE 60%



**NEWSLETTER**  
 SIGN UP TO RECEIVE THESE GREAT BENEFITS!

- ▶ \$10 OFF YOUR NEXT PURCHASE
- ▶ HEALTH TIPS & FACTS
- ▶ SALES & CLEARANCE NOTICES
- ▶ PERSONALIZED OFFERS

YOUR EMAIL ADDRESS



In Stock | Category: [Dietary](#)

Description Supplement Facts

Print Save Like Tweet

BG18 contains Black Garlic, which starts out just like regular garlic but then it is fermented in precise, highly-controlled conditions for over 60 days, which is what gives it its black color. And the longer it ferments, the more it increases in potency. Eventually, it will transform to contain 18 different amino acids and other nutrients that are desperately needed by the human body. While some are hesitant to try it because of its black color, in capsule form, it is very easy to digest and 100% tasteless and odorless.

### Related Products



LiverVitals Liver Enzyme Rejuvenation

Select options



StimActiv Blue Green Algae Supplement

Select options



Neurocare Diabetic Nerve Pain Supplement

Select options



Genevix Dietary Supplement

Select options

### PRODUCTS

Men's Health  
 Women's Health  
 Nutrition

### SHOPPING & HELP

My Cart  
 My Account  
 Return Policy  
 Privacy Policy

Login  
 Shop  
 Disclaimer

### ABOUT WBS

Contact Us  
 WBS Blog  
 Meet Dr. Cohen

855.811.0411

INFO@WHOLEBODYSUPPLEMENT.COM



ALL INFORMATION PASSED TO OR FROM THIS WEBSITE IS SECURED WITH FULL 256-BIT SSL ENCRYPTION

All content is copyright 2019 Whole Body Supplements. The products and the claims made about specific products on or through this site have not been evaluated by the United States Food and Drug Administration (FDA) and are not intended to diagnose, treat, cure or prevent disease. Consult your doctor.

**PX 6**

**DECLARATION OF JAMES A. PRUNTY**

I, James A. Prunty, hereby state that I have personal knowledge of the facts set forth below. If called as a witness, I could and would testify as follows:

1. I am a United States citizen and am over eighteen years of age. I am employed by the Federal Trade Commission (“FTC”) as an attorney in the Division of Advertising Practices, Bureau of Consumer Protection. My office address is 600 Pennsylvania Ave., NW, Washington, D.C. 20580.

2. As an attorney with the FTC, I was assigned to work on the Commission’s case in *FTC and Maine v. Health Research Laboratories, LLC, et al.*, 2:17-CV-00467-JDL (D. Maine).

3. In the course of that investigation, I contacted a consumer named Patrick Murphy, who had been identified as a customer of Health Research Laboratories.

4. On multiple occasions after the litigation was concluded, Mr. Murphy continued to send me, via FedEx, brochures that he received in the mail from Health Research Laboratories.

5. A true and correct copy of one of the brochures that Mr. Murphy sent to me in October 2018 via FedEx is attached as Attachment 1. However, Mr. Murphy’s name and home address are redacted in Attachment 1 to protect his personally identifiable information.

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

Executed on: December 5, 2019  
Washington, D.C.

/s/ James A. Prunty

\_\_\_\_\_  
James A. Prunty

# **Prunty Declaration**

## **ATTACHMENT 1**

Superfood Discoveries for Superior Health



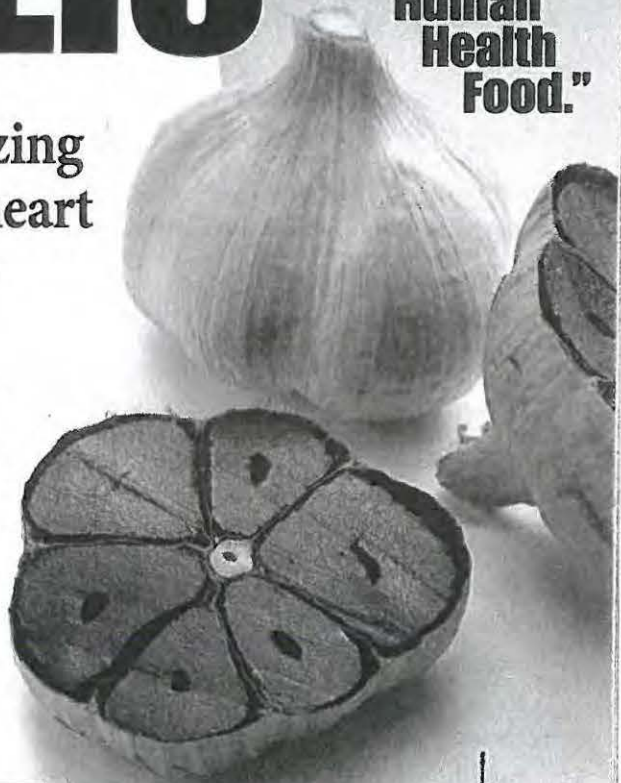
Throughout History ...

# BLACK GARLIC

AVG

Called by Doctors and Scientists:  
**"The Perfect Human Health Food."**

Has shown an amazing power to improve heart and cardiovascular health, maintain normal cholesterol levels, boost your immune system.



And MUCH MORE!

**See inside now...**



Richard Cohen, M.D.

To learn about a extraordinary city in Japan where many people live to a healthy 100+ with none of these common health problems we suffer from here in America...



Supported by Concrete Clinical Studies:

WALL STREET JOURNAL

Yale

# Cutting-Edge Natural Medicine

"If you're looking for a stronger heart and complete health overhaul...

# Black Garlic is one of the few "Full Body Healers" on earth I trust 100%."

**Black Garlic is a proven miracle for... Cholesterol... Hypertension... Diabetes... Your Heart... Your Brain... Hyperglycemia... Weight Control and more.**

Dear Friend,

What I'm about to tell you is really pretty amazing...

You see, there's a place in Japan, called the Aomori prefecture, which is the **garlic capital of Japan...**

This ONE district produces nearly 80% of the total garlic crop in Japan.

**But what it's really famous for around the world is its fermented, healing Black Garlic!** A proven super-food that has helped its citizens for thousands of years to live longer and healthier than you or I can expect to.

In fact, this Japanese city could be considered a miraculous "Blue Zone," much like nearby Okinawa. This is defined by National Geographic Magazine as a place where people eat a unique diet that gives them extraordinary health benefits.

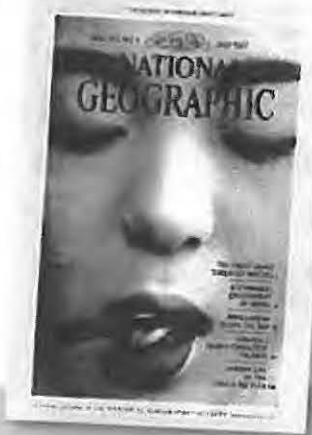
Black Garlic as a healing and longevity agent first gained a modern following and global popularity after Hirosaki University professor, Jiniti Sasaki, showed that Black Garlic reduced cell size of certain serious diseases.

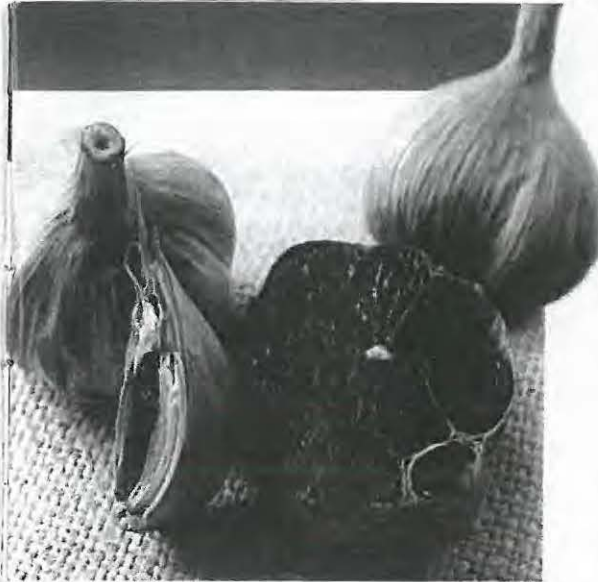
He knew he was on to something important when he conducted the same research using white garlic, but did not yield the same healthier results.

And while his clinical research confirmed that black garlic absolutely has unique healing properties...

**This was NOT news to the Japanese people who have been using it for thousands of years to live longer and healthier!**

So while you may occasionally see garlic used as a ingredient in a natural





## ONLY Black Garlic gives you a whopping 23 essential, health improving nutrients.

### 6 Essential Minerals:

- Sodium
- Potassium
- Magnesium
- Calcium
- Iron
- Zinc

### 18 Important Amino Acids:

- Isoleucine
- Luecine
- Lysine
- Methionine
- Histidine
- Phenylalanine
- Tryptophan
- Valine
- Arginine
- Alanine
- Asparagine
- Glutamine
- Glycine
- Proline
- Serine
- Tyrosine
- Cystine
- Threonine

**BG18 is loaded with these nutrients your body needs!**



supplement to promote good health, it is not anywhere near as potent and effective as fermented Black Garlic extract!

**Because you see, when normal white garlic is fermented it undergoes an amazing transformation that COMPLETELY alters its chemical makeup ... and turns it into a supreme superfood!**

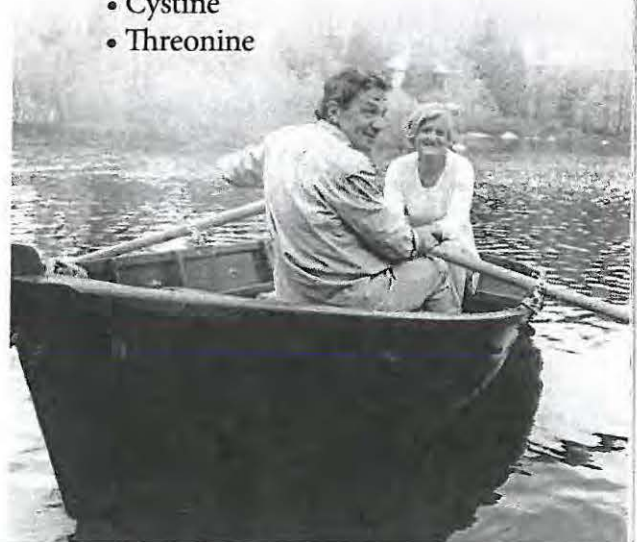
Black garlic is fermented for a precise period of time at a high temperature, and under high humidity. This process turns garlic cloves dark, gives them a sweet taste, and alters their consistency. And it also makes them more potent and beneficial.

**The proven health benefits it offers you are astounding!**

**For example:**

- Black Garlic has been shown to have positive effects for more than 150 different health issues due to its numerous powerful natural phyto-chemicals.

*Continued on page 5.*



**Call now 1-888-200-1834 for BG18 and see how it can help YOU.**

# BLACK GARLIC...

Is like rocket fuel for your body, your health and your longevity!



So how exactly does it help people in Japan live longer, healthier lives? Let's look at 6 ways it can help you do the same...

## 1) It Helps Prevents Plaque Buildup...

In fact, it can help reverse plaque build-up in arteries — not just slow it down. Black Garlic keeps blood vessels barrier-free to create a smooth blood flow and alleviates symptoms of fatigue. It also strongly inhibits calcium binding, which is responsible for plaque build up.

**2) Reduces Blood Pressure and Cholesterol...** Black Garlic helps reduce high blood pressure and lowers high levels of bad cholesterol and triglycerides.

**3) Helps Naturally Regulate Weight...** Black Garlic helps enhance a healthy weight, enhances digestion, removes waste, and improves energy. It also lessens the effects of an unhealthy diet on your blood and liver. Black Garlic helps you get the best, easiest, most natural slimming results without the frustrations that come with diets.

**4) Immunity Booster...** Black Garlic helps reduce inflammation and boost immune function. The allicin in black garlic, a sulfur-rich compound, is a powerful weapon against bacteria, viruses, fungi, and parasites. And it contains twice the antioxidant punch of fresh garlic, because of the fermentation process. Black Garlic may be as effective as an immune-boosting shot, and is an ideal preventative remedy.

“Black Garlic has also been used by millions of Americans to improve heart health!”

**5) Powerful Anti-Aging...** Black Garlic is a great energizer and helps prolong a healthy life! It also helps repair age-damaged skin with double the amount of antioxidants than regular garlic. Like rust attacking metal, free radicals eat away at your cells and destroy them, causing aging. Black Garlic rejuvenates your body by positively impacting cellular health and strength.

**6) Amazing Detox Agent...** Black Garlic acts as a blood purifier and cleanses your body. It has antibacterial, anti-fungal properties and kills bacteria linked to stomach ulcers. Black Garlic supports cell regeneration and alkalizes your body to protect against disease. It also features abundantly rich oxygen to protect against abnormal cell growth, viruses, and bacteria.

And you can get all this with just TWO BG18 Black Garlic capsules a day!



These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.





## Meet Dr. Richard Cohen, MD



**Richard Cohen, M.D. is a nationally-recognized medical expert.** As a specialist in nutritional medicine, he brings over two decades of experience in treating age-related illness.

He completed his undergraduate degree at Duke University with honors. And received his medical degree from Hahnemann Medical University in Philadelphia. Dr. Cohen is a member of the American College for the Advancement of Medicine.

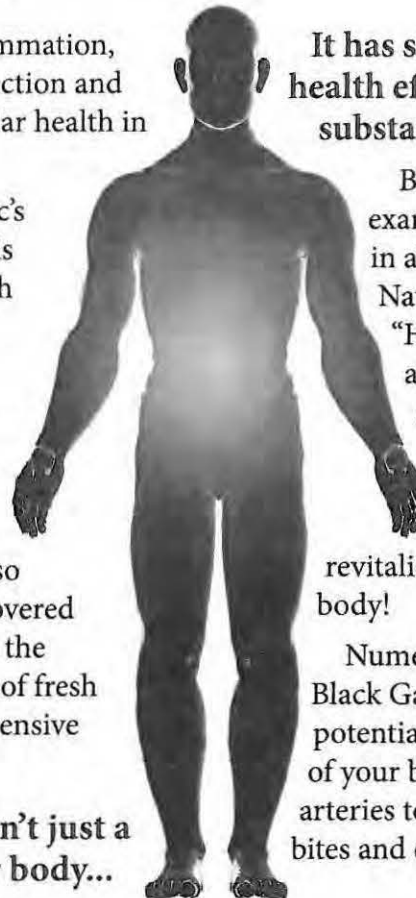
Dr. Cohen's expertise has earned him the attention of physicians and health professionals across the U.S. He has trained the American medical community on dietary issues for over 20 years. And recently, he was recognized as a leading authority in using diet, nutritional supplements and lifestyle to enhance well-being.

In recent years, he has helped develop a number of successful, innovative treatments like BG18 to help his patients eliminate a variety of health problems.



*Continued from page 3.*

- It can reduce inflammation, boost immune function and boost cardiovascular health in multiple ways.
- One of Black Garlic's main compounds is allicin, a sulfur-rich compound that is likely its most powerful weapon against bacteria, viruses, fungi, and parasites.
- Black Garlic has also recently been discovered to contain TWICE the antioxidant punch of fresh garlic due to its extensive aging process.



**It has significant, unique health effects that NO other substance on earth has.**

Black Garlic is the best example of a food offered in abundance by Mother Nature, turned into a "Health Bonanza" by ancient man through a simple, yet astonishing process, and then proven by modern science to have a revitalizing effect on your body!

Numerous studies show Black Garlic's amazing health potential in nearly every area of your body, from clogged arteries to preventing insect bites and ear infections.

**Black Garlic isn't just a cure-all for your body...**

*Continued next page...*

**Call now 1-888-200-1834 for BG18 and see how it can help YOU.**

# Raw Garlic vs. Black Garlic



**There's NO Comparison When it Comes to Healthy Benefits For You...**

**As raw garlic ferments and turns black... An astonishing transformation takes place that can improve your health and vitality!**

This chart shows just one example of the how the fermentation process changes essential amino acids in garlic. These essential amino acids are protein-building blocks that are NOT produced by your body. They must be included in your diet.

Essential Amino Acids	Raw Garlic (per 100g)	Black Garlic (per 100g)
Isoleucine	217 mg	371 mg
Leucine	308 mg	779 mg
Lysine	273 mg	385 mg
Methionine	76 mg	210 mg
Histidine	113 mg	287 mg
Phenylalanine	183 mg	461 mg
Tryptophan	66 mg	102 mg
Valine	291 mg	610 mg

This is only ONE example of what happens to raw garlic during the fermentation process. This is truly amazing... How black garlic creates new nutrients that are enhanced by the fermentation process!

BG18 is packed with the power of 1200 mg of potent, no-taste, no-odor, fermented Black Garlic in daily use capsules.



There's even solid evidence, as seen in Japan's Aomori province, and more, that Black Garlic can help slow your aging process.

Black Garlic contains a wide range of phytochemicals that act together to produce a wide variety of responses in your body. It's

also rich in critical nutrition like manganese, calcium, phosphorus, selenium, and vitamins B6 and C, so it's beneficial for your bones as well as your thyroid.

Garlic also helps your body cleanse itself of toxic heavy metals, such as lead, mercury, cadmium and arsenic.



### Clinical studies abound on the amazing effectiveness of Black Garlic...

One of Black Garlic's most potent secret weapon is a compound called Allicin.

Researchers have found that it's a highly-effective natural "antibiotic" that takes care of anything in its path. Even better, in the face of Allicin, bacteria aren't able to resist it. Something rarely seen in medical circles.

In studies, Black Garlic has shown consistent, positive results over fresh garlic, says Matthew Budoff, a professor at the David Geffen School of Medicine at University of California, Los Angeles.

He is also the co-author of a study that found Black Garlic reduced the amount of soft, newly formed plaque

in arteries, compared with placebo.

And in a 2009 animal study, Japanese researchers found that black garlic was more effective than fresh garlic in reducing the size of tumors. The study was published in the journal Medicinal and Aromatic Plant Science and Technology.

In another study, black garlic was found to have twice the antioxidant levels as fresh garlic—as the aging/fermenting process appears to double the antioxidants.

Black garlic is also packed with high concentrations of sulfurous compounds, especially one called s-allylcysteine.

Science has shown a number of health benefits from SAC, including inhibition of cholesterol formation.

*Continued next page...*

## Look at What People are Saying About BG18...



"I'm a natural health consultant and my wife and I have a therapy practice where we recommend supplements. I'm grateful for having BLACK GOLD BG-18 in

my life! The main features I like about this product are heart health, a boosted immune system and living with less problems."

— Douglas S.



"I feel stronger, feel my general well being is better, and also feel I have stronger immunity. I also have my husband taking this product and he also will not be without it now!"

— Jeannine S.



"I'm a senior, 83 years old, and just had a good to excellent health checkup!"

— Maria G.



"My blood sugar levels have improved. My A1C dropped by 2 points. My blood pressure has also been lowered. I recommend this product because IT WORKS!"

— Lorraine T.

These testimonials are from real users of BG18. Results may vary based on the user.

Call now 1-888-200-1834 for BG18 and see how it can help YOU.

# Could Black Garlic be the Japanese Secret to Significantly Reducing Heart Attack Risk? For all natural, safe, effective heart health, nothing even compares to Black Garlic!

That's why, for many people across the U.S., Black Garlic has been the answer to reducing their risk of America's #1 killer...

Each year, 635,000 people in the U.S. have their first heart attack! And cardio-vascular disease is the leading cause of global death, causing 17.3 million deaths a year – a number that's expected to grow to more than 23.6 million by 2030.

However, can you guess which ONE country seems to *easily* avoid this serious epidemic... Yes, you, guessed it... JAPAN!

Despite smoking and blood pressure levels similar to those in Western countries, the Japanese are seemingly IMMUNE from the ravages of heart disease.

So what are they doing differently? They are HUGE believers in, and users of, Black Garlic! And this discovery has turned out to be a true miracle elixir for your heart, and your entire cardiovascular system.

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.

**Call now for BG18 and claim the same health benefits for yourself!**



There's also great news for those who suffer from type 2 diabetes...

This condition can wreak havoc on your health due to the effects of oxidative stress. Uncontrolled diabetes may lead to serious complications like kidney disease, heart disease, nerve damage and vision problems – sometimes even blindness.

However, the potent antioxidants in black garlic have shown to

lessen oxidative stress caused by increasing blood sugar levels. Multiple studies have found that its high level of antioxidants exert an even stronger effect than regular garlic and could be even more helpful in preventing complications of diabetes.

There's NO doubt... Black Garlic is a perfect "Wonder Food" that EVERYONE should consider taking every day.

*Continued on page 10.*



# Black Garlic also helps you in an unexpected way... *When it comes to your weight.*



It's no secret that belly fat and poor heart health go hand in hand. In fact, studies show that fat around your stomach poses a higher risk than any other fat, and contributes to high blood pressure, poor metabolism and high triglycerides.

**Some good news is that just 2 BG18 capsule a day can help you lose weight and reduce your risk in several different ways ...**

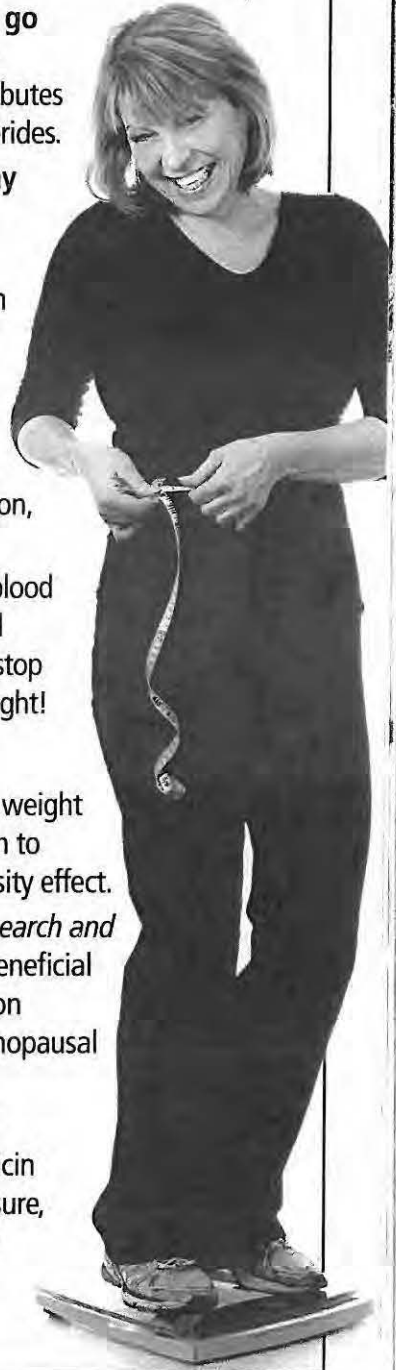
- ▶ Allicin, an active component of black garlic, has shown to enhance weight loss.
- ▶ Black Garlic has a high level of iodine, an effective nutrient for treating hyperthyroid conditions, which nearly always leads to extra weight gain.
- ▶ Black Garlic also can help process fat, enhance digestion, remove waste, and improve energy.
- ▶ Plus, it lessens the effects of an unhealthy diet on your blood and liver. So you can boost your immunity, reduce blood pressure, protect your blood vessels from damage, and stop inflammation all while helping you reach your ideal weight!

### Clinically proven to work...

- ▶ Korean researchers published findings from an animal weight loss study in the *Journal of Nutrition*. Garlic was shown to reduce body weight and showed a significant antiobesity effect.



- ▶ A 2012 study in *Nutrition Research and Practice* reported incredible beneficial effects of aged garlic extract on cardiovascular risk in postmenopausal women.
- ▶ And the *American Journal of Hypertension* showed that allicin positively impacts blood pressure, insulin, and triglyceride levels.



Call now 1-888-200-1834 for BG18 and see how it can help YOU.



**In BG18 you'll get only  
100% pure, premium-  
sourced black garlic extract.**

- ✓ Protect your heart!
- ✓ Lower high cholesterol!
- ✓ Find your ideal weight!
- ✓ Protect against diabetes!
- ✓ Cleanse your body of toxins!



*Continued from page 8.*

### **So how is Black Garlic transformed into something so special?**

Developed in Asia, black garlic has been gaining popularity among Westerners for several years now, but it has recently caught the eye of the health-minded due to studies revealing its impressive nutritional properties.

Black garlic is produced by “fermenting” whole bulbs of fresh garlic in a humidity-controlled environment in temperatures of about 60 to 90 degrees F for 86 days. No additives, no preservatives, just pure garlic.

Once out of the heat, the bulbs are left to oxidize. This lengthy process causes the garlic cloves to turn black and develop a soft texture.

As the white cloves slowly transition into their final black appearance, compounds in the fresh garlic transform into a whole new range of compounds.

In its potent, Blackened form, it is then dried and the powdered extract can be put in a capsule. Just

like you'll find in our BG18 pure Black Garlic extract formula.

### **Our BG18 Black Garlic formula gives you the full, raw, health-improving power of Black Garlic!**

**BG18 has only ONE purpose:** To give you the same gift of longevity, health and vitality it gives the Japanese people who take it regularly.

***Especially when it comes to ending your health problems, low energy and issues related to poor heart health, diabetes overweight issues, aging and more, without drugs.***

You might find other products that have ingredients for one or the other of these issues, but I guarantee you won't find ANYTHING with the 1,000+ year track record and unique healing power as the Black Garlic in BG18.

BG18 is the *only* 100% all natural solution you need to help add healthy years to your life, and right the ship when it comes to your heart health! All this in a single, daily dose that costs only pennies a day.

*Continued on page 12.*



# A potent, cell-protecting antioxidant is at the heart of Black Garlic

Because of its unique composition, black garlic is recognized for its high antioxidant content, with one... S-allyl-cysteine... having huge scientific interest for its potency.

A study published in 2012 in the *Journal Oxidative Medicine and Cellular Longevity* showed that this antioxidant is especially abundant in black garlic, unlike common white garlic, which contains only small amounts. As a result, black garlic can help fight oxidative stress, free radical damage and cellular aging. In addition, the antioxidant power of S-allyl-cysteine has health benefits for the cardiovascular system.

## The cardio-protective effect of black garlic...

Black garlic can also improve your lipid profile, an important factor in protecting against cardiovascular problems. This beneficial effect was the object of a study published in the journal *Nutrition*, where researchers evaluated the potential of black

garlic among 55 people with high blood cholesterol levels. They found increases in 'good' HDL-cholesterol in patients supplemented with black garlic compared with those given a placebo.

## Black garlic also has significant anti-inflammatory effects...

Black garlic also contains two compounds – AGE-1 and AGE-2 – which a number of studies suggest offer anti-inflammatory help. To evaluate these effects, Korean researchers studied levels of molecules in the inflammatory response.

Published in the journal, *Phytotherapy Research*, their findings confirmed the anti-inflammatory action of AGE-1 which, reduced levels of nitric oxide and prostaglandin. Secretion of proinflammatory cytokines was similarly suppressed by AGE-1.

These observations suggest that the AGE-1 compound present in black garlic can have a potent anti-inflammatory effect.

**BG18 can deliver all these health benefits to you! Call now.**

Call now 1-888-200-1834 for BG18 and see how it can help YOU.

11



# Black Garlic:

As reported by the *Wall Street Journal*...

Black garlic has shown potential health benefits in animal studies, including a report last year by Korean researchers that it helped control cholesterol in rats fed a high-fat diet. Another aged garlic product, called Kyolic from Japan, has shown benefits in humans.

The evidence is "quite compelling" that Black Garlic seems to help mitigate cardiac risk factors, such as high cholesterol and blood pressure, says David L. Katz, director of Yale University's Yale-Griffin Prevention Research Center.



If you're looking to add healthy years to your life, and want to avoid many of the health problems that plague so many seniors, call toll-free 1-888-200-1834 now for BG18.



Continued from page 10.

Reply now 100% risk free for all-natural, health-restoring, risk-reducing BG18!

I've arranged for you to try premium quality BG18 — risk-free — for 60 days, so you can see for yourself how it can improve your entire well-being and appearance almost instantly.

As a health professional, I highly recommend you try BG18 now.

In my opinion, it is the most potent superfood, health-improving formula on the market today! And the ONLY one I'm confident can improve your risky health issues and help you get back to normal.

Don't wait... reply now to start on BG18 and get special, first-time buyer only low pricing. Plus, if you reply now, you'll also get a special offer on our astounding HydraFuel product!

Don't put your good health at risk. BG18 is a popular, natural solution for men and women of all ages who struggle to maintain heart health, healthy blood sugar levels and more. And of course you're backed by our 100% Money Back Guarantee...

Yes, your reply is 100% risk free... If you're not 100% satisfied with your improved health after using BG18, simply send it back for a full refund of your



# Doctors' Opinion...



## Question:

**What is the single, greatest health benefit of Black Garlic?**

## Answer:

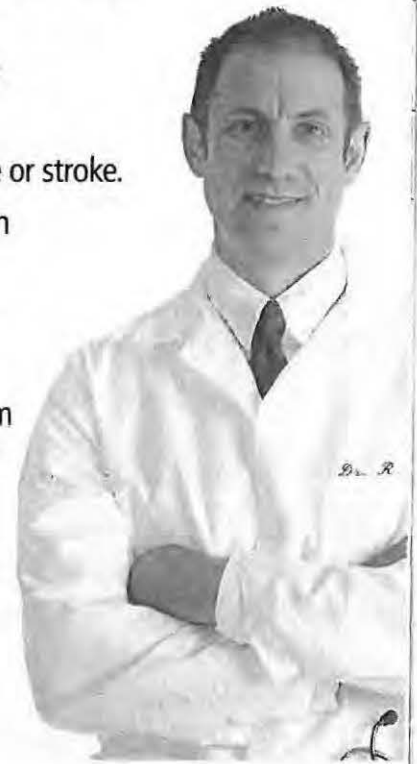
**In my experienced medical opinion, Black Garlic's most important benefit is its all natural help for heart issues and diabetes.**

**From potential life extension to antioxidant help to disease protection, no doubt, Black Garlic can do a lot to help you. But what I see in so many people is poor heart health and serious blood sugar issues. And I believe that is where its greatest benefit lies.**

## And if you have BOTH, that is a dangerous combination...

- 2 out of 3 people with diabetes die of heart disease or stroke.
- 47% of Americans are unaware that diabetes can lead to heart disease.
- 58% don't know that it can affect their sex life.
- 28% don't believe diabetes is a serious disease.
- Having high amounts of sugar in the bloodstream develops into fat that clogs, narrows, and inflames the blood vessels, causing additional wear and tear.

**I'm confident BG18 can help improve both of these dangerous health issues and get you on firmer footing. And no other natural healer can help protect you from both like Black Garlic can. Call now for BG18 and see for yourself.**



**purchase price within 60 days.  
No questions asked.**

**I look forward to hearing from you!**

**Sincerely,**

*Richard Cohen M.D.*

**Richard Cohen, M.D.  
Whole Body Supplements  
Medical Director**

**P.S. Amazing BG18, packed with 1200 mg of pure Black Garlic gives you the power of a variety of needed good-health nutrients all in two capsules!**

**Most notably, it can help your entire cardio system run smoothly. Reply now if you want to enjoy the longer life**



**Call now 1-888-200-1834 for BG18 and see how it can help YOU.**

and ultimate health benefits Japanese people enjoy every day! BG18 is 100% effective and safe to use daily! Remember, thousands of people have already used it to help extend the healthy years of their life! **Call now risk free 1-888-200-1834.**

**P.P.S. Sign up for our FREE weekly email newsletter!** It's called *Dr. Cohen's Healthy News Now...* and it discusses the latest news on many different health issues. Our customers love it! **Just give us your email address when you place your order for BG18.**

**Get up to 7 Bottles of BG18 FREE!**

**That's right...**  
See your Risk Free Reply Form now for details! Proven help is on the way for your heart and entire body!



## Grab This Combo Offer and Save

**When you reply for BG18 now, you also qualify for a special, discounted supply of our trusted HydraFuel Formula.**

Support your cellular hydration with this premium formula that contains 14 vitamins and minerals to help keep your cells 100% healthy and hydrated... and you looking and feeling young!

You'll also give your body the combined antioxidant activity of 29 vitalizing superfruits, phytonutrients, herbs and vegetable extracts to hydrate your dried out cells!

Improve heart health, boost energy, improve sexual health, beat stress, improve performance and reduce wrinkles... These are just a few of the benefits found in HydraFuel.

It can fill in your cells' nutrient gaps to give your health a quick and lasting jumpstart. Which is especially important if your health has been suffering as a result of poor digestion.

Try the amazing powers of HydraFuel for yourself. You'll SEE and FEEL the difference that Optimum Cellular Hydration can create for you. You'll look and feel years younger... feel more energy... sleep better... move better... and enjoy a revival of your health!

**Don't wait... Reply now and get this perfect companion product to BG18.**



- Vitamin C
- Vitamin E
- Vitamin B1
- Riboflavin
- Niacin
- Vitamin B6
- Folic acid
- Vitamin B12
- Biotin
- Pantothenic acid
- Calcium
- Magnesium
- Zinc
- Chromium
- SynerTea®
- Amla
- Spectra: which contains over 2 dozen fruit and vegetable extracts



# BG18 Risk-Free Reply Form

Up to \$384.85 in total savings and get Free Shipping!

**YES!** I'm ready to reap the same amazing health rewards the Japanese have enjoyed for centuries. I've seen the impressive research on Black Garlic from leading medical institutions around the world that prove taking black garlic can substantially improve my health! I understand I'm covered by your 60-day money back guarantee... Either BG18 works as promised, or I can get a full and fast refund. Please send me the following supply:

**SUPER-INTENSIVE:** I get a 5 month supply, plus a 7 month bonus supply absolutely FREE! I pay only \$219.95 and get FREE SHIPPING! **\$604.40 \$219.95 60 DAYS RISK FREE! SAVE \$384.45!**

**MEGA-INTENSIVE:** I get a 3 month supply, plus a 3 month bonus supply absolutely FREE! I pay only \$139.95 and get FREE SHIPPING! **\$304.70 \$139.95 60 DAYS RISK FREE! SAVE \$164.75!**

**ULTRA-INTENSIVE:** I get a 2 month supply, plus a 1 month bonus supply absolutely FREE! I pay only \$84.95 and get FREE SHIPPING! **\$154.85 \$84.95 60 DAYS RISK FREE! SAVE \$69.90!**

**INTENSIVE:** I get a 1 month supply for only \$44.95 + \$5.95 S&H! **\$49.95 \$44.95 SAVE \$5.00!**

**TOTAL PACKAGE:** I get everything is the Mega-Intensive Package plus buy 3 months of HydraFuel for only \$249.95 and get another 3 months FREE! All of this with FREE SHIPPING! **\$604.40 \$249.95 60 DAYS RISK FREE! SAVE \$354.45!**

**Select Your Preferred Method of Payment:**

Enclosed is my check, cash or money order for: \$ \_\_\_\_\_  
(Make check payable to Whole Body Supplements, 165 Pleasant Ave., South Portland, ME 04106)

Please bill my credit card:  VISA  MASTER  DISC. VBR  AMERICAN EXPRESS

Card #: \_\_\_\_\_ Expires: \_\_\_\_/\_\_\_\_/\_\_\_\_

Name: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

E-mail: \_\_\_\_\_ Tel: (\_\_\_\_) \_\_\_\_\_

**For Fastest Service  
Call Toll-Free:  
888-200-1834**

Mail Now in the enclosed envelope:  
Whole Body Supplements  
165 Pleasant Ave.  
South Portland, ME 04106  
Or visit:  
[www.WholeBodySupplement.com](http://www.WholeBodySupplement.com)

## Our Iron-Clad Guarantee: Try the BG18 Risk-Free For 60 Days.

**If You Don't Feel 100% Better - YOU'LL GET YOUR MONEY BACK!**

YOU will be the only judge. You've read about the amazing and unique health benefits of BG18. For up to 60 days, you can use it completely risk free in your own home and see your results. If you are not 100% satisfied, you can request a full refund of your purchase price. No questions asked.



PRSR STD  
U.S. Postage  
**PAID**  
Berne, IN  
Permit #43

N111XHWP KEYCODE 61461275 12738912 BIN#45



Whole Body Supplements  
165 Pleasant Ave.  
South Portland, ME 04106  
BG18-S4-US

**FREE SHIPPING!**

See Inside to Learn More About This...

# BLACK GOLD

That is transforming people's health, especially for their **HEARTS.**



**"Nothing improves lives like this does."**

- ✓ Increases energy
- ✓ Strengthens the immune system
- ✓ Promotes anti-aging effects
- ✓ Enhances recovery from fatigue
- ✓ Improves restfulness
- ✓ Supports healthy circulation



Richard Cohen, M.D.,  
Scientific Advisor

**See More Inside Now...**

**PX 7**

WILLARD K. TOM  
General Counsel

VICTOR F. DeFRANCIS  
SYDNEY M. KNIGHT  
Federal Trade Commission  
600 Pennsylvania Ave., N.W.  
Mail Drop NJ-3212  
Washington, D.C. 20580  
Tel: (202) 326-3495, -2162  
Fax: (202) 326-3259  
email: vdefrancis@ftc.gov

RECEIVED  
OCT 28 2010

AT 8:30 \_\_\_\_\_ M  
WILLIAM T. WALSH  
CLERK

PAUL J. FISHMAN  
United States Attorney  
J. ANDREW RUYMANN  
Assistant United States Attorney  
402 East State Street, Room 430  
Trenton, NJ 08608  
Tel: (609) 989-2190  
Fax: (609) 989-2360

Attorneys for Plaintiff  
Federal Trade Commission

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

_____ )	
FEDERAL TRADE COMMISSION, )	
)	Hon. Joel A. Pisano
Plaintiff, )	
)	CV-09-399-JAP
v. )	
)	
XACTA 3000, INC., a corporation, )	
BARUCH LEVIN, individually and )	
as an officer of the corporation, and )	
YEHUDA LEVIN a/k/a JUDA LEVIN, )	
individually and as an officer )	
of the corporation, )	
)	
Defendants. )	
_____ )	

**STIPULATED FINAL JUDGMENT AND ORDER FOR INJUNCTIVE AND  
OTHER EQUITABLE RELIEF AS TO DEFENDANTS XACTA 3000, INC.  
AND YEHUDA LEVIN**

Plaintiff, the Federal Trade Commission ("FTC" or "Commission"), filed a Complaint for Injunctive and Other Equitable Relief against Defendants Xacta 3000, Inc., Baruch Levin, and Yehuda Levin ("Complaint") pursuant to Section 13(b) of the Federal Trade Commission Act (FTC Act), 15 U.S.C. § 53(b), alleging deceptive acts or practices and false advertisements in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

The Commission and Defendants Xacta 3000, Inc. and Yehuda Levin ("Defendants") have stipulated to entry of the following agreement for permanent injunction and settlement of claims for monetary relief in settlement of the Commission's allegations against Defendants.

The Court, having been presented with this Stipulated Final Judgment and Order for Injunctive and Other Equitable Relief as to Defendants Xacta 3000, Inc. and Yehuda Levin (Order), finds as follows:

**FINDINGS**

1. This Court has jurisdiction over the subject matter of this case and jurisdiction over Defendants. Venue in the District of New Jersey is proper.

2. The acts and practices of Defendants are in or affecting commerce, as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

3. The Complaint states a claim upon which relief can be granted under Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, and the Commission has the authority to seek the relief it has requested.

4. Defendants waive all rights to seek judicial review or otherwise challenge or contest the validity of this Order. Defendants also waive any claim that they may have held under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action to the date of this Order.

5. This Order reflects the negotiated agreement of the Commission and Defendants, and Defendants have entered into this Order freely and without coercion.

6. The Commission and Defendants stipulate and agree to entry of this Order under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), without trial or final adjudication of any issue of fact or law. By entering into this stipulation, Defendants do not admit or deny any of the allegations set forth in the Complaint, other than jurisdictional facts.

7. This action and the relief awarded herein are in addition to, and not in lieu of, other remedies as may be



provided by law.

8. Pursuant to Federal Rule of Civil Procedure 65(d), the provisions of this Order are binding upon Defendants, and their officers, agents, servants, representatives, employees, and all other persons or entities in active concert or participation with them, who receive actual notice of this Order by personal service or otherwise.

9. Nothing in this Order obviates the obligation of Defendants to comply with Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45 and 52.

10. The Commission's action against Defendants is an exercise of the Commission's police or regulatory power as a governmental unit.

11. The paragraphs of this Order shall be read as the necessary requirements for compliance and not as alternatives for compliance, and no paragraph serves to modify another paragraph unless expressly so stated.

12. Each party shall bear its own costs and attorneys' fees.

13. Entry of this Order is in the public interest.

**ORDER**

**DEFINITIONS**

1. "Advertising" and "promotion" mean any written or verbal statement, illustration, or depiction designed to effect a sale or create interest in the purchasing of goods, whether it appears in a brochure, newspaper, magazine, pamphlet, leaflet, circular, mailer, book insert, free standing insert, letter, catalogue, poster, chart, billboard, public transit card, point of purchase display, packaging, package insert, label, film, slide, radio, television or cable television, audio program transmitted over a telephone system, program-length commercial ("infomercial"), the Internet, email, press release, video news release, or in any other medium.

2. "Commerce" means as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

3. "Covered product" means any dietary supplement, food, drug, or device.

4. "Individual Defendant" means Yehuda Levin.

5. "Corporate Defendant" means Xacta 3000, Inc. and its successors and assigns.

6. "Food," "drug," and "device" mean as defined in Section 15 of the FTC Act, 15 U.S.C. § 55.

7. The terms "and" and "or" in this Order shall be construed conjunctively or disjunctively as necessary, to make the applicable sentence or phrase inclusive rather than exclusive.

8. The term "including" in this Order means "including without limitation."

I.

**PROHIBITED BUSINESS ACTIVITIES**

**IT IS HEREBY ORDERED** that Defendants, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, are hereby permanently enjoined and restrained from manufacturing, labeling, advertising, promoting, offering for sale, selling, or distributing; or assisting others in manufacturing, labeling, advertising, promoting, offering for sale, selling, or distributing; any Covered Product, in or affecting commerce.

II.

**EQUITABLE MONETARY RELIEF**

**IT IS FURTHER ORDERED** that:

A. Judgment is hereby entered in favor of the Commission, and against Defendants for equitable monetary relief, including, but not limited to, consumer redress, in the amount of fourteen million five hundred thousand U.S. Dollars (\$14,500,000), the

total amount of consumer injury caused by the activities alleged in the Commission's complaint; *provided, however*, that this judgment shall be suspended subject to the conditions set forth in Section III of this Order;

B. All funds paid pursuant to this Order shall be deposited into a fund administered by the Commission or its agent to be used for equitable relief, including, but not limited to, consumer redress, and any attendant expenses for the administration of such equitable relief. Defendants shall cooperate fully to assist the Commission in identifying consumers who may be entitled to redress pursuant to this Order. If the Commission determines, in its sole discretion, that redress to consumers is wholly or partially impracticable or funds remain after redress is completed, the Commission may apply any remaining funds for such other equitable relief (including consumer information remedies) as it determines to be reasonably related to Defendants' practices alleged in the Complaint. Any funds not used for such equitable relief shall be deposited to the United States Treasury as disgorgement. Defendants shall have no right to challenge the Commission's choice of remedies under this Section. Defendants shall have no right to contest the manner of distribution chosen by the Commission. This judgment for equitable monetary relief is solely remedial in

nature and is not a fine, penalty, punitive assessment, or forfeiture;

C. In accordance with 31 U.S.C. § 7701, as amended, Defendants are hereby required, unless they have done so already, to furnish to the Commission their taxpayer identifying number and/or social security number, which shall be used for purposes of collecting and reporting on any delinquent amount arising out of the Defendants' relationship with the government.

D. Defendants relinquish all dominion, control, and title to the funds paid to the fullest extent permitted by law. Defendants shall make no claim to, or demand for return of, the funds, directly or indirectly, through counsel or otherwise.

E. Defendants agree that the facts as alleged in the Complaint filed in this action shall be taken as true without further proof in any bankruptcy case or subsequent civil litigation pursued by the Commission to enforce its rights to any payment or money judgment pursuant to this Order, including but not limited to a nondischargeability complaint in any bankruptcy case. Defendants further stipulate and agree that the facts alleged in the Complaint establish all elements necessary to sustain an action by the Commission pursuant to Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S.C. § 523(a)(2)(A), and that this Order shall have collateral estoppel effect for

such purposes.

F. Proceedings instituted under this Section are in addition to, and not in lieu of, any other civil or criminal remedies that may be provided by law, including any other proceedings the Commission may initiate to enforce this Order.

### III.

#### RIGHT TO REOPEN

**IT IS FURTHER ORDERED** that:

A. By agreeing to this Order, Defendants reaffirm and attest to the truthfulness, accuracy, and completeness of the financial statements signed by Corporate Defendant on October 11, 2009 and by Individual Defendant on May 3, 2010 and provided to the Commission, including all attachments and subsequent amendments and corrections thereto. Plaintiff's agreement to this Order is expressly premised upon the truthfulness, accuracy, and completeness of Defendants' financial condition, as represented in the financial statement referenced above, which contains material information upon which Plaintiff relied in negotiating and agreeing to the terms of this Order;

B. If, upon motion of the FTC, the Court finds that Defendants failed to disclose any material asset, materially misrepresented the value of any asset, or made any other material misrepresentation in or omission from his or its financial

statement or supporting documents, the suspended judgment entered in Section II.A shall become immediately due and payable.

*Provided, however, that, in all other respects, this Order shall remain in full force and effect, unless otherwise ordered by the Court; and*

C. Any proceedings instituted under this Section shall be in addition to, and not in lieu of, any other civil or criminal remedies that may be provided by law, including, but not limited to, contempt proceedings, or any other proceedings that the Commission or the United States might initiate to enforce this Order. For purposes of this Section, Defendants waive any right to contest any of the allegations in the Commission's Complaint.

#### IV.

##### **PROHIBITIONS REGARDING CONSUMER INFORMATION**

**IT IS FURTHER ORDERED** that Defendants, and their officers, agents, servants, and employees, and all other persons in active concert or participation with any of them who receive actual notice of this Order by personal service or otherwise, are hereby permanently restrained and enjoined from:

A. Disclosing, using, or benefitting from customer information, including the name, address, telephone number, email address, social security number, other identifying information, or any data that enables access to a customer's account

(including a credit card, bank account, or other financial account), of any person which Defendants obtained prior to entry of this Order in connection with the sale of Kinoki Foot Pads; and

B. Failing to dispose of such customer information in all forms in their possession, custody, or control within thirty (30) days after entry of this Order. Disposal shall be by means that protect against unauthorized access to the customer information, such as by burning, pulverizing, or shredding any papers, and by erasing or destroying any electronic media, to ensure that the customer information cannot practicably be read or reconstructed.

*Provided, however,* that customer information need not be disposed of, and may be disclosed, to the extent requested by a government agency or required by a law, regulation, or court order.

V.

#### COMPLIANCE MONITORING

**IT IS FURTHER ORDERED** that, for the purpose of monitoring and investigating compliance with any provision of this Order and investigating the accuracy of Defendants' financial statements upon which the Commission's agreement to this Order is expressly premised:

A. Within ten (10) days of receipt of written notice from



a representative of the Commission, Defendants shall submit additional written reports, sworn to under penalty of perjury; produce documents for inspection and copying; appear for deposition; and/or provide entry during normal business hours to any business location in each Defendant's possession or direct or indirect control to inspect the business operation;

B. In addition, the Commission is authorized to use all other lawful means, including, but not limited to:

1. Obtaining discovery from any person, without further leave of court, using the procedures described in Fed. R. Civ. P. 30, 31, 33, 34, 36, 45, and 69; and
2. Having its representatives pose as consumers and suppliers to Defendants, their employees, or any other entity managed or controlled in whole or in part by any Defendant, without the necessity of identification or prior notice; and

C. Defendants each shall permit representatives of the Commission to interview any employee, employer, consultant, independent contractor, representative, or agent who has agreed to such an interview, relating in any way to any conduct subject to this Order. The person interviewed may have counsel present. *Provided*, however, that nothing in this Order shall limit 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, to obtain any documentary material, tangible things, testimony, or information relevant to unfair or deceptive acts or practices in or affecting commerce (within the meaning of 15 U.S.C. § 45(a)(1)).

**VI.**

**COMPLIANCE REPORTING**

**IT IS FURTHER ORDERED** that, in order that compliance with the provisions of this Order may be monitored:

A. For a period of three (3) years from the date of entry of this Order,

1. Individual Defendant shall notify the Commission in writing of the following:
  - a. Any changes in such Defendant's residence, mailing addresses, and telephone numbers, within ten (10) days of such change;
  - b. Any changes in such Defendant's employment status (including self-employment) and any change in such Defendant's ownership in any business entity, within ten (10) days of such change. Such notice shall include the name and address of each business that such

Defendant is affiliated with, employed by, creates or forms, or performs services for; a detailed description of the nature of the business; and a detailed description of such Defendant's duties and responsibilities in connection with the business or employment; and

- c. Any changes in such Defendant's name or use of any aliases or fictitious names within ten (10) days of the date of such change; and
2. Defendants shall notify the Commission in writing of any changes in structure of Corporate Defendant or any business entity that any Defendant directly or indirectly controls, or has an ownership interest in, that may affect compliance obligations arising under this Order, including, but not limited to: incorporation or other organization; a dissolution, assignment, sale, merger, or other action; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order; or a change in the business name or address, at least thirty (30) days prior to such

change, *provided that*, with respect to any proposed change in the business entity about which Defendant learns less than thirty (30) days prior to the date such action is to take place, Defendant shall notify the Commission as soon as is practicable after obtaining such knowledge.

B. Sixty (60) days after the date of entry of this Order, and annually thereafter for a period of five (5) years, Defendants each shall provide a written report to the FTC, which is true and accurate and sworn to under penalty of perjury, setting forth in detail the manner and form in which they have complied and are complying with this Order. This report shall include, but not be limited to:

1. For Individual Defendant:
  - a. such Defendant's then-current residence address, mailing addresses, and telephone numbers;
  - b. such Defendant's then-current employment status (including self-employment), including the name, addresses, and telephone numbers of each business that such Defendant is affiliated with, employed by, or performs services for; a detailed description of the

nature of the business; and a detailed description of such Defendant's duties and responsibilities in connection with the business or employment; and

c. Any other changes required to be reported under Subsection A of this Section;

2. For all Defendants:

a. A copy of each acknowledgment of receipt of this Order, obtained pursuant to the Section titled "Distribution of Order;" and

b. Any other changes required to be reported under Subsection A of this Section.

C. Each Defendant shall notify the Commission of the filing of a bankruptcy petition by such Defendant within fifteen (15) days of filing.

D. For purposes of this Order, Defendants shall, unless otherwise directed by the Commission's authorized representatives, send by overnight courier (not the U.S. Postal Service) all reports and notifications to the Commission that are required by this Order to:

Associate Director for Enforcement  
Federal Trade Commission  
600 Pennsylvania Avenue, NW  
Washington, DC 20580  
RE: *FTC v. Xacta 3000, Inc., et al.* (D.N.J),

Case No. CV-09-399 (JAP)

*Provided that*, in lieu of overnight courier, Defendants may send such reports or notifications by first-class mail, but only if Defendants contemporaneously send an electronic version of such report or notification to the Commission at DEBrief@ftc.gov.

E. For purposes of compliance reporting and monitoring required by this Order, the Commission is authorized to communicate directly with each Defendant.

## VII.

### RECORD-KEEPING PROVISIONS

**IT IS FURTHER ORDERED** that, for a period of six (6) years from the date of entry of this Order, Corporate Defendant, and Individual Defendant, for any business for which he is the majority owner or directly or indirectly controls, are hereby restrained and enjoined from failing to create and retain the following records:

A. Accounting records that reflect the cost of goods or services sold, revenues generated, and the disbursement of such revenues;

B. Personnel records accurately reflecting the name, address, and telephone number of each person employed in any capacity by such business, including as an independent contractor; that person's job title or position; the date upon

which the person commenced work; and the date and reason for the person's termination, if applicable;

C. Customer files containing the names, addresses, telephone numbers, dollar amounts paid, quantity of items or services purchased, and description of items or services purchased, to the extent such information is obtained in the ordinary course of business;

D. Complaint and refund requests (whether received directly, indirectly, or through any third party) and any responses to those complaints or requests; and

E. All records and documents necessary to demonstrate full compliance with each provision of the Order, including but not limited to, copies of acknowledgments of receipt of this Order required by the Sections titled "Distribution of Order" and "Acknowledgment of Receipt of Order" and all reports submitted to the FTC pursuant to the Section titled "Compliance Reporting."

### VIII.

#### DISTRIBUTION OF ORDER

**IT IS FURTHER ORDERED** that, for a period of three (3) years from the date of entry of this Order, Defendants shall deliver copies of the Order as directed below:

A. Corporate Defendant: Each Corporate Defendant must deliver a copy of this Order to (1) all of its principals,

officers, directors, and managers; and (2) any business entity resulting from any change in structure set forth in Subsection A.2 of the Section titled "Compliance Reporting." For current personnel, delivery shall be within five (5) days of service of this Order upon such Defendant. For new personnel, delivery shall occur prior to them assuming their responsibilities. For any business entity resulting from any change in structure set forth in Subsection A.2 of the Section titled "Compliance Reporting," delivery shall be at least ten (10) days prior to the change in structure.

B. Individual Defendant as Control Person: For any business that Individual Defendant controls, directly or indirectly, or in which such Defendant has a majority ownership interest, such Defendant shall deliver a copy of this Order to (1) all principals, officers, directors, and managers of that business; and (2) any business entity resulting from any change in structure set forth in Subsection A.2 of the Section titled "Compliance Reporting." For current personnel, delivery shall be within five (5) days of service of this Order upon Defendant. For new personnel, delivery shall occur prior to them assuming their responsibilities. For any business entity resulting from any change in structure set forth in Subsection A.2 of the Section titled "Compliance Reporting," delivery shall be at least



ten (10) days prior to the change in structure.

C. Defendants must secure a signed and dated statement acknowledging receipt of the Order, within thirty (30) days of delivery, from all persons receiving a copy of the Order pursuant to this Section.

**IX.**

**ACKNOWLEDGMENT OF RECEIPT OF ORDER**

**IT IS FURTHER ORDERED** that Defendants, within five (5) business days of receipt of this Order as entered by the Court, shall submit to the Commission a truthful sworn statement acknowledging receipt of this Order.

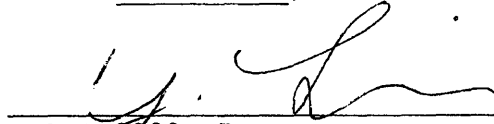
X.

RETENTION OF JURISDICTION

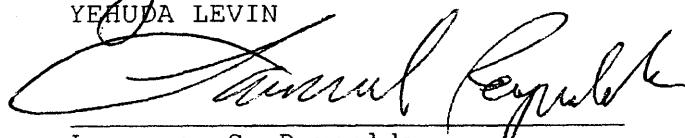
IT IS FURTHER ORDERED that this Court shall retain jurisdiction of this matter for purposes of construction, modification, and enforcement of this Order.


IT IS SO ORDERED.

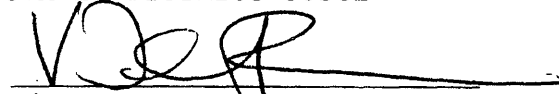
Dated: Oct. 27, 2010

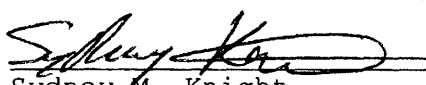
  
\_\_\_\_\_  
XACTA 3000, Inc.  
By: Yehuda Levin

  
\_\_\_\_\_  
YEHUDA LEVIN

  
\_\_\_\_\_  
Lawrence S. Reynolds  
Attorney for Xacta 3000, Inc.

  
\_\_\_\_\_  
JOEL A. PISANO  
UNITED STATES DISTRICT JUDGE

  
\_\_\_\_\_  
Victor DeFrancis  
Federal Trade Commission

  
\_\_\_\_\_  
Sydney M. Knight  
Federal Trade Commission

ATTORNEYS FOR PLAINTIFF

**UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

FEDERAL TRADE COMMISSION,	)	
	)	
Plaintiff,	)	
	)	CIVIL ACTION NO.
v.	)	
	)	04-cv-5794
TRANSDERMAL PRODUCTS INTERNATIONAL	)	
MARKETING CORPORATION, and	)	ORDER
WILLIAM H. NEWBAUER,	)	
	)	
Defendants.	)	
	)	

WHEREAS Plaintiff, the Federal Trade Commission (“FTC” or “Commission”), has commenced this action by filing the Complaint herein; Defendants Transdermal Products International Marketing Corporation and William H. Newbauer have waived service of the Summons and Complaint; the parties have been represented by the attorneys whose names appear hereafter; and the parties have agreed to settlement of this action upon the following terms and conditions, without adjudication of any issue of fact or law and without Defendants admitting liability for any of the matters alleged in the Complaint;

**NOW, THEREFORE,** on the joint motion of Plaintiff and Defendants, it is hereby **ORDERED, ADJUDGED, and DECREED** as follows:

1. This Court has jurisdiction over the subject matter of this case and jurisdiction over all parties. Venue in the Eastern District of Pennsylvania is proper under 28 U.S.C. § 1391(b) and 15 U.S.C. § 53(b).
2. The Complaint states a claim upon which relief can be granted against the

Defendants under Sections 5(a), 12, and 13(b) of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. §§ 45(a), 52, and 53(b).

3. The acts and practices of Defendants were, and are, in or affecting commerce, as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

4. Defendants waive all rights to seek judicial review or otherwise challenge or contest the validity of this Order. Defendants also waive any claims that they may have held under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action to the date of this Order.

5. Each party shall bear its own costs and attorneys’ fees.

6. Entry of this Order is in the public interest.

#### DEFINITIONS

For purposes of this Order, the following definitions apply:

1. “Commerce” means as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

2. “Competent and reliable scientific evidence” means tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

3. Unless otherwise specified, “Defendants” mean Transdermal Products International Marketing Corporation and its successors and assigns (“Transdermal”) and William H. Newbauer (“Newbauer”).

4. “Drug,” “device” and “cosmetic” mean as defined in Section 15 of the FTC Act, 15 U.S.C. § 55.

5. “Endorsement” means as defined in 16 C.F.R. § 255.0(b).

6. The term “including” in this Order means “including, without limitation.”
7. “Transdermal product” means any product applied to the skin to deliver the product’s ingredients into the body.

## I.

### PROHIBITED BUSINESS ACTIVITIES

Unless otherwise permitted by the provisions of Part VI of this Order, **IT IS**

**HEREBY ORDERED** that:

- A. Defendants, whether acting directly or through any corporation, subsidiary, division, or other entity, are hereby permanently enjoined from engaging, participating, or assisting, in any manner whatsoever, directly or indirectly, in the labeling, advertising, marketing, promotion, offering for sale, distribution, or sale of any transdermal product for the purpose of losing or controlling weight; and
- B. Defendants and their officers, agents, servants, employees, and all persons and entities in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, whether acting directly or through any corporation, subsidiary, division, or other entity, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any dietary supplement, drug, device or cosmetic, in or affecting commerce, are hereby permanently enjoined from making, or assisting others in making, expressly or by implication, including through the use of endorsements or any trade name, any oral or written representation that:
  1. Any such product causes substantial weight loss without reducing calories

or increasing exercise;

2. Any such product safely enables users to lose more than three pounds per week for a period of more than four weeks; or
3. Any such product causes permanent weight loss.

## II.

### PROHIBITED MISREPRESENTATIONS

**IT IS FURTHER ORDERED** that Defendants, and their officers, agents, servants, employees, and all persons and entities in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, whether acting directly or through any corporation, subsidiary, division, or other entity, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any transdermal product, dietary supplement, food, drug, device or cosmetic, in or affecting commerce, are hereby permanently enjoined from making or assisting others in making any false or misleading statement of material fact, expressly or by implication, including through the use of endorsements, that any transdermal product, dietary supplement, food, drug, device or cosmetic has been approved or is awaiting approval by the Food and Drug Administration for any purpose.

## III.

### REPRESENTATIONS PROHIBITED UNLESS TRUE AND SUBSTANTIATED

**IT IS FURTHER ORDERED** that Defendants, and their officers, agents, servants, employees, and all persons and entities in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, whether acting directly or through any corporation, subsidiary, division, or other entity, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any transdermal

product, dietary supplement, food, drug, device or cosmetic, in or affecting commerce, are permanently enjoined from making or assisting others in making any representation, expressly or by implication, of material fact, including through the use of endorsements or trade names:

- A. That any such product:
  - 1. Causes weight loss;
  - 2. Melts away or burns body fat (or words of similar import), or otherwise affects the body's metabolism of fat; or
- B. About the benefits, performance, efficacy, safety, or side effects of any such product;

unless, at the time the representation is made, the representation is true, and they possess and rely upon competent and reliable scientific evidence that substantiates the representation.

#### IV.

### PROHIBITED MISREPRESENTATIONS ABOUT TESTS, STUDIES, AND RESEARCH

**IT IS FURTHER ORDERED** that Defendants, and their officers, agents, servants, employees, and all persons and entities in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, whether acting directly or through any corporation, subsidiary, division, or other entity, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any transdermal product, dietary supplement, food, drug, device or cosmetic, in or affecting commerce, are hereby permanently enjoined from making or assisting others in making any false or misleading statement, expressly or by implication, of material fact, including through the use of endorsements, about the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

**V.****MEANS AND INSTRUMENTALITIES**

**IT IS FURTHER ORDERED** that Defendants, and their officers, agents, servants, employees, and all persons and entities in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, whether acting directly or through any corporation, subsidiary, division, or other entity, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any transdermal product, dietary supplement, food, drug, device or cosmetic, in or affecting commerce, are hereby permanently enjoined from providing the means and instrumentalities with which to make, expressly or by implication, any false or misleading statement of material fact, including, but not limited to, the representations contained in Sections I - IV above. For purposes of this Part, “means and instrumentalities” shall mean any information, including but not necessarily limited to any advertising, labeling, promotional, or purported substantiation materials, for use by trade customers in their marketing of any transdermal product, dietary supplement, food, drug, device or cosmetic, in or affecting commerce.

**VI.****FOOD AND DRUG ADMINISTRATION**

**IT IS FURTHER ORDERED** that nothing in this Order prohibits Defendants from:

- A. Making any representation for any drug that is, at the time the representation is made, permitted in labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and
- B. Making any representation for any product that is, at the time the representation is



made, specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration.

## VII.

### MONETARY JUDGMENT AND CONSUMER REDRESS

**IT IS FURTHER ORDERED** that Judgment is hereby entered against Defendants, jointly and severally, in the amount of one hundred eighty thousand dollars (\$180,000) to be paid to the Federal Trade Commission, as follows:

A. Sixty thousand dollars (\$60,000) on or before July 31, 2007; sixty thousand dollars (\$60,000) on or before July 31, 2008; and sixty thousand dollars (\$60,000) on or before January 30, 2009. Defendants shall make such payments by certified cashier's check made payable to the Federal Trade Commission, Division of Finance, 600 Pennsylvania Ave., NW, Washington, DC 20580, Reference Information FTC v. Transdermal Products International Marketing Corporation, et al., Matter No. X050023, or by wire transfer in accord with directions provided by the FTC.

B. In the event of any default in payment, interest shall accrue, computed pursuant to 28 U.S.C. § 1961 from the date of default to the date of payment. If such default continues beyond 15 calendar days, then defendants consent to entry of judgment, immediately due and payable, in the amount of nine hundred thousand dollars (\$900,000), representing the total sales at issue in this matter, less any amount already paid.

C. While defendants do not admit any of the facts alleged in the Complaint other than jurisdictional facts, defendants agree that the facts as alleged in the Complaint shall be taken as true in the event of any subsequent litigation to collect amounts due pursuant to this Order, including but not limited to a nondischargeability complaint in any bankruptcy case.

D. The judgment entered pursuant to this Section VII is equitable monetary relief, solely remedial in nature, and not a fine, penalty, punitive assessment or forfeiture.

E. Defendants acknowledge and agree that any money paid pursuant to this Order is irrevocably paid to the FTC for purposes of settlement between the FTC and defendants, and defendants relinquish all rights, title, and interest to such money.

F. Unless they have done so already, defendants are hereby required, in accordance with 31 U.S.C. § 7701, to furnish to the FTC their tax identification numbers, which shall be used for purposes of collecting and reporting on any delinquent amount arising out of this Order.

### VIII.

#### RIGHT TO REOPEN

**IT IS FURTHER ORDERED** that, within five (5) business days after entry of this Order, Defendants each shall submit to the FTC a truthful sworn statement that shall acknowledge receipt of this Order and shall reaffirm and attest to the truth, accuracy and completeness of the financial statements previously submitted to the FTC. The FTC's agreement to this Order and the Court's approval are expressly premised on the truthfulness, accuracy and completeness of the financial statements and supporting documents submitted to the FTC and dated December 8, 2005, December 12, 2005, and August 2, 2006. If, upon motion by the FTC, the Court finds that the financial statements or supporting documents of any Defendant contain any material misrepresentation or omission, then judgment shall be entered in the amount of nine hundred thousand dollars (\$900,000), immediately due and payable (less any amounts turned over to the FTC pursuant to Section VII of this Order); *provided, however*, that in all other respects this Order shall remain in full force and effect unless otherwise ordered by the Court; and, *provided further*, that proceedings instituted under this provision would be in addition to,

and not in lieu of, any other civil or criminal remedies as may be provided by law, including any other proceedings that the FTC may initiate to enforce this Order. For purposes of this Section VIII, Defendants waive any right to contest any of the allegations in the Complaint.

## IX.

### DISTRIBUTION OF ORDER

**IT IS FURTHER ORDERED** that, for a period of three (3) years from the date of entry of this Order, Defendants shall deliver copies of the Order as directed below:

- A. **Corporate Defendant:** Defendant Transdermal must deliver a copy of this Order to all of its principals, officers, directors, and managers. Transdermal also must deliver copies of this Order to all of its employees, agents, and representatives who engage in conduct related to the subject matter of the Order. For current personnel, delivery shall be within five (5) days of service of this Order upon Defendant. For new personnel, delivery shall occur prior to them assuming their responsibilities.
- B. **Individual Defendant as Control Person:** For any business that Defendant Newbauer controls, directly or indirectly, or in which Newbauer has a majority ownership interest, Newbauer must deliver a copy of this Order to all principals, officers, directors, and managers of that business. Defendant Newbauer must also deliver copies of this Order to all employees, agents, and representatives of that business who engage in conduct related to the subject matter of the Order. For current personnel, delivery shall be within five (5) days of service of this Order upon Defendant. For new personnel, delivery shall occur prior to them assuming their responsibilities.

- C. **Individual Defendant as Employee or Non-control Person:** For any business where Defendant Newbauer is not a controlling person of a business but otherwise engages in conduct related to the subject matter of this Order, Newbauer must deliver a copy of this Order to all principals and managers of such business before engaging in such conduct.
- D. Defendants Transdermal and Newbauer must use all reasonable means and efforts to secure a signed and dated statement acknowledging receipt of the Order, within thirty (30) days of delivery, from all persons receiving a copy of the Order pursuant to this Section.

#### X.

### COMPLIANCE MONITORING

**IT IS FURTHER ORDERED** that, for the purpose of monitoring and investigating compliance with any provision of this Order:

- A. Within ten (10) days of receipt of written notice from a representative of the Commission, Defendants each shall submit additional written reports, sworn to under penalty of perjury; produce documents for inspection and copying; appear for deposition; and/or provide entry during normal business hours to any business location in such Defendant's possession or direct or indirect control to inspect the business operation;
- B. In addition, the Commission is authorized to monitor compliance with this Order by all other lawful means, including but not limited to the following:
1. Obtaining discovery from any person, without further leave of court, using the procedures prescribed by Fed. R. Civ. P. 30, 31, 33, 34, 36, and 45;

2. Posing as actual or prospective consumers, trade customers or suppliers to Defendants, Defendants' employees, or any other entity managed or controlled in whole or in part by Defendants, without the necessity of identification or prior notice; and
- C. Defendants shall permit representatives of the Commission to interview any employer, consultant, independent contractor, representative, agent, or employee who has agreed to such an interview, relating in any way to any conduct subject to this Order. The person interviewed may have counsel present.

*Provided, however,* that nothing in this Order shall limit 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, to obtain any documentary material, tangible things, testimony, or information relevant to unfair or deceptive acts or practices in or affecting commerce (within the meaning of 15 U.S.C. § 45(a)(1)).

## XI.

### COMPLIANCE REPORTING

**IT IS FURTHER ORDERED** that, in order that compliance with the provisions of this Order may be monitored:

- A. For a period of three (3) years from the date of entry of this Order,
  1. Defendant Newbauer shall notify the Commission of the following:
    - a. Any changes in his residence, mailing addresses, and telephone numbers, within ten (10) days of the date of such change;
    - b. Any changes in his employment status (including self-employment), and any change in his ownership in any business

entity, within ten (10) days of the date of such change. Such notice must include the name and address of each business that Newbauer is affiliated with, employed by, creates or forms, or performs services for; a statement of the nature of the business; and a statement of his duties and responsibilities in connection with the business or employment; and

c. Any changes in his name or use of any aliases or fictitious names; and

2. Defendants shall notify the Commission of any changes in corporate structure, and any changes in any business entity that they or either of them directly or indirectly control(s), or has an ownership interest in, that may affect compliance obligations arising under this Order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor entity; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order; the filing of a bankruptcy petition; or a change in the corporate name or address, at least thirty (30) days prior to such change, *provided* that, with respect to any proposed change in the corporation about which Defendants learn less than thirty (30) days prior to the date such action is to take place, Defendants shall notify the Commission as soon as is practicable after obtaining such knowledge.

B. Ninety (90) days after the date of entry of this Order, Defendants each shall provide a written report to the FTC, sworn to under penalty of perjury, setting

forth in detail the manner and form in which they have complied and are complying with this Order. This report must include, but not be limited to:

1. For Defendant Newbauer:
  - a. The then-current residence address, mailing addresses, and telephone numbers of Newbauer; and
  - b. The then-current employment and business addresses and telephone numbers of Newbauer, a description of the business activities of each such employer or business, and the title and responsibilities of Newbauer for each such employer or business.
2. For Defendants Transdermal and Newbauer:
  - a. A copy of each acknowledgment of receipt of this Order, obtained pursuant to Section IX; and
  - b. Any other changes required to be reported under Part A of this Section.
- C. For the purposes of this Order, Defendants shall, unless otherwise directed by the Commission's authorized representatives, mail all written notifications to the Commission to: Associate Director for Enforcement, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, DC 20580. Attn: FTC v. Transdermal International Products Marketing Corp. et al., Matter No. X050023.
- D. For purposes of the compliance reporting required by this Order, the Commission is authorized to communicate directly with Defendants.

## XII.

### RECORD KEEPING PROVISIONS

**IT IS FURTHER ORDERED** that, for a period of six (6) years from the date of entry of this Order, Defendant Transdermal and its successors and assigns, and Defendant Newbauer in connection with any business where (1) he is the majority owner, an officer, or director of the business, or directly or indirectly manages or controls the business and (2) the business engages in, or assists others engaged in, the manufacturing, advertising, promotion, offering for sale, sale, or distribution of any transdermal product, dietary supplement, drug, device or cosmetic, and their agents, employees, officers, corporations, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, are hereby restrained and enjoined from failing to create and retain the following records:

- A. Accounting records that reflect the cost of goods, services, or programs sold, revenues generated, and the disbursement of such revenues;
- B. Personnel records accurately reflecting: the name, address, and telephone number of each person employed in any capacity by such business, including as an independent contractor; that person's job title or position; the date upon which the person commenced work; and the date and reason for the person's termination, if applicable;
- C. Customer files containing the names, addresses, telephone numbers, dollar amounts paid, quantity of goods, services, or programs purchased, and description of goods, services, or programs purchased, to the extent such information is obtained in the ordinary course of business;
- D. Complaints and refund requests (whether received directly, indirectly, or through



any third party) and any responses to those complaints or requests;

- E. Copies of all sales scripts, training materials, advertisements, promotional materials, or other marketing materials;
- F. All materials that were relied upon in making any representations contained in the materials identified in Part E of this Section;
- G. All other documents evidencing or referring to the accuracy of any claim therein or to the safety or efficacy of any transdermal product, dietary supplement, drug, device or cosmetic, including, but not limited to, all tests, reports, studies, demonstrations, or other evidence that confirm, contradict, qualify, or call into question the safety or efficacy of any such product, service or program;
- H. Records accurately reflecting the name, address, and telephone number of each person or entity engaged in the development or creation of any testing obtained for the purpose of advertising, labeling, promoting, offering for sale, distributing, or selling any transdermal product, dietary supplement, drug, device or cosmetic; and
- I. All records and documents necessary to demonstrate full compliance with each provision of this Order, including but not limited to, copies of acknowledgments of receipt of this Order, required by Sections VIII and IX, and all reports submitted to the FTC pursuant to Section XI.

**XIII.**

**RETENTION OF JURISDICTION**

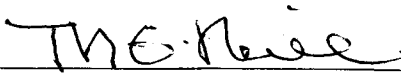
**IT IS FURTHER ORDERED** that this Court shall retain jurisdiction of this matter for purposes of construction, modification, and enforcement of this Order.

**XIV.**

**SCOPE OF ORDER**

**IT IS FURTHER ORDERED** that this Order resolves only claims against the named Defendants and does not preclude the Commission from initiating further action or seeking any remedy against any other persons or entities, including without limitation persons or entities who may be subject to portions of this Order by virtue of actions taken in concert or participation with Defendants, and persons or entities in any type of indemnification or contractual relationship with Defendants.

**SO ORDERED** this 24 day of July, 2007.

  
\_\_\_\_\_  
THOMAS N. O'NEILL, JR.  
United States District Judge  
Eastern District of Pennsylvania

**SO STIPULATED:**

JAMES A. KOHM  
Associate Director for Enforcement

  
\_\_\_\_\_  
LEMUEL W. DOWDY

TRANSDERMAL PRODUCTS  
INTERNATIONAL MARKETING  
CORPORATION

By:   
\_\_\_\_\_  
WILLIAM H. NEWBAUER, President

  
\_\_\_\_\_  
WILLIAM H. NEWBAUER  
Individually

*Marc Durant 6/21/07*

\_\_\_\_\_  
JOEL N. BREWER

Attorneys

Federal Trade Commission

600 Pennsylvania Ave., N.W.

Washington, D.C. 20580

202-325-2981 (telephone)

202-326-2967 (telephone)

202-326-2558 (facsimile)

\_\_\_\_\_  
MARC DURANT

SHARI AMSTER

Durant & Durant

325 Chestnut Street, Suite 1116

Philadelphia, PA 19106

215-592-1818 (telephone)

215-592-9994 (facsimile)

Attorneys for Transdermal International

Marketing Corporation and William H.

Newbauer

LODGED

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

2005 JAN 11 PM 1:44  
FILED U.S. DISTRICT COURT  
CENTRAL DISTRICT OF CALIF.  
MAGUILES  
*[Signature]*

Priority  
Send  
Enter  
Closed  
~~JS-5/JS-6~~  
JS-2/JS-3  
Scan Only  
*[Handwritten marks]*

ORIGINAL  
FILED  
CLERK, U.S. DISTRICT COURT  
JAN 12 2005  
CENTRAL DISTRICT OF CALIFORNIA  
BY *[Signature]* DEPUTY

UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA

FEDERAL TRADE COMMISSION,  
  
Plaintiff,  
  
v.  
  
ENFORMA NATURAL PRODUCTS,  
INC. and ANDREW GREY,  
  
Defendants,  
  
and  
  
TWENTY-FOUR SEVEN, LLC,  
MICHAEL EHRMAN and DONNA  
DiFERDINANDO,  
  
Respondents.

CV 00-04376-SVW (CWx)

*[Signature]*  
**[proposed]**  
**STIPULATED FINAL ORDER  
FOR PERMANENT INJUNCTION  
AND SETTLEMENT OF CLAIMS  
FOR MONETARY RELIEF AS TO  
DEFENDANTS ENFORMA  
NATURAL PRODUCTS, INC. AND  
ANDREW GREY, AND  
RESPONDENTS MICHAEL  
EHRMAN AND TWENTY-FOUR  
SEVEN, LLC**

**INTRODUCTION AND PROCEDURAL HISTORY**

On May 11, 2000, the Court entered a Stipulated Final Order and Settlement of Claims for Monetary Relief as to Defendants Enforma Natural Products, Inc. ("Enforma") and Andrew Grey ("Grey") (the "Stipulated Final Order") in this case. Paragraph XVI of that Stipulated Final Order specifically retains this Court's "jurisdiction of this matter for purposes of construction, modification, and enforcement . . . ."

DOCKETED ON CM  
JAN 13 2005  
BY *[Signature]* 009

314

SCANNED

1 On January 4, 2002, Plaintiff, the Federal Trade Commission  
2 (“Commission”) filed its first of two applications for an Order to Show Cause,  
3 seeking a finding of civil contempt against Defendants Enforma and Grey, and  
4 Respondent Michael Ehrman (“Ehrman”) in connection with the post-Stipulated  
5 Final Order marketing of Fat Trapper, Fat Trapper Plus and Exercise In A Bottle.

6 On July 23, 2002, the Commission filed its second application for an Order  
7 to Show Cause, seeking a temporary restraining order, a preliminary injunction  
8 and a finding of civil contempt against Defendants Enforma and Grey and  
9 Respondents Twenty-Four Seven, LLC (“Twenty-Four Seven” or “24/7”) and  
10 Donna DiFerdinando (“DiFerdinando”) in connection with the post-Stipulated  
11 Final Order marketing of Acceleron and Chitozyme.

12 The Commission and Defendants Enforma and Grey, hereinafter referred to  
13 collectively as “Defendants,” and Respondents Ehrman and 24/7, hereinafter  
14 referred to collectively as “Respondents,” have stipulated to the entry of the  
15 following Stipulated Final Order for Permanent Injunction and Settlement of  
16 Claims for Monetary Relief as to Defendants Enforma Natural Products, Inc. and  
17 Andrew Grey, and Respondents Michael Ehrman and Twenty-Four Seven, LLC  
18 (“Order”) in settlement of the Commission’s first and second applications for  
19 Orders to Show Cause against them. The Court, being duly advised in the  
20 premises, finds:

21  
22 **FINDINGS**

- 23 1. This Court has jurisdiction over the subject matter of this case and it  
24 has jurisdiction over all parties hereto.
- 25 2. Venue lies properly with this Court.
- 26 3. The January 4, 2002 and July 23, 2002 civil contempt applications  
27 state a claim upon which relief can be granted, and the Commission has the  
28 authority to seek the relief which is stipulated to in this Order.

1           4.     The acts and practices of Defendants and Respondents were and are  
2 in or affecting commerce, as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

3           5.     Defendants and Respondents waive all rights to seek judicial review  
4 of, or otherwise to challenge or contest the validity of, this Order. Defendants and  
5 Respondents also waive any claim that they may have held under the Equal Access  
6 to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action to the  
7 date of this Order, and concerning the prosecution of *FTC v. Garvey*, CV-00-  
8 09358-GAF (C.D. Cal.). The Plaintiff waives its right to pursue any de novo  
9 action based on Defendants' and Respondents' acts and practices to the date of  
10 this Order.

11           6.     Each party shall bear its own costs and attorneys' fees.

12           7.     Entry of this Order is in the public interest.

13           8.     Pursuant to Federal Rule of Civil Procedure 65(d), the provisions of  
14 this Order are binding upon Defendants and Respondents, and their officers,  
15 agents, servants, employees and all other persons or entities in active concert or  
16 participation with them, who receive actual notice of this Order by personal service  
17 or otherwise.

18           9.     Defendants and Respondents expressly deny any wrongdoing or  
19 liability for any of the matters alleged in the two civil contempt applications.  
20 There have been no findings or admissions of wrongdoing or liability by the  
21 Defendants or Respondents.

22           10.    Nothing in this Order obviates Defendants' and Respondents'  
23 obligation to comply with Sections 5 and 12 of the Federal Trade Commission Act,  
24 15 U.S.C. §§ 45, 52.

25           11.    This Order was drafted jointly by Plaintiff, Defendants, and  
26 Respondents and reflects the negotiated agreement among the parties.

SCANNED

1           12. This Order supersedes the Stipulated Final Order entered by this  
2 Court on May 11, 2000. However, the Monetary Relief provisions of Paragraph  
3 VII of the Stipulated Final Order are not affected by this Order.

4  
5 **DEFINITIONS**

6 For the purpose of this permanent injunction Order, the following  
7 definitions shall apply:

- 8           A. “Defendants” means Enforma Natural Products, Inc. and Andrew  
9 Grey.  
10           B. “Respondents” means Twenty-Four Seven, LLC and Michael  
11 Ehrman.  
12           C. “Advertising” means any written or verbal statement, illustration or  
13 depiction that is designed to effect a sale or create interest in the  
14 purchasing of goods or services, whether it appears in a brochure,  
15 newspaper, magazine, pamphlet, leaflet, circular, mailer, book insert,  
16 free standing insert, letter, catalogue, poster, chart, billboard, public  
17 transit card, point of purchase display, packaging, package insert,  
18 label, film, slide, radio, television or cable television, audio program  
19 transmitted over a telephone system, program-length commercial  
20 (“infomercial”), Internet or in any other medium.  
21           D. “Weight loss product” means any product, service or program  
22 manufactured, labeled, packaged, distributed, advertised, promoted,  
23 offered for sale, or sold for the express or implied purpose of causing  
24 weight loss, maintaining weight loss, maintaining weight, or  
25 otherwise affecting weight gain or loss, whether individually or in any  
26 combination. For the purposes of this Order only, “weight loss  
27 product” does not mean or include an exercise program or exercise  
28 equipment.

S. LANNETT

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

E. "Food," "drug," and "device" shall mean as defined in Section 15 of the FTC Act, 15 U.S.C. § 55. For purposes of this Order only, "device" does not mean or include exercise equipment.

F. "Video advertisement" means any advertisement intended for dissemination through television broadcast, cablecast, home video, theatrical release, or via interactive media such as the Internet or an online service.

G. "Clearly and prominently" means as follows:

(1) In an advertisement communicated through an electronic medium, the disclosure shall be presented simultaneously in both the audio and video portions of the advertisement. *Provided, however,* that in any advertisement presented solely through video or audio means, the disclosure may be made through the same means in which the advertisement is presented. The audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. The video disclosure shall be of a size and shade, and shall appear on the screen for a duration, sufficient for an ordinary consumer to read and comprehend it. In addition to the foregoing, in interactive media the disclosure shall also be unavoidable and shall be presented prior to the consumer incurring any financial obligation.

(2) In a print advertisement, promotional material, or instructional manual, the disclosure shall be in a type size and location sufficiently noticeable for an ordinary consumer to read and comprehend it, in print that contrasts with the background against which it appears. In multipage documents, the disclosure shall appear on the cover or first page.



SEARCHED

1 (3) On a product label, the disclosure shall be in a type size and  
2 location on the principal display panel sufficiently noticeable  
3 for an ordinary consumer to read and comprehend it, in print  
4 that contrasts with the background against which it appears.

5 The disclosure shall be in all of the languages that are present in the  
6 advertisement. Nothing contrary to, inconsistent with, or in mitigation of the  
7 disclosure shall be used in any advertisement or on any label.

8 H. "Competent and reliable scientific evidence" means tests, analyses,  
9 research, studies, or other evidence based on the expertise of professionals in the  
10 relevant area, that have been conducted and evaluated in an objective manner by  
11 persons qualified to do so, using procedures generally accepted in the profession to  
12 yield accurate and reliable results.

13 I. "Endorsement" shall mean as defined in 16 C.F.R. § 255.0.  
14

## 15 PROHIBITED BUSINESS ACTIVITIES

### 16 I.

17 **IT IS HEREBY ORDERED** that Defendants and Respondents, directly or  
18 through any corporation, partnership, subsidiary, division, trade name, or other  
19 device, and their officers, agents, servants, employees and attorneys, and all other  
20 persons or entities in active concert or participation with them who receive actual  
21 notice of this Order, by personal service or otherwise, are hereby permanently  
22 restrained and enjoined from the manufacturing, labeling, packaging, advertising,  
23 promotion, offering for sale, sale or distribution of any weight loss product.  
24

### 25 II.

26 **IT IS FURTHER ORDERED** that Defendants and Respondents, directly  
27 or through any corporation, partnership, subsidiary, division, trade name, or other  
28 device, and their officers, agents, servants, employees, and attorneys, and all

S LANNELL

1 persons or entities in active concert or participation with them who receive actual  
2 notice of this Order, by personal service or otherwise, in connection with the  
3 manufacturing, labeling, advertising, promotion, offering for sale, sale, or  
4 distribution of any dietary supplement, food, drug, or device, in or affecting  
5 commerce, are hereby permanently restrained and enjoined from making or  
6 assisting others in making, expressly or by implication, including through the use  
7 of endorsements or product names, any representation about the benefits,  
8 performance, or efficacy of any such dietary supplement, food, drug, or device  
9 product unless, at the time the representation is made, Defendants and  
10 Respondents possess and rely upon competent and reliable scientific evidence that  
11 substantiates the representation.

12  
13 **PROHIBITION ON MISREPRESENTING TESTS OR STUDIES**

14 **III.**

15 **IT IS FURTHER ORDERED** that Defendants and Respondents, directly  
16 or through any corporation, partnership, subsidiary, division, or other device, and  
17 their officers, agents, servants, employees, and attorneys, and all other persons or  
18 entities in active concert or participation with them who receive actual notice of  
19 this Order, by personal service or otherwise, in connection with the manufacturing,  
20 labeling, packaging, advertising, promotion, offering for sale, sale, or distribution  
21 of any product, service or program, in or affecting commerce, shall not  
22 misrepresent, in any manner, expressly or by implication, the existence, contents,  
23 validity, results, conclusions or interpretations of any test, study, or research.

24  
25 **TRADE NAME EXCISION**

26 **IV.**

27 **IT IS FURTHER ORDERED** that Defendants and Respondents, directly  
28 or through any corporation, partnership, subsidiary, division, or other device, and

STAMP-ELL

1 their officers, agents, servants, employees and attorneys, and all other persons or  
2 entities in active concert or participation with them who receive actual notice of  
3 this Order, by personal service or otherwise, in connection with the licensing,  
4 manufacturing, labeling, packaging, advertising, promotion, offering for sale, sale  
5 or distribution of any products, trade names, trademarks, services or programs in  
6 or affecting commerce, shall immediately cease using, and shall not sell, rent,  
7 lease, license or otherwise transfer, or permit others to use, the trade names or  
8 trademarks “Carb Trapper Plus,” “Dessert Avert,” “Exercise In A Bottle,” “Fat  
9 Trapper,” “Fat Trapper Plus” and “Hunger Ease” and shall immediately destroy all  
10 packages, labels, advertisements and marketing materials bearing those trade  
11 names in their possession, custody or control.

12  
13 **PAID ADVERTISEMENTS AND DISCLOSURES**

14 **V.**

15 **IT IS FURTHER ORDERED** that Defendants and Respondents, directly  
16 or through any corporation, subsidiary, division, or other device, in connection  
17 with the labeling, advertising, promotion, offering for sale, sale, or distribution of  
18 any product or program in or affecting commerce, shall not create, produce, sell,  
19 or disseminate:

20 A. Any advertisement that misrepresents, directly or by implication, that  
21 it is not a paid advertisement;

22 B. Any television commercial or other video advertisement fifteen (15)  
23 minutes in length or longer or intended to fill a broadcasting or cablecasting time  
24 slot of fifteen (15) minutes in length or longer that does not display visually,  
25 clearly and prominently, and for a length of time sufficient for an ordinary  
26 consumer to read, within the first thirty (30) seconds of the advertisement and  
27 immediately before each presentation of ordering instructions for the product or  
28 service, the following disclosure:

SCANNED

1 “THE PROGRAM YOU ARE WATCHING IS A PAID  
2 ADVERTISEMENT FOR [THE PRODUCT OR SERVICE].”

3 Provided that, for the purposes of this provision, the oral or visual  
4 presentation of a telephone number, e-mail address or mailing address for viewers  
5 to contact for further information or to place an order for the product or service  
6 shall be deemed a presentation of ordering instructions so as to require the display  
7 of the disclosure provided herein; or

8 C. Any radio commercial or other radio advertisement five (5) minutes in  
9 length or longer that does not broadcast, clearly and audibly, within the first thirty  
10 (30) seconds of the advertisement and immediately before each presentation of  
11 ordering instructions for the product or service, the following disclosure:

12 “THE PROGRAM YOU ARE LISTENING TO IS A PAID  
13 ADVERTISEMENT FOR [THE PRODUCT OR SERVICE].”

14 Provided that, for the purposes of this provision, the presentation of a telephone  
15 number, e-mail address or mailing address for listeners to contact for further  
16 information or to place an order for the product or service shall be deemed a  
17 presentation of ordering instructions so as to require the announcement of the  
18 disclosure provided herein.

19  
20 **EQUITABLE MONETARY RELIEF**

21 **VI.**

22 **IT IS FURTHER ORDERED** that:

23 A. Defendants and Respondents shall, jointly and severally, pay to the  
24 Commission for consumer redress or disgorgement to the United States Treasury,  
25 or both, three hundred thousand (\$300,000.00) dollars. In fulfilling this obligation,  
26 Defendants and Respondents shall, within five (5) days of the entry of this Order,  
27 deposit the sum of three hundred thousand (\$300,000.00) dollars by electronic  
28

SCANNED

1 funds transfer into an escrow account to be established by the Commission for the  
2 purpose of receiving the payment due under the provisions of this Order.

3 B. All funds paid pursuant to this Order shall be deposited into a fund  
4 administered by the Commission or its agent to be used for equitable relief,  
5 including but not limited to consumer redress, and any attendant expenses for the  
6 administration of such equitable relief. These funds shall, in the discretion of the  
7 Commission, be used to provide refunds to consumers who purchased from  
8 Defendants and Respondents the products Fat Trapper Plus, Exercise In A Bottle,  
9 Accelaron, or Chitozyme from the time period of May 12, 2000 to the date of the  
10 entry of this Order.

11 C. In the event that direct redress to consumers is wholly or partially  
12 impracticable or funds remain after redress is completed, such funds shall be  
13 deposited to the United States Treasury as disgorgement. Defendants and  
14 Respondents shall have no right to challenge the Commission's choice of remedies  
15 under this Part. Defendants and Respondents shall have no right to contest the  
16 manner of distribution chosen by the Commission. No portion of any payments  
17 under the judgment herein shall be deemed a payment of any fine, penalty, or  
18 punitive assessment.

19 D. Defendants and Respondents relinquish all dominion, control, and title  
20 to the funds paid to and property transferred to the Commission, for use according  
21 to the terms of this Order. Defendants and Respondents shall make no claim to or  
22 demand for the return of the funds, directly or indirectly, through counsel or  
23 otherwise; and in the event of bankruptcy of any Defendant or Respondent,  
24 Defendants and Respondents acknowledge that the funds are not part of the  
25 debtor's estate, nor does the estate have any claim or interest therein.

26  
27  
28

SCANNED

**CUSTOMER LISTS**

**VII.**

**IT IS FURTHER ORDERED** that, except as provided in this Order, Defendants, Respondents, and their officers, agents, servants, employees, and attorneys and all other persons or entities who receive actual notice of this Order by personal service or otherwise, are permanently restrained and enjoined from selling, renting, leasing, transferring, or otherwise disclosing the name, address, telephone number, credit card number, bank account number, e-mail address, or other identifying information of any person obtained as a result of paying any money to any Defendant or Respondent, at any time prior to entry of this Order, in connection with the purchase of any weight loss product. *Provided, however,* that Defendants and Respondents may disclose such identifying information to any law enforcement agency, or as required by any law, regulation, or court order.

**RIGHT TO REOPEN**

**VIII.**

**IT IS FURTHER ORDERED** that, within five (5) days after the date of entry of this Order, Defendant Grey, individually and on behalf of (a) Defendant Enforma and (b) Respondent 24/7; and Respondent Ehrman, shall each execute and submit to the Commission a truthful sworn statement that shall acknowledge receipt of this Order. The Commission's agreement to this Order is expressly premised on the truthfulness, accuracy, and completeness of Defendants' and Respondents' financial condition as reflected in the totality of the information provided in the "Financial Statement of Individual Defendant" Grey, dated January 29, 2004; the "Financial Statement of Corporate Defendant" Enforma, dated January 29, 2004; Respondent Ehrman's "Financial Statement of Individual Defendant," dated February 11, 2004; and the Balance Sheets as of December 31, 2003 of Completely Direct, Inc., Greater Capital Resources, XS Capital Unlimited

SCANNED

1 LLC, NeoShaper Fitness Products, LLC, Interactive Technologies, Inc., and Riot  
2 Direct, LLC. If, upon motion by the Commission, the Court finds that:

- 3 1. the financial information contained in the “Financial Statement of  
4 Individual Defendant” Grey, dated January 29, 2004; the “Financial  
5 Statement of Corporate Defendant” Enforma, dated January 29, 2004;  
6 and the Balance Sheets as of December 31, 2003 of Completely  
7 Direct, Inc., Greater Capital Resources, XS Capital Unlimited LLC,  
8 NeoShaper Fitness Products, LLC, Interactive Technologies, Inc., and  
9 Riot Direct, LLC failed to disclose any material asset, materially  
10 misrepresented the value of any asset, or made any other material  
11 misrepresentation or omission, the Court shall enter judgment for  
12 consumer redress against Defendants and Respondent 24/7, jointly  
13 and severally, in favor of the Commission, in the amount of four  
14 million dollars (\$4,000,000); or
- 15 2. the financial information contained in Respondent Ehrman’s  
16 “Financial Statement of Individual Defendant,” dated February 11,  
17 2004 failed to disclose any material asset, materially misrepresented  
18 the value of any asset, or made any other material misrepresentation  
19 or omission, the Court shall enter judgment for consumer redress  
20 against Respondent Ehrman in favor of the Commission, in the  
21 amount of four million dollars (\$4,000,000)

22 *provided, however*, that in all other respects this Order shall remain in full force  
23 and effect unless otherwise ordered by the Court; and, *provided further*, that  
24 proceedings instituted under this Part would be in addition to, and not in lieu of,  
25 any other civil or criminal remedies as may be provided by law, including any  
26 other proceedings that the Commission may initiate to enforce this Order. For  
27 purposes of enforcing this Part only, Defendants and Respondents waive any right  
28 to contest any of the allegations in the Complaint.

SCANNED

## COMPLIANCE MONITORING

### IX.

**IT IS FURTHER ORDERED** that, for the purpose of monitoring and investigating compliance with any provision of this Order,

A. Within ten (10) days of receipt of written notice from a representative of the Commission, Defendants and Respondents each shall submit additional written reports, sworn to under penalty of perjury; produce documents for inspection and copying; appear for deposition; and/or provide entry during normal business hours to any business location in such Defendants' or Respondents' possession or direct or indirect control to inspect the business operation;

B. In addition, the Commission is authorized to monitor compliance with this Order by all other lawful means, including but not limited to the following:

1. obtaining discovery from any person, without further leave of court, using the procedures prescribed by Fed. R. Civ. P. 30, 31, 33, 34, 36, and 45;
2. posing as consumers and suppliers to Defendants and Respondents, their employees, or any other entity managed or controlled in whole or in part by Defendants and Respondents, without the necessity of identification or prior notice;

*Provided* that nothing in this Order shall limit 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, to obtain any documentary material, tangible things, testimony, or information relevant to unfair or deceptive acts or practices in or affecting commerce (within the meaning of 15 U.S.C. § 45(a)(1)).

C. Defendants and Respondents shall permit representatives of the Commission to interview any employer, consultant, independent contractor, representative, agent, or employee who has agreed to such an interview, relating in



SCANNED

1 any way to any conduct subject to this Order. The person interviewed may have  
2 counsel present.

4 **COMPLIANCE REPORTING BY DEFENDANTS AND RESPONDENTS**

5 **X.**

6 **IT IS FURTHER ORDERED** that, in order that compliance with the  
7 provisions of this Order may be monitored:

8 A. For a period of five (5) years from the date of entry of this Order,  
9 Defendants and Respondents shall notify the Commission of any changes in  
10 corporate structure of Enforma, 24/7, or any business entity that Grey or Ehrman  
11 directly or indirectly control, or have an ownership interest in, whose business is  
12 within the subject matter of this Order, including Paragraphs I - V, including but  
13 not limited to a dissolution, assignment, sale, merger, or other action that would  
14 result in the emergence of a successor corporation; the creation or dissolution of a  
15 subsidiary, parent, or affiliate that engages in any acts or practices subject to this  
16 Order; the filing of a bankruptcy petition; or a change in the corporate name or  
17 address, at least thirty (30) days prior to such change, *provided* that, with respect to  
18 any proposed change in the corporation about which the Defendants and  
19 Respondents learn less than thirty (30) days prior to the date such action is to take  
20 place, Defendants and Respondents shall notify the Commission as soon as is  
21 practicable after obtaining such knowledge.

22 B. For a period of five (5) years from the date of entry of this Order,  
23 Defendant Grey and Respondent Ehrman shall notify the Commission of the  
24 following:

- 25 1. Any changes in their residence, mailing addresses, and  
26 telephone numbers, within ten (10) days of the date of such  
27 change;  
28

RECEIVED

- 1           2. Any changes in employment status (including self-
- 2           employment) of Grey or Ehrman, and any changes in the
- 3           ownership of Grey or Ehrman in any business entity within ten
- 4           (10) days of the date of such change. Such notice shall include
- 5           the name and address of each business that Grey or Ehrman is
- 6           affiliated with, employed by, creates or forms, or performs
- 7           services for; a statement of the nature of the business; and a
- 8           statement of Grey's or Ehrman's duties and responsibilities in
- 9           connection with the business;
- 10          3. Any changes in their name or use of any aliases or fictitious
- 11          names.

12           C. Ninety (90) days after the date of entry of this Order, Defendants and  
13 Respondents each shall provide a written report to the FTC, sworn to under  
14 penalty of perjury, setting forth in detail the manner and form in which they have  
15 complied and are complying with this Order. This report shall include, but not be  
16 limited to:

- 17           1. For Defendant Grey and Respondent Ehrman:
  - 18           a. Their then-current residence address, mailing addresses,
  - 19           and telephone numbers;
  - 20           b. Their then-current employment and business addresses
  - 21           and telephone numbers, a description of the business
  - 22           activities of each such employer or business, and the title
  - 23           and responsibilities of Grey and Ehrman, for each such
  - 24           employer or business; and
  - 25           c. Any other changes required to be reported under
  - 26           subparagraphs A and B of this Part.
- 27           2. For all Defendants and Respondents:
- 28

SCANNED

- a. A copy of each acknowledgment of receipt of this Order, obtained pursuant to Part XII;
- b. Any other changes required to be reported under subparagraphs A and B of this Part; and
- c. Copies of all then current advertisements, promotional materials, sales scripts, training materials, or other marketing materials utilized by Defendants and Respondents in the advertising, marketing, promotion, offering for sale, distribution or sale of any dietary supplement, food, drug, or device in the United States.

D. For the purposes of this Order, Defendants and Respondents shall, unless otherwise directed by the Commission's authorized representatives, mail all written notifications to the Commission to:

Associate Director for Advertising Practices  
Federal Trade Commission  
600 Pennsylvania Avenue, N.W.  
Washington, D.C. 20580  
Re: FTC v. Enforma Natural Products, Inc., et al., Case No. 00-04376 SVW (CWx) (C.D. Cal.).

E. For purposes of the compliance reporting and monitoring required by this Order, Defendants and Respondents shall provide the Commission with their counsel's name and address for the purpose of communications regarding this Order and shall notify the Commission of any change in their counsel for the purpose of this Order.

**RECORD KEEPING PROVISIONS**

**XI.**

**IT IS FURTHER ORDERED** that, for a period of five (5) years from the date of entry of this Order, Defendant Grey and Respondent Ehrman, in connection with each business in which they, jointly or severally, are the majority

SCANNED

1 owners or an officer or director of the business, or directly or indirectly manage, or  
2 control the business and the business conducted is within the subject matter of this  
3 Order, including Paragraphs I - V, and their agents, employees, officers,  
4 corporations, successors, and assigns, and those persons in active concert or  
5 participation with them who receive actual notice of this Order by personal service  
6 or otherwise, are hereby restrained and enjoined from failing to create and retain  
7 the following records in connection with that business:

- 8 A. Accounting records that reflect the cost of goods or services sold,  
9 revenues generated, and the disbursement of such revenues;
- 10 B. Personnel records accurately reflecting: the name, address, and  
11 telephone number of each person employed in any capacity by such  
12 business, including as an independent contractor; that person's job  
13 title or position; the date upon which the person commenced work;  
14 and the date and reason for the person's termination, if applicable; and
- 15 C. Copies of all sales scripts, training materials, advertisements, or other  
16 marketing materials.

17  
18 **DISTRIBUTION OF ORDER BY DEFENDANTS AND RESPONDENTS**

19 **XII.**

20 **IT IS FURTHER ORDERED** that, for a period of five (5) years from the  
21 date of entry of this Order,

- 22 A. Defendant Enforma and Respondent 24/7 shall deliver a copy of this  
23 Order to all principals, officers, directors, and managers. Defendant  
24 Enforma and Respondent 24/7 also must deliver copies of this Order  
25 to all of their employees, agents, and representatives having  
26 responsibilities with respect to the subject matter of this Order, and  
27 shall secure from each such person a signed and dated statement  
28 acknowledging receipt of the Order, including Paragraphs I - V. For

1 current personnel, delivery shall be within five (5) days after the date  
2 of service of this Order upon Defendant Enforma and Respondent  
3 24/7. For new personnel, delivery shall occur prior to them assuming  
4 their responsibilities;

5 B. Defendant Grey and Respondent Ehrman shall deliver a copy of this  
6 Order to the principals, officers, directors, and managers of any  
7 business in which they, jointly or severally, control, directly or  
8 indirectly, or in which they have a majority ownership interest and the  
9 business conducted is within the subject matter of this order, including  
10 Paragraphs I - V. Defendant Grey and Respondent Ehrman must also  
11 deliver a copy of this Order to all employees, agents, and  
12 representatives of that business who engage in conduct related to the  
13 subject matter of this Order. For current personnel, delivery shall be  
14 within (5) days of service of this Order upon Defendant Grey and  
15 Respondent Ehrman. For new personnel, delivery shall occur prior to  
16 them assuming their responsibilities.

17 C. Defendants and Respondents must secure a signed and dated  
18 statement acknowledging receipt of the Order, within thirty (30) days  
19 of delivery, from all persons receiving a copy of the Order pursuant to  
20 this Part.

21  
22 **ACKNOWLEDGMENT OF RECEIPT OF ORDER**  
23 **BY DEFENDANTS AND RESPONDENTS**

24 **XIII.**

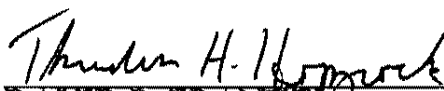
25 **IT IS FURTHER ORDERED** that each Defendant and Respondent, within  
26 five (5) business days of receipt of this Order as entered by the Court, must submit  
27 to the Commission a truthful sworn statement acknowledging receipt of this Order.  
28

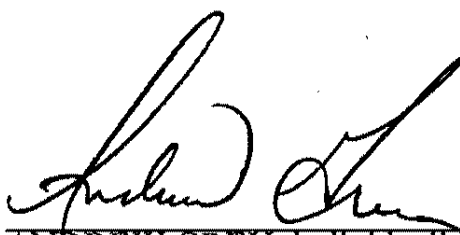
RETENTION OF JURISDICTION


XIV.


IT IS FURTHER ORDERED that this Court shall retain jurisdiction of this matter for purposes of construction, modification and enforcement of this Order.

SO STIPULATED:

  
\_\_\_\_\_  
DAVID P. FRANKEL  
THEODORE H. HOPPOCK  
Federal Trade Commission  
600 Pennsylvania Ave., N.W., Rm. S-4002  
Washington, D.C. 20580  
(202) 326-2812, -3087 (voice)  
(202) 326 3259 (facsimile)  
Attorneys for Plaintiff  
FEDERAL TRADE COMMISSION

  
\_\_\_\_\_  
ANDREW GREY, individually  
and on behalf of defendant  
Enforma Natural Products, Inc.  
and respondent Twenty-Four  
Seven, LLC

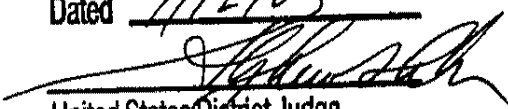
  
\_\_\_\_\_  
Michael Ehrman

  
\_\_\_\_\_  
Eric L. Dobberteen  
Arnold & Porter LLP  
777 South Figueroa Street  
Los Angeles, CA 90017-5844  
(213) 243-4055 (voice)  
(213) 243-4199 (facsimile)

Attorneys for Defendants  
ANDREW GREY and  
ENFORMA NATURAL  
PRODUCTS, INC. and  
Respondents MICHAEL  
EHRMAN and TWENTY-  
FOUR SEVEN, LLC

IT IS SO ORDERED

Dated 11/12/05

  
\_\_\_\_\_  
United States District Judge

SO ORDERED

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

**SO ORDERED**, this \_\_\_\_\_ day of \_\_\_\_\_, 200\_\_\_\_\_.

SCANNED

~~UNITED STATES DISTRICT JUDGE~~

SCANNED

UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

ENFORMA NATURAL PRODUCTS,  
INC. and ANDREW GREY,

Defendants,

and

TWENTY-FOUR SEVEN, LLC,  
MICHAEL EHRMAN and DONNA  
DiFERDINANDO,

Respondents.

CV 00-04376-SVW (CWx)

**[AFFIDAVIT OF  
DEFENDANT OR  
RESPONDENT (FILL IN  
NAME) \_\_\_\_\_]**

[Name of defendant or respondent], being duly sworn, hereby states and  
affirms as follows:



1 My name is \_\_\_\_\_. My current residence address is  
2 \_\_\_\_\_ . I am a citizen  
3 of the United States and am over the age of eighteen. I have personal knowledge  
4 of the facts set forth in this Affidavit.

5 1. I am a defendant [*or respondent*] in FTC v. Enforma Natural  
6 Products, Inc., et al., Case No. 00-04376 SVW (CWx) (C.D. Cal.).

7 2. On [*date*], I received a copy of the Order Granting Permanent  
8 Injunction Against Defendants Enforma Natural Products, Inc. and Andrew Grey  
9 and Respondents Twenty-Four Seven, LLC and Michael Ehrman, which was  
10 signed by the Honorable Stephen V. Wilson and entered by the Court on [*date of*  
11 *entry of Order*]. A true and correct copy of the Order I received is appended to this  
12 Affidavit.

13 I declare under penalty of perjury under the laws of the United States that  
14 the foregoing is true and correct. Executed on [*date*], at [*city and state*].

15  
16  
17 [Type full name of defendant or respondent beneath signature]

18  
19 State of \_\_\_\_\_, City of \_\_\_\_\_

20 Subscribed and sworn to before me  
21 this \_\_\_\_\_ day of \_\_\_\_\_, 2004.

22 \_\_\_\_\_  
23 Notary Public  
24 My Commission Expires:  
25 \_\_\_\_\_

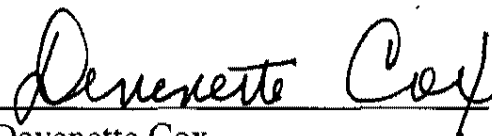
## CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on January 10, 2005, a true and correct copy of the foregoing [proposed] Stipulated Final Order for Permanent Injunction and Settlement of Claims for Monetary Relief as to Defendants Enforma Natural Products, Inc. and Andrew Grey, and Respondents Michael Ehrman and Twenty-Four Seven, LLC was served via Federal Express on:

SCANNED

Eric L. Dobberteen, Esq.  
Arnold & Porter  
777 South Figueroa Street, 44<sup>th</sup> Floor  
Los Angeles, CA 90017-5844  
ATTORNEYS FOR DEFENDANTS AND RESPONDENTS TWENTY-FOUR SEVEN LLC AND MICHAEL EHRMAN

Robert L. Corbin, Esq.  
Corbin & Fitzgerald  
601 West Fifth Street, Suite 1150  
Los Angeles, CA 90071  
ATTORNEYS FOR RESPONDENT DONNA DiFERDINANDO

  
Devenette Cox  
Investigator  
Division of Advertising Practices  
Federal Trade Commission

**PX 8**

DECLARATION OF ELIZABETH J. AVERILL

My name is Elizabeth Averill. I declare under penalty of perjury under the laws of the United States that the following is true, and that I have personal knowledge of the facts set forth below. If called as a witness, I could and would competently testify as follows.

1. I am a U.S. citizen over the age of 18 and am employed as an attorney in the Federal Trade Commission’s Bureau of Consumer Protection, Division of Enforcement (“Division of Enforcement”). My business address is 600 Pennsylvania Avenue, N.W., CC-9528, Washington, D.C. 20580. I have been assigned to work on the compliance investigation and litigation related to *Federal Trade Commission and Maine v. Health Research Laboratories, LLC, et al.*, 2:17-cv-00467-JDL.

2. On July 3, 2019, I received an email from Andrew Lustigman, counsel for Health Research Laboratories, LLC (“HRL”) and Kramer Duhon. A true and correct copy of the email is included as Attachment A.

3. The July 3, 2019 email from Mr. Lustigman included as an attachment a certification of previous submissions made by Kramer Duhon and HRL to the Federal Trade Commission. A true and correct copy of the certification is included as Attachment B.

Executed on: December 16, 2019  
Washington, D.C.

/s/ Elizabeth J. Averill  
Elizabeth J. Averill

## **Averill Declaration**

## **ATTACHMENT A**

**From:** [Lustigman, Andrew B.](#)  
**To:** [Frisby, Robert M.](#); [Shaffer, Scott A.](#)  
**Cc:** [DEbrief](#); [Averill, Elizabeth](#); [Brendan O'Neil](#)  
**Subject:** RE: FTC v. Health Research Laboratories, Case No. 2:17-cv-00467-JDL (FTC File No. X180007)  
**Date:** Wednesday, July 03, 2019 12:15:33 PM  
**Attachments:** [FTC Certification Document 2019\\_07\\_03\\_105234.pdf](#)

---

Robert –

Attached please find the requested certification. Can we set up a call for next week to go over your other items. I believe that my client has been fully responsive to your requests. Since there is apparently a miscommunication, perhaps we can resolve any open issues with a brief call. Let me know potential avaials.

Best,  
Andy

**Andrew B. Lustigman**

## OLSHAN

OLSHAN FROME WOLOSKY LLP  
1325 Avenue of the Americas  
(Entrance is on 53<sup>rd</sup> Street between Sixth and Seventh Avenues)  
New York, NY 10019  
Direct: [212.451.2258](tel:212.451.2258)  
Facsimile: [212.451.2222](tel:212.451.2222)  
Email: [ALustigman@olshanlaw.com](mailto:ALustigman@olshanlaw.com)  
Web: [www.olshanlaw.com](http://www.olshanlaw.com)

---

**From:** Frisby, Robert M. [mailto:[RFRISBY@ftc.gov](mailto:RFRISBY@ftc.gov)]  
**Sent:** Monday, July 1, 2019 11:55 AM  
**To:** Lustigman, Andrew B. <[ALustigman@olshanlaw.com](mailto:ALustigman@olshanlaw.com)>; Shaffer, Scott A. <[SShaffer@olshanlaw.com](mailto:SShaffer@olshanlaw.com)>  
**Cc:** DEbrief <[DEbrief@ftc.gov](mailto:DEbrief@ftc.gov)>; Averill, Elizabeth <[eaverill@ftc.gov](mailto:eaverill@ftc.gov)>; Brendan O'Neil <[brendan.oneil@maine.gov](mailto:brendan.oneil@maine.gov)>  
**Subject:** FTC v. Health Research Laboratories, Case No. 2:17-cv-00467-JDL (FTC File No. X180007)

Please find the attached letter.

Robert M. Frisby  
Attorney  
Division of Enforcement  
Bureau of Consumer Protection  
Federal Trade Commission  
Washington, D.C. 20580  
Tel: 202-326-2098  
[rfrisby@ftc.gov](mailto:rfrisby@ftc.gov)

---

Electronic transmissions by the law firm of Olshan Frome Wolosky LLP may contain information that is confidential or proprietary, or protected by the attorney-client privilege or work product doctrine. If you are not the intended recipient, be aware that any disclosure, copying, distribution or use of the contents hereof is strictly prohibited. If you have received this transmission in error, please notify Olshan Frome Wolosky LLP at once at [212.451.2300](tel:212.451.2300).

# **Averill Declaration**

## **ATTACHMENT B**



**CERTIFICATION**

Pursuant to 28 U.S.C. § 1746, I hereby declare and certify under penalty of perjury under the laws of the United States of America that the information and materials provided to the Federal Trade Commission in and accompanying the correspondences sent by my attorneys dated June 20, 2019, May 3, 2019 and January 30, 2019 was true and correct to the best of my knowledge, information and belief based on my examination of the books and records of Health Research Laboratories, LLC and Whole Body Supplements, LLC.

Dated: July 2, 2019

  
KRAMER DUHON

# Exhibit RX 3

**UNITED STATES DISTRICT COURT  
DISTRICT OF MAINE**

<b>FEDERAL TRADE</b>	)	
<b>COMMISSION, et al.,</b>	)	
	)	
<b>Plaintiffs,</b>	)	
	)	
<b>v.</b>	)	<b>2:17-cv-00467-JDL</b>
	)	
<b>HEALTH RESEARCH</b>	)	
<b>LABORATORIES, LLC, et al.,</b>	)	
	)	
<b>Defendants.</b>	)	

**ORDER**

The Federal Trade Commission and the State of Maine (collectively, “Plaintiffs”) bring this civil contempt proceeding against Health Research Laboratories, LLC, Kramer Duhon, and Whole Body Supplements, LLC (collectively, “Contempt Defendants”), for alleged violations of Section II.H of the Stipulated Final Judgment and Order previously entered in this action (“the Judgment”). In addition to moving for an Order to Show Cause (ECF No. 21), the Plaintiffs move to modify the Judgment (ECF No. 22). Health Research Laboratories and Duhon cross-move to modify the Judgment (ECF No. 30), and the Contempt Defendants move to stay the contempt proceedings until the cross-motions to modify the Judgment are resolved (ECF No. 31). For the reasons that follow, I deny the Plaintiffs’ motion for an Order to Show Cause and the Plaintiffs’ motion to modify the Judgment; I deny as moot the Contempt Defendants’ motion to stay; and I grant the Plaintiffs the opportunity to file a motion seeking leave to file an amended motion for an Order to Show Cause.

## I. LEGAL STANDARD

“Civil contempt may be imposed to compel compliance with a court order or to compensate a party harmed by non-compliance.” *United States v. Saccoccia*, 433 F.3d 19, 27 (1st Cir. 2005) (citing *McComb v. Jacksonville Paper Co.*, 336 U.S. 187, 191 (1949)). “To prove civil contempt, a movant must show 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.” *Hawkins v. Dep’t of Health & Human Servs.*, 665 F.3d 25, 31 (1st Cir. 2012) (quoting *Saccoccia*, 433 F.3d at 27). When evaluating whether a court order is “clear and unambiguous,” the question is “not whether the order is clearly worded as a general matter.” *Saccoccia*, 433 F.3d at 28. Instead, the “clear and unambiguous” prong “requires that the words of the court’s order have clearly and unambiguously forbidden the precise conduct on which the contempt allegation is based.” *Id.* (emphasis omitted) (citing *Perez v. Danbury Hosp.*, 347 F.3d 419, 424 (2d Cir. 2003)). Indeed, the language of the order must leave “no reasonable doubt” that the allegedly contumacious conduct is prohibited. *Id.* (quoting *Project B.A.S.I.C. v. Kemp*, 947 F.2d 11, 17 (1st Cir. 1991)).

## II. DISCUSSION

On July 31, 2020, I issued an Order holding that Section II.H of the Judgment was facially ambiguous. *See FTC v. Health Research Labs., LLC*, No. 2:17-cv-00467-JDL, 2020 WL 4431497, at \*7 (D. Me. July 31, 2020). The Order left open the question of whether the Plaintiffs may introduce extrinsic evidence for the purpose of showing that Section II.H of the Judgment “clearly and unambiguously” prohibited “the

precise conduct” on which their contempt allegations are based. *Id.* at \*4 n.2 (quoting *Saccoccia*, 433 F.3d at 28). Thus, the Order did not finally resolve whether Section II.H of the Judgment was “clear and unambiguous” for civil contempt purposes. *Id.*

On August 10, 2020, a video status conference was held to establish the framework for addressing the pending motions. At the conference, the Plaintiffs maintained their position that extrinsic evidence is admissible for purposes of determining whether Section II.H is clear and unambiguous, but indicated that in any event, they lacked sufficient extrinsic evidence to specifically prove that Section II.H clearly and unambiguously prohibits the conduct on which their contempt allegations are based. Thus, the Plaintiffs consented to a final ruling on the “clear and unambiguous” prong with respect to Section II.H without further briefing or hearing on that issue.

Because I have previously determined that Section II.H is facially ambiguous, and because the Plaintiffs do not seek a hearing at which to offer extrinsic evidence to cure the ambiguity, I conclude that Section II.H does not “clearly and unambiguously” prohibit the Contempt Defendants’ allegedly contumacious conduct. Accordingly, I conclude as a matter of law that the allegations in the Plaintiffs’ motion for an Order to Show Cause fail to support a finding of civil contempt under Section II.H, and the Plaintiffs’ motion for an Order to Show Cause is denied. Additionally, because the Plaintiffs have represented that their motion to modify the Judgment “is predicated on Defendants’ contempt” under Section II.H, ECF No. 42 at 2, their motion to modify the Judgment is denied.

At the status conference, the Plaintiffs expressed their intent to proceed on an alternative theory—that the Contempt Defendants violated Section III, not Section II.H, of the Judgment—and orally moved for leave to file an amended motion for an Order to Show Cause accordingly. The Contempt Defendants opposed the Plaintiffs’ request for leave to file an amended motion. I declined to rule on the Plaintiffs’ motion without the benefit of briefing by the parties on the same.

### III. CONCLUSION

For the foregoing reasons, it is **ORDERED** that the Plaintiffs’ motion for an Order to Show Cause (ECF No. 21) and the Plaintiffs’ motion to modify the Judgment (ECF No. 22) are **DENIED**, and the Contempt Defendants’ motion to stay briefing relating to the Plaintiffs’ motion for an Order to Show Cause (ECF No. 31) is **DENIED** as moot. Additionally, it is **ORDERED** that the Defendants shall notify the Court within 7 days whether they intend to withdraw their cross-motion to modify the Judgment (ECF No. 30). Finally, it is **ORDERED** that the Plaintiffs shall file any motion for leave to file an amended motion for an Order to Show Cause, accompanied by the proposed amended motion, by October 31, 2020, after which briefing will proceed according to the schedule set forth in D. Me. Local R. 7.

**SO ORDERED.**

**Dated: August 12, 2020**

/s/ JON D. LEVY  
**CHIEF U.S. DISTRICT JUDGE**

# Exhibit RX 4



# Federal Trade Commission

---

## Section 5 Revisited: Time for the FTC to Define the Scope of Its Unfair Methods of Competition Authority

Remarks of Joshua D. Wright\*  
Commissioner, Federal Trade Commission

at the

Symposium on Section 5 of the Federal Trade Commission Act

The Willard InterContinental  
Washington, D.C.

February 26, 2015

Good afternoon. Thank you for the kind introduction and warm welcome. I am delighted to be here today. I would like to thank Baker Hostetler, and especially Carl Hittinger, for organizing this terrific symposium and for the generous invitation to share my views with you this afternoon. Events such as this one are no small task to organize and they serve an incredibly important role in the development of antitrust and consumer protection law because they offer a vital platform for the honest exchange of ideas among practitioners, consumer advocates, agency officials, members

---

\* The views stated here are my own and do not necessarily reflect the views of the Commission or any other Commissioner. I am grateful to my attorney advisor, Jan M. Rybnicek, for his invaluable assistance in preparing this speech.



of the judiciary, and Congress. Given the caliber of the panelists at today's event, I have no doubt that we will all walk away having learned something new about Section 5.

I have made no secret of the fact that I believe there is no more important challenge facing the Commission today than finally articulating the appropriate scope and role of the agency's "unfair methods of competition" authority under Section 5. The historical record reveals a remarkable and unfortunate gap between the theoretical promise of Section 5 as articulated by Congress over a century ago and its application in practice by the Commission. Congress intended Section 5 to play a key role in the Commission's competition mission by allowing the agency to leverage its institutional advantages to develop evidenced-based competition policy. However, the record suggests that the Commission's use of Section 5 has done very little to influence antitrust doctrine or to inform judicial thinking since the agency's inception. In order to fulfill Section 5's promise, and finally provide meaning and purpose to the agency's signature competition statute, it is clear that the Commission must first provide a framework for how it intends to use its "unfair methods of competition" authority.

That is why, soon after joining the Commission, I publicly distributed a proposed policy statement outlining my views as to how the Commission should use its Section 5 authority. My hope was that doing so would start—or at least restart—a conversation on the topic and help the Commission identify areas of consensus upon which we as an agency could build. I view the release of my proposed policy statement as an

unequivocal success in this regard. In the two years since issuing my policy statement, I have been pleased by the many thoughtful contributions to the marketplace of ideas discussing the scope and role of Section 5. Academics and practitioners have responded to the Section 5 debate with dozens of articles and hundreds of pages of analysis. Current and former Commissioners also have shared their views. Conferences have been held, replies have been written, criticisms leveled, blogs posted, and speeches made—there was even a Section 5 hashtag on Twitter for a few days. The point is, a substantial record has been compiled. These contributions have helped bring several key policy questions into focus and, in my view, positioned the agency to undertake the long overdue task of issuing a policy statement that both strengthens the Commission’s ability to target anticompetitive conduct and provides meaningful guidance to the business community about the contours of Section 5.

I would like begin today by briefly taking stock of the Section 5 debate. I would like to summarize the case for formal agency guidance defining the boundaries of Section 5 and dispel a couple of myths about the disadvantages to drawing some meaningful parameters around the Commission’s “unfair methods of competition” authority. Beyond taking stock of the current debate, I also would like to share with you what I think is the next logical step in rehabilitating Section 5 and making it a productive member of the competition community as the Commission embarks upon its second century of protecting competition and consumers. Lastly, I would like to

discuss some of my concerns about what is likely to happen to the FTC's Section 5 authority if the Commission fails to provide guidance. I intend to leave time for questions at the end of my remarks, so please do not be shy when that time comes.

Before I get too far along in my comments, however, I am obligated to provide a short disclaimer familiar to most of you, and that is that the views I express today are my own and not necessarily those of the Commission or any of the other Commissioners. With that bit of business out of the way, let's jump right in.

## **I. THE CASE FOR FORMAL GUIDANCE DEFINING THE SCOPE OF THE FTC'S "UNFAIR METHODS OF COMPETITION" AUTHORITY**

I have shared my views on why the Commission should issue formal guidance defining the parameters of the agency's "unfair methods of competition" authority in countless forums since coming to the Commission.<sup>1</sup> Rather than using my time today to restate each of those arguments in detail again, I would like to quickly touch upon what I view as the most salient points before moving on to what I propose the agency should do as a first step to rehabilitating Section 5 so that it can contribute effectively to the Commission's competition mission as Congress intended.

---

<sup>1</sup> See, e.g., Joshua D. Wright, *Recalibrating Section 5: A Response to the CPI Symposium*, 11 CPI ANTITRUST CHRON., Nov. 2013, available at [http://www.ftc.gov/sites/default/files/documents/public\\_statements/recalibrating-section-5-response-cpi-symposium/1311section5.pdf](http://www.ftc.gov/sites/default/files/documents/public_statements/recalibrating-section-5-response-cpi-symposium/1311section5.pdf); Joshua D. Wright, Comm'r, Fed. Trade Comm'n, Section 5 Recast: Defining the Federal Trade Commission's Unfair Methods of Competition Authority, Remarks at the Executive Committee of the New York State Bar Association's Antitrust Section (June 19, 2013), [http://www.ftc.gov/sites/default/files/documents/public\\_statements/section-5-recast-defining-federal-trade-commissions-unfair-methods-competition-authority/130619section5recast.pdf](http://www.ftc.gov/sites/default/files/documents/public_statements/section-5-recast-defining-federal-trade-commissions-unfair-methods-competition-authority/130619section5recast.pdf).

There are at least two principal reasons the Commission’s “unfair methods of competition” authority has not lived up to its Congressional promise, both of which would be solved by formal guidance explaining how the agency intends to implement Section 5 as part of its competition mission. The first reason arises from a combination of (1) the agency’s administrative process advantages and (2) the vague and ambiguous nature of the agency’s “unfair methods of competition” authority. Together these two characteristics pose a unique barrier to the application of Section 5 in a manner that consistently benefits rather than harms consumers.

The vague and ambiguous nature of Section 5 is well known. Proposed definitions for what constitutes an “unfair method of competition” have varied substantially over time and belief that the modern FTC has now somehow moved beyond this inherent product of its institutional design are no more than wishful thinking. Indeed, for at least the past twenty years, commissioners from both parties have acknowledged that a principled standard for the application of Section 5 would be a welcome improvement. The lack of institutional commitment to a stable definition of what constitutes an “unfair method of competition” leads to two sources of problematic variation in the agency’s interpretation of Section 5. One is that the agency’s interpretation of the statute in different cases need not be consistent even when the individual Commissioners remain constant. Another is that as the members of the Commission change over time, so does the agency’s Section 5 enforcement policy,

leading to wide variations in how the Commission prosecutes “unfair methods of competition” over time. In short, the scope of the Commission’s Section 5 authority today is as broad or as narrow as a majority of commissioners believes it is.

This uncertainty surrounding the scope of Section 5 is exacerbated by the administrative procedures available to the Commission. Consider the following empirical observation. The FTC has voted out a number of complaints in administrative adjudication that have been tried by administrative law judges in the past nearly twenty years. In each of those cases, after the administrative decision is appealed to the Commission, the Commission has ruled in favor of FTC staff and found liability. In other words, in 100 percent of cases where the administrative law judge ruled in favor of the FTC staff, the Commission affirmed liability; and in 100 percent of the cases in which the administrative law judge ruled found no liability, the Commission reversed.<sup>2</sup> This is a strong sign of an unhealthy and biased institutional process. By way of contrast, when the antitrust decisions of federal district court judges are appealed to the federal courts of appeal, plaintiffs do not come anywhere close to a 100 percent success rate—indeed, the win rate is much closer to 50 percent. Even bank robbery prosecutions have less predictable outcomes than administrative adjudication at the FTC. One interpretation of these historical data is that the process at the FTC

---

<sup>2</sup> See, e.g., David Balto, *Can the FTC be a Fair Umpire?*, THE HILL (Aug. 14, 2013), <http://thehill.com/blogs/congress-blog/economy-a-budget/316889-can-the-ftc-be-a-fair-umpire>; Doug Melamed, Comments to Fed. Trade Comm’n Workshop Concerning Section 5 of the FTC Act (Oct. 14, 2008), available at <http://ftc.gov/os/comments/section5workshop/537633-00004.pdf>

stacks the deck against the parties. Another is that the FTC has an uncanny knack for picking cases; a knack unseen heretofore within any legal institution. I will allow discerning readers to choose the most likely of these interpretations—but suffice it to say the “case selection” theory requires one to also grapple with the fact that Commission decisions, when appealed, are reversed at a rate four times greater than antitrust opinions by generalist federal judges.<sup>3</sup>

Significantly, the combination of institutional and procedural advantages with the vague nature of the Commission’s Section 5 authority gives the agency the ability, in some cases, to elicit a settlement even though the conduct in question very likely may not be anticompetitive. This is because firms typically will prefer to settle a Section 5 claim rather than to go through lengthy and costly litigation in which they are both shooting at a moving target and have the chips stacked against them. Such settlements also perpetuate the uncertainty that exists as a result of the ambiguity associated with the agency’s “unfair methods of competition” authority by encouraging a process by which the contours of Section 5 are drawn through settlements without any meaningful adversarial proceeding or substantive analysis of the Commission’s authority.

The second principal reason Section 5 has failed to contribute effectively to the Commission’s competition mission is because of the absence of even a minimal level of certainty for businesses. A stable definition of what constitutes an “unfair method of

---

<sup>3</sup> See Joshua D. Wright & Angela M. Diveley, *Do Expert Agencies Outperform Generalist Judges? Some Preliminary Evidence from the Federal Trade Commission*, J. ANTITRUST ENFORCEMENT 1, 16 (2012).

competition” would provide businesses with important guidance about what conduct is lawful and what conduct is unlawful under Section 5. The benefit of added business certainty is less important than ensuring Section 5 enforcement actions—including consents—actually reach and deter anticompetitive conduct rather than chill procompetitive conduct. However, guidance to the business community surely is important. Indeed, the FTC has issued nearly 50 sets of guidelines on a variety of topics, many of them much less important than Section 5, to help businesses understand how the Commission applies the law and to allow practitioners to better advise their clients on how to comply with their legal obligations. Without a stable definition of what constitutes an “unfair method of competition,” businesses must make difficult decisions about whether the conduct they wish to engage in will trigger an investigation or worse. Such uncertainty inevitably results in the chilling of some legitimate business conduct that would otherwise have enhanced consumer welfare but for the firm’s fear that the Commission might intervene and the attendant consequences of that intervention. Those fears would be of little consequence if the agency’s authority was defined and businesses could plan their affairs to steer clear of its boundaries.

Some commentators have asserted that formal agency guidance would too severely restrict the Commission’s enforcement mission.<sup>4</sup> They warn that defining the

---

<sup>4</sup> See, e.g., Sharis A. Pozen & Anne K. Six, *Section 5 Guidelines: Fixing a Problem that Doesn’t Exist?*, 9 CPI ANTITRUST CHRON., Sept. 2013, available at <https://www.competitionpolicyinternational.com/section-5-guidelines-fixing-a-problem-that-doesn-t-exist/>; Edith Ramirez, Chairwoman, Fed. Trade Comm’n, *Unfair Methods and the Competitive Process: Enforcement Principles for the Federal Trade Commission’s Next*

boundaries of the Commission's "unfair methods of competition" authority would achieve stability and clarity only at the expense of creating an enforcement regime that fails to adequately protection competition. These commentators instead urge reliance upon the same case-by-case approach that has garnered success in the context of the traditional antitrust law. Under this view, the scope of the Commission's authority to prosecute unfair methods of competition is best determined by reading the leading cases to identify which enforcement principles the Commission applies when determining whether to prosecute a particular business practice under Section 5.

Although the desire to strike the correct balance between flexibility and certainty is well intended, the so-called common law approach to defining Section 5 is a recipe for unprincipled and inconsistent enforcement and an invitation for an outside institution—the courts or Congress in particular—to define Section 5 for the FTC. The approach of reading a stack of Section 5 consents elicited from parties bargaining in the shadow of the administrative process advantages for the FTC just discussed to decipher its meaning ultimately offers no certainty and results in a boundless standard under which the Commission may prosecute any conduct as an unfair method of competition.

As I have recently written, this is because reliance upon the common law method for developing "unfair methods of competition" law mistakenly assumes that the

---

Century, Keynote Address at the George Mason Law Review and Law & Economics Center Antitrust Symposium: The FTC: 100 Years of Antitrust and Competition Policy (Feb 13, 2014), *available at* [http://www.ftc.gov/system/files/documents/public\\_statements/314631/140213section5.pdf](http://www.ftc.gov/system/files/documents/public_statements/314631/140213section5.pdf).



common law virtues that have proved beneficial to the development of the traditional antitrust laws apply equally in the context of Section 5.<sup>5</sup> They do not. Fundamental differences between the inputs and outputs of traditional litigation and the inputs and outputs of Section 5 enforcement prevent the common law process from generating meaningful guidance for what constitutes an “unfair method of competition.” But you do not have to take my word for it. Indeed, the Commission has employed the so-called case-by-case approach for a century and, to date, Section 5 has not meaningfully contributed to competition policy. In addition to failing to produce any direct and positive influence on antitrust law during that time period, Section 5 cannot point to a single standalone “unfair methods of competition” victory affirmed by a federal appeals court in the modern antitrust era. One hundred years is ample time for a robust natural experiment to evaluate the virtues of the Commissions’ case-by-case approach to Section 5. The results are in. The common law method has proven incapable of generating meaningful guidance as to what constitutes an “unfair method of competition.” To expect better results from the same approach is unwise.

Moreover, as I have already mentioned, the Commission has provided guidance in a number of areas of competition and consumer protection law—many of them far less important than the scope of Section 5—without compromising its enforcement agenda. Consider an obvious example in the arena of competition law, the Horizontal

---

<sup>5</sup> See generally Jan M. Rybnicek & Joshua D. Wright, *Defining Section 5 of the FTC Act: The Failure of the Common Law Method and the Case for Formal Agency Guidelines*, 21 GEO. MASON L. REV. 1287 (2014).

Merger Guidelines, which explain how the antitrust agencies analyze the likely competitive effects of a merger. Those guidelines have proven to be one of the most significant contributions to antitrust law and policy and have greatly benefited the antitrust agencies, the federal courts, and the business community.

Similarly, in response to Congressional criticism about how the FTC was implementing its consumer protection authority under Section 5, and amidst serious threats of shut down the agency, the Commission issued policy statements explaining how it analyzes whether conduct was unfair or deceptive.<sup>6</sup> Today the Commission's deception and unfairness policy statements are widely regarded as a major success *and* serve as a key basis for the Commission to more confidently litigate disputes when its authority is challenged. The FTC should be proud of the fact that it has not reflexively refused to place limits on its own discretion when appropriate. Historically, even if at times under some pressure from Congress, the FTC has embraced limits on discretion both in the name of sound policy and to strengthen the foundation of questionable legal authority. Guidance regarding what precisely constitutes an "unfair method of competition" under Section 5 would similarly improve significantly the FTC's competition mission and shore up an obvious weakness in its authority.

---

<sup>6</sup> See FTC Policy Statement on Unfairness (1980), appended to Final Order, Int'l Harvester Co., 104 F.T.C. 949, 1070 (1984), *available at* <http://ftc.gov/bcp/policystmt/ad-unfair.htm>; FTC Policy Statement on Deception (1983), appended to Final Order, Cliffdale Assocs., Inc. 103 F.T.C. 110, 174 (1984), *available at* <http://www.ftc.gov/bcp/policystmt/ad-decept.htm>.

## II. THE TIME IS RIPE FOR THE FTC TO VOTE ON THE SCOPE OF THE AGENCY'S "UNFAIR METHODS OF COMPETITION" AUTHORITY

Having summarized the case for formal "unfair methods of competition" guidance, let me now turn to the current state of play and what I believe the Commission should do next. The last two years have witnessed what amounts to a healthy and fruitful public comment period on the appropriate scope and role of the Commission's "unfair methods of competition" authority. During that time, members of the antitrust bar, academics, consumer advocates, and business stakeholders have together participated in dozens of panel discussions on Section 5 and penned countless articles debating various proposals. Members of Congress, too, have sent letters to the Commission urging us to act and have even raised the scope of Section 5 as an issue during Congressional hearings.<sup>7</sup> Commentators have had no shortage of opportunities to weigh in with their views on what the Commission should do with respect to Section 5, as well as to consider and respond to the views offered by others. And this of course only represents the most recent round of commentary, which necessarily builds on decades of scholarship and debate—much of it offered by experts at today's symposium—as well as a formal workshop on the scope of Section 5 organized by Chairman Leibowitz in 2008. I do not know of any topic in competition policy that has

---

<sup>7</sup> See Letter from Members of the House and Senate Judiciary Comms. to FTC Chairwoman Edith Ramirez (Oct. 23, 2013), available at [http://judiciary.house.gov/\\_files/news/2013/Signed%20Letter%20to%20FTC.pdf](http://judiciary.house.gov/_files/news/2013/Signed%20Letter%20to%20FTC.pdf); Hearing on "The FTC at 100: Where Do We Go From Here?", Before the Subcomm. on Commerce, Manufacturing, and Trade of the H. Comm. on Energy and Commerce, 113th Cong. 1 (Dec. 3, 2013).

been deliberated more thoroughly before a policy decision has been made than the scope and role of the Commission's "unfair methods of competition" authority.

Significantly, each of my colleagues at the Commission has also voiced, to varying extents, her opinion about the appropriate scope and role of Section 5.<sup>8</sup> This is a welcome addition to the conversation and one that I do not believe any previous Commission has enjoyed. Importantly, the gap between each Commissioners' views, and indeed the views of an overwhelming majority of commentators generally, appears to be relatively narrow and essentially limited only to the question of how efficiencies should be treated when deciding whether to pursue an enforcement action under Section 5. This is an important milestone and one that I think this Commission should seize upon. I am optimistic that this Commission can finally do what other Commissions have been unable to do: issue agency guidance defining what constitutes an "unfair method of competition" under Section 5. Indeed, as I will elaborate upon in a moment, I believe any of the three primary definitions of an "unfair method of competition" that have been articulated by myself or my colleagues is better than the status quo. As such, if there is consensus within the Commission on any of these three alternative definitions, the Commission ought to vote to adopt that definition for what

---

<sup>8</sup> Interview with Commissioner Terrell McSweeney, MONOPOLY MATTERS (ABA Section of Antitrust Law, Unilateral Conduct Comm.), Fall 2014, at 3, 4; Maureen K. Ohlhausen, Comm'r, Fed. Trade Comm'n, Section 5: Principles of Navigation, Remarks before the U.S. Chamber of Commerce (July 25, 2013), *available at* [http://www.ftc.gov/sites/default/files/documents/public\\_statements/section-5-principles-navigation/130725section5speech.pdf](http://www.ftc.gov/sites/default/files/documents/public_statements/section-5-principles-navigation/130725section5speech.pdf); Ramirez, *supra* note 4; Julie Brill, Comm'r, Fed. Trade Comm'n, Remarks at the Technology Policy Institute Aspen Forum (Aug. 20, 2013), *available at* [http://youtu.be/9V\\_YEu1FIAE](http://youtu.be/9V_YEu1FIAE).

constitutes an “unfair methods of competition.” And, after 100 years without any meaningful guidance on Section 5 and with Congress watching, it ought to do so now.

With this in mind, next week I intend to put each of the three principal definitions for how to define an “unfair method of competition” up for a vote by the Commission. The precise language of the three proposed definitions are attached as an appendix to this speech, which will be available on the Commission’s website later today. The three proposed definitions reflect the three definitions of an “unfair method of competition” contemplated by current Commissioners, including myself. Each proposal includes at its core the element that an “unfair method of competition” under Section 5 requires evidence that the conduct in question “harms or is likely to harm competition significantly” as that term is understood under the traditional federal antitrust laws. Harm to competition is a concept that is readily understandable and that has been deeply embedded into antitrust jurisprudence since the early part of the last century. Each of my colleagues has acknowledged that Section 5 should only be used to prosecute conduct that actually is anticompetitive. This is a significant and welcome area of consensus in light of past commissioners’ efforts to use Section 5 to remedy a variety of social and environmental ills unrelated to competition.<sup>9</sup> This element

---

<sup>9</sup> See Michael Pertschuk, Chairman, Fed. Trade Comm’n, Remarks before the Annual Meeting of the Section of Antitrust and Economic Regulation, Association of American Law Schools (Dec. 27, 1977) (asserting that Section 5 can be used to remedy “social and environmental harms” such as “resource depletion, energy waste, environmental contamination, worker alienation, [and] the psychological and social consequences of producer-stimulated demands”).

prevents the Commission from reverting to considering non-economic factors, such as whether the practice harms small business or whether it violates public morals, when deciding whether to prosecute conduct as an “unfair method of competition.” Significantly, however, this element also allows the Commission to challenge conduct that, for one reason or another, might not fit within established Sherman Act or Clayton Act precedent, and thus might find resistance initially in the federal courts. In doing so, it allows the Commission to leverage its institutional advantages to develop evidenced-based competition policy that can then shape antitrust doctrine in the federal courts.

The second element of each definition that I will offer for a vote is that Section 5 cannot be used to challenge conduct where there is well-forged case law under the traditional federal antitrust laws. The federal judiciary has provided little lasting guidance on the appropriate scope of Section 5. But, as one court has explained, and many current and former commissioners have acknowledged, this requirement ensures that the Commission will not use Section 5 to shop for favorable law to attack conduct governed by the more rigorous requirements of Section 2 of the Sherman Act.<sup>10</sup> Prosecuting the same or similar conduct under disparate standards blurs the lines between lawful and unlawful commercial behavior and invites the Commission to evade advances in antitrust law designed to protect consumers from false positives and

---

<sup>10</sup> *Boise Cascade Corp. v. FTC*, 637 F.2d 573, 582 (9th Cir. 1980) (stating that where there is “well forged” case law governing the challenged conduct, the Commission cannot prosecute the conduct under Section 5 because doing so might “blur the distinction between guilty and innocent commercial behavior”).

false negatives. Whether well-forged case law exists in any particular case will of course remain within the Commission's discretion, but the requirement nevertheless adds an important measure of stability regarding the agency's "unfair methods of competition" authority.

The area in which each of the three proposed definitions differs is in how efficiencies are treated under Section 5. This is the area in which my colleagues have expressed slightly different preferences. My preferred approach is that Section 5 only be used where there are no cognizable efficiencies present. In my view, where the parties can show cognizable efficiencies the agency is better off challenging the conduct under the traditional antitrust rules that are better designed for balancing. I do not believe the Commission's track record in administrative adjudication—in terms of both substance and process—justifies the view that it has a comparative advantage in cases requiring balancing. I will give my colleagues an opportunity to vote on this proposal, but I will not be surprised if a majority of them view this approach as too restrictive.

The second option incorporates into the definition of "unfair methods of competition" a test my colleague Commissioner Ohlhausen has thoughtfully advocated for as an element of her own policy statement, which requires that any antitrust harm be disproportionate to any cognizable efficiencies.<sup>11</sup>

---

<sup>11</sup> See Ohlhausen, *supra* note 8, at 10.

The third option requires the Commission to show that the harms are not outweighed by the cognizable efficiencies before bringing an “unfair methods of competition” claim under Section 5. This approach has been pointed to by Chairwoman Ramirez as the appropriate framework to apply for “unfair methods of competition” cases and essentially employs the modern day “rule of reason” when deciding whether conduct violates Section 5.<sup>12</sup> The basic view underlying this definition of an unfair method of competition is that the institutional differences between administrative adjudication and federal court do not require any adjustment to the rule of reason framework. While I do not believe a rule of reason approach is the best available choice, in my view, any of the three potential options I have discussed would be superior to the status quo. Each would create a stable definition for what constitutes an unfair method of competition and tether that definition to modern economics. Accordingly, to be clear, I intend to vote in support of each of these proposals in hopes that one gains the support of a majority of the Commission.

While I am truly hopeful at least one definition of “unfair methods of competition” attracts three votes, I am also acutely aware that optimism in light of a record of a century without guidelines is indulged at my own risk. So what happens next? There are a few possibilities. One possibility is that the Commission defines an

---

<sup>12</sup> See Ramirez, *supra* note 4, at 8 (“Our most recent Section 5 cases show that the Commission will condemn conduct only where, as with invitations to collude, the likely competitive harm outweighs the cognizable efficiencies.”).



“unfair method of competition” next week. Indeed, my hope is that my colleagues will recognize the important consensus that exists on the scope and role of Section 5 and take a modest step in articulating the agency’s enforcement policy with respect to Section 5 by adopting one of these three proposed definitions.

A second possibility is that a majority of my colleagues choose to vote “no” on each of these proposals. That possibility does not require much in the way of additional explanation. While a “no” vote by the full Commission would be non-public, close observers of the agency will surely take note of the lack of any press release or announcement that the agency at long last has produced Section 5 guidelines.

A third possibility, worse still in my view, is that a majority of Commissioners simply may choose not to vote at all. Under Commission rules, the full Commission need not vote unless and until a majority has formed. Thus, it is possible that my motion finds itself languishing in agency procedural purgatory, because Commissioners are not required to vote. I believe either of these last two possibilities would be a lost opportunity for the FTC and would send the wrong message about the Commission’s desire for Section 5 to live up to its Congressional promise.

### **III. IF THE COMMISSION FAILS TO ARTICULATE THE SCOPE OF SECTION 5, CONGRESS MAY DEFINE IT FOR THE AGENCY**

Not only is the question of what constitutes an “unfair method of competition” particularly ripe for agency action in light of the considerable thought that has been devoted to the issue in recent years, but I also believe that there exists a significant

risk—maybe now more so than at anytime in FTC history—that if the Commission fails to take action to define the scope of the Section 5 soon, Congress may choose to define the statute for the Commission. Indeed, in recent years numerous members of Congress have grown interested in the scope of the Commission “unfair methods of competition” authority and have voiced concerns regarding the absence of any clear standard to which the business community can turn in order to better understand the agency’s enforcement policy. Members of both the Senate and House Judiciary Committees have sent Chairwoman Ramirez a letter urging the Commission to finally provide guidance that would make Section 5 enforcement transparent, fair, predictable, and reasonably stable over time. Other members of Congress have raised questions about the vague and ambiguous nature of Section 5 during recent Congressional hearings. I do not believe this interest should be taken lightly, and continued resistance on the part of the Commission to define the parameters of Section 5 could spur legislative action.

If Congress were to define Section 5, it without question would result in a more restrictive definition of what constitutes an “unfair method of competition” than anything the Commission would implement. Indeed, the simplest and most obvious solution Congress might adopt, and one that would have the added benefit for many of harmonizing the powers of the FTC and the Department of Justice’s Antitrust Division, would be to define an “unfair method of competition” under Section 5 as a violation of the Sherman Act or Clayton Act. A slightly broader, and just as simple solution for

Congress would be to define an unfair method as either a violation of the Sherman Act or Clayton Act or an invitation to collude. A third possibility, and one that attacks the Section 5 problem not from a standpoint of substance but rather of procedure, would be for Congress to remove the Commission's administrative advantages altogether and allow the federal courts to supervise the Commission's use of Section 5 and define the boundaries of what constitutes an "unfair method of competition" when necessary. Although at one point this might have seemed like an unlikely option, recent legislative proposals stripping the agency of its administrative powers in the context of merger challenges in order to align the preliminary injunction standards between the FTC and the Department of Justice suggest that this might not be so farfetched of a possibility.<sup>13</sup>

In short, if the FTC continues to refuse to define what constitutes an "unfair method of competition," it should not be surprised when and if Congress becomes intensely interested in introducing legislation to finally solve a problem created more than a century ago. A solution to the Section 5 problem is inevitable. It is my sincere hope that this Commission seizes the opportunity it has before it now to solve the Section 5 problem on its own terms rather than leaving the solution to Congress.

Thank you for your time. I am happy to take any questions.

---

<sup>13</sup> See Brent Kendall, *A Challenge to the FTC Methods*, WALL STREET JOURNAL (Nov. 15, 2014), <http://www.wsj.com/articles/a-challenge-to-ftc-methods-1416184116>; *Hearing on the SMARTER Act of 2014 Before the Subcomm. on Regulatory Reform, Commercial and Antitrust Law of the H. Comm. on the Judiciary*, 113th Cong. 2 (Apr. 3, 2014); Joshua D. Wright, Comm'r, Fed. Trade Comm'n, *Judging Antitrust*, Remarks at the Global Antitrust Institute Invitational Moot Court Competition (Feb. 21, 2015), *available at* [http://www.ftc.gov/system/files/documents/public\\_statements/626231/150221judgingantitrust-1.pdf](http://www.ftc.gov/system/files/documents/public_statements/626231/150221judgingantitrust-1.pdf) (expressing support for the passage of the SMARTER Act).

## APPENDIX

### Option 1 – Efficiencies Screen

An “unfair method of competition” is an act or practice (1) that harms or is likely to harm competition significantly, (2) that lacks cognizable efficiencies, and (3) for which there is not well-forged case law under the traditional antitrust laws that might cause the distinction between lawful and unlawful commercial behavior to become blurred.

### Option 2 – Disproportionality Test

An “unfair method of competition” is an act or practice (1) that harms or is likely to harm competition significantly, (2) where the harms are disproportionate to the cognizable efficiencies, and (3) for which there is not well-forged case law under the traditional antitrust laws that might cause the distinction between lawful and unlawful commercial behavior to become blurred.

### Option 3 – Rule of Reason

An “unfair method of competition” is an act or practice (1) that harms or is likely to harm competition significantly, (2) where the harms are not outweighed by the cognizable efficiencies, and (3) for which there is not well-forged case law under the traditional antitrust laws that might cause the distinction between lawful and unlawful commercial behavior to become blurred.

# Exhibit RX 5

## EXHIBIT A

### Federal Trade Commission Adjudicative Proceedings Updated as of January 1, 2015

Source: FTC Website, at <https://www.ftc.gov/enforcement/cases-proceedings/adjudicative-proceedings>

Includes proceedings in which Part 3 Complaint was filed; *excludes* cases filed exclusively in Federal Court

	A	B	C	D	E	F	G
	TITLE <sup>1</sup>	DOCKET NUMBER	STATUS	UPDATED	ALJ Liability Decision	Commission Liability Decision	Commission WIN or LOSS
1.	<a href="#">Axon/VieVu, In the Matter of (Administrative)</a>	9389	Pending	January 8, 2020	Case Pending	Case Pending	N/A
2.	<a href="#">Post Holdings, Inc.; In the Matter of (Administrative)</a>	D-9388	Pending	January 6, 2020	Case Pending	Case Pending	N/A
3.	<a href="#">Illumina Inc./Pacific Biosciences of California, Inc., In the Matter of (Administrative)</a>	D-9387	Pending	January 6, 2020	Party Abandoned Merger	Party Abandoned Merger	N/A
4.	<a href="#">RagingWire Data Centers, Inc., In the Matter of (Administrative)</a>	9386		January 6, 2020	Case Pending	Case Pending	N/A
5.	<a href="#">Evonik/PeroxyChem, In the Matter of (Administrative)</a>	9384		January 2, 2020	Case Pending	Case Pending	N/A
6.	<a href="#">Cambridge Analytica, LLC, In the Matter of (Administrative)</a>	9383		December 18, 2019	Case Settled	Case Settled	N/A

<sup>1</sup> Columns A-D were copied directly from the FTC Website, at: <https://www.ftc.gov/enforcement/cases-proceedings/adjudicative-proceedings> (as of January 9, 2020 at 12:00 pm Eastern)

	A	B	C	D	E	F	G
	TITLE <sup>1</sup>	DOCKET NUMBER	STATUS	UPDATED	ALJ Liability Decision	Commission Liability Decision	Commission WIN or LOSS
7.	<a href="#">Benco/Schein/Patterson, In the Matter of (Administrative)</a>	9379	Pending	November 8, 2019	Liability (2 out of 3 defendants)	No Appeal	WIN
8.	<a href="#">Otto Bock HealthCare North America, Inc., In the Matter of (Administrative)</a>	9378	Pending	November 6, 2019	Liability	Liability (Upheld ALJ)	WIN
9.	<a href="#">1-800 Contacts, Inc. In the Matter of (Administrative)</a>	9372		October 8, 2019	Liability	Liability (Upheld ALJ)	WIN
10.	<a href="#">Fidelity National Financial/Stewart Information Services, In the Matter of (Administrative)</a>	9385	Closed	September 25, 2019	Party Abandoned Merger	Party Abandoned Merger	N/A
11.	<a href="#">Louisiana Real Estate Appraisers Board, In the Matter of (Administrative)</a>	9374	Pending	August 15, 2019	Case Pending	Case Pending	N/A
12.	<a href="#">Impax Laboratories, Inc., In the Matter of (Administrative)</a>	9373	Pending	August 2, 2019	No Liability	Liability (Reversed ALJ)	WIN
13.	<a href="#">Sanford Health/Sanford Bismarck/Mid Dakota Clinic, In the Matter of (Administrative)</a>	9376	Closed	July 9, 2019	Party Abandoned Merger	Party Abandoned Merger	N/A
14.	<a href="#">Tronox/Cristal USA, In the Matter of (Administrative)</a>	9377	Pending	May 29, 2019	Liability	Case Settled (Divestiture Ordered)	N/A
15.	<a href="#">Chicago Bridge &amp; Iron Company N.V., ...In the Matter of (Administrative)</a>	9300		May 11, 2019	Liability	Case Settled (Divestiture Ordered)	N/A
16.	<a href="#">Monier Lifetile LLC, Boral Ltd., and Lafarge S.A, In the Matter of (Administrative)</a>	9290		February 5, 2019	Case Settled (Divestiture Ordered)	Case Settled (Divestiture Ordered)	N/A

	A	B	C	D	E	F	G
	TITLE <sup>1</sup>	DOCKET NUMBER	STATUS	UPDATED	ALI Liability Decision	Commission Liability Decision	Commission WIN or LOSS
17.	<a href="#">Wilhelm Wilhelmsen/Drew Marine, In the Matter of</a> (Administrative)	9380		August 1, 2018	Party Abandoned Merger	Party Abandoned Merger	N/A
18.	<a href="#">CDK Global and Auto/Mate, In the Matter of</a> (Administrative)	9382		March 26, 2018	Party Abandoned Merger	Party Abandoned Merger	N/A
19.	<a href="#">J.M. Smucker/Conagra, In the Matter of</a> (Administrative)	9381		March 8, 2018	Party Abandoned Merger	Party Abandoned Merger	N/A
20.	<a href="#">Jerk, LLC, d/b/a Jerk.com, In the Matter of</a> (Administrative)	9361		January 8, 2018	N/A	Liability (Summary Decision)	WIN
21.	<a href="#">ProMedica Health System, Inc., a corporation, In the Matter of</a> (Administrative)	9346		October 16, 2017	Liability	Liability (Upheld ALJ)	WIN
22.	<a href="#">DraftKings, Inc. / FanDuel Limited, In the Matter of</a> (Administrative)	9375		July 14, 2017	Party Abandoned Merger	Party Abandoned Merger	N/A
23.	<a href="#">Advocate Health Care Network, NorthShore University HealthSystem, In the Matter of</a> (Administrative)	9369		March 20, 2017	Party Abandoned Merger	Party Abandoned Merger	N/A
24.	<a href="#">ECM BioFilms, Inc., also d/b/a Enviroplastics International, In the Matter of</a> (Administrative)	9358		March 16, 2017	Liability	Liability (Upheld ALJ)	WIN
25.	<a href="#">California Naturel, In the Matter of</a> (Administrative)	9370		December 12, 2016	N/A	Liability (Summary Decision)	WIN
26.	<a href="#">The Penn State Hershey Medical Center/PinnacleHealth System, In the Matter of</a> (Administrative)	9368		October 23, 2016	Party Abandoned Merger	Party Abandoned Merger	N/A
27.	<a href="#">LabMD, Inc., In the Matter of</a> (Administrative)	9357		September 29, 2016	No Liability	Liability (Reversed ALJ)	WIN



	A	B	C	D	E	F	G
	TITLE <sup>1</sup>	DOCKET NUMBER	STATUS	UPDATED	ALJ Liability Decision	Commission Liability Decision	Commission WIN or LOSS
28.	<a href="#">Superior/Canexus, In the Matter of (Administrative)</a>	9371		August 3, 2016	Party Abandoned Merger	Party Abandoned Merger	N/A
29.	<a href="#">Cabell Huntington Hospital/St. Mary's Medical Center, In the Matter of (Administrative)</a>	9366		July 6, 2016	N/A	N/A (Case dismissed due to new state law in West Virginia on "cooperative agreements")	N/A
30.	<a href="#">Staples/Office Depot, In the Matter of (Administrative)</a>	9367		May 19, 2016	Party Abandoned Merger	Party Abandoned Merger	N/A
31.	<a href="#">Steris/Synergy Health, In the Matter of (Administrative)</a>	9365		October 7, 2015	N/A	N/A (Case dismissed after losing PI Motion in federal court)	N/A
32.	<a href="#">Sysco/USF Holding/US Foods, In the Matter of (Administrative)</a>	9364		June 29, 2015	Party Abandoned Merger	Party Abandoned Merger	N/A
33.	<a href="#">McWane, Inc., and Star Pipe Products, Ltd., In the Matter of (Administrative)</a>	9351		April 17, 2015	Liability  In ALJ's Initial Decision on May 9, 2013, held that evidence did not support complaint counsel's charges that McWane illegally conspired with Sigma and Star to raise and stabilize fittings prices. Based on these findings, he dismissed the first three counts in the seven-count FTC complaint. But ALJ ruled that the evidence did support other four counts in the administrative complaint, and his Initial Decision would have required McWane to stop engaging in the conduct outlined in those counts.	Liability (Upheld and Reversed ALJ, in part)  Commission affirmed, in part, a May 2013 Initial Decision by the ALJ, finding McWane unlawfully maintained a monopoly in the domestic "fittings" product market.  The Commission dismissed the remaining counts. Dismissed Counts 1 and 2 in the public interest, because no majority position was reached (Ramirez/Brill were deadlocked with Ohlhausen/Wright). Count 3, which the ALJ dismissed, was not appealed by complaint counsel. Commission reversed ALJ's finding of liability on Count 4; and dismissed Counts 5 and 7 after determining it was not necessary to address merits, based on other findings.	WIN
34.	<a href="#">Phoebe Putney Health System, Inc., ...In the Matter of (Administrative)</a>	9348		March 31, 2015	Case Settled	Case Settled	N/A

	A TITLE <sup>L</sup>	B DOCKET NUMBER	C STATUS	D UPDATED	E ALI Liability Decision	F Commission Liability Decision	G Commission WIN or LOSS
35.	<a href="#">Graco Inc., Illinois Tool Works Inc., and ITW Finishing LLC, In the Matter of (Administrative)</a>	9350		March 25, 2015	Case Settled	Case Settled	N/A
36.	<a href="#">AmeriGas and Blue Rhino, In the Matter of (Administrative)</a>	9360		January 9, 2015	Case Settled	Case Settled	N/A